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# OKROGLA MIZA O RAKU MEHURJA

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ZBORNIK PREDAVANJ

Maribor, 28.3.2024

# OKROGLA MIZA O RAKU MEHURJA

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# PROGRAM SREČANJA

Četrtek, 28.3.2024

V predavalnici stolpnice UKC Maribor (16. nadstropje)

- 1. 15:00-15:10 Registracija**
- 2. 15:10-15:15 Uvodni pozdrav**  
*Jure Verbančič, dr. med.*
- 3. 15:15-15:25 Slikovna diagnostika**  
*Saša Bombek Rudolf, dr. med.*
- 4. 15:25-15:35 Patohistološka diagnostika**  
*Tomaž Rojko, dr. med.*
- 5. 15:35-15:45 Kirurška diagnostika -TUR**  
*Andrej Avsenak dr. med., Niko Kavčič dr. med.*
- 6. 15:45-15:55 Kirurško zdravljenje - radikalna cistektomija**  
*Boštjan Kramar dr. med., Uroš Kacjan dr. med.*
- 7. 15:55-16:05 Novosti v sistemski terapiji raka mehurja**  
*Jasna Knez Arbeiter, dr. med.*
- 8. 16:05-16:15 Obsevanje pri raku mehurja**  
*Nataša Pulko dr. med.*
- 9. 16:15-16:25 Verifikacija obsevalnega polja pri obsevanju mehurja**  
*Lejla Ibrahimović, dipl. inž. radiol. tehnol.*
- 10. 16:25-16:35 Klinični primer**  
*Jure Verbančič, dr. med.*
- 11. 16:35-16:45 Razprava**

**Avtorji (po abecednem vrstnem redu):**

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## **Kazalo**

Rak mehurja – uvod .....	5
MR mehurja – ocena invazije.....	7
Patohistološka diagnostika raka mehurja.....	9
Kirurška diagnostika – TURM.....	11
Radiakalna cistektomija.....	13
Novosti v sistemskem zdravljenju raka mehurja.....	15
Vloga obsevanja pri raku mehurja .....	17
Verifikacija obsevalnega polja.....	19
Prikaz primera.....	22

# Rak mehurja – uvod

## *Bladder cancer – overview of the topic*

Jure Verbančič, dr. med.<sup>1</sup>

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### Povzetek

Rak mehurja delimo med mišično ne-invazivne in mišično invazivne tumorje. Mišično invazivni rak mehurja spada med redkejše rake. Predstavlja le 2,5 % vseh rakov in se pogosteje pojavlja pri moških. V Sloveniji je za rakom mehurja leta 2020 zbolelo 395 ljudi. Vrh incidence je med 65. in 85. letom starosti. Približno dve tretjini ugotovljenih primerov je odkrita v omejeni obliki, 20% v lokalno napredovali in okoli 10% primerov v razširjeni obliki.

Ocenjeno 5-letno preživetje pri omejeni bolezni je približno 71 %, 39 % pri lokalno napredovali bolezni (prizadete bližnje bezgavke) in le 8 % pri razsejani bolezni (oddaljeni zasevki v druge organe).

Večino (90%) vseh tumorjev mehurja predstavljajo urothelijski karcinomi. Dejavniki tveganja za nastanek raka mehurja so kajenje cigaret, starost, moški spol, izpostavljenost kemikalijam. Približno 50-65 % rakov mehurja pri moških in 20-30 % pri ženskah je povezanih s kajenjem.

Najpogosteji simptom raka mehurja je hematurija, ki je neboleča. Ostali simptomi so lahko nevidna hematurija, urgenca uriniranja, dizurija in povečana frekvenca uriniranja. Simptomi napredovale bolezni pa so bolečina v medenici in retenga urina.

Ob postavljenem sumu, da gre za rak mehurja, je potrebna čim hitrejša diagnostična obdelava in zdravljenje glede na razširjenost bolezni in stanje zmogljivosti bolnika.

**Ključne besede:** rak mehurja, incidenca, preživetje, dejavniki tveganja, simptomi

### Abstract

Bladder cancer is divided into non-muscle-invasive and muscle-invasive tumors. Muscle invasive bladder cancer is one of the rarer cancers. It accounts for only 2.5% of all cancers and is more common in men. In Slovenia, 395 people fell ill with bladder cancer in 2020. The peak incidence is between the ages of 65 and 85. About two-thirds of the identified cases are detected in a limited form, 20% in locally advanced and about 10% of cases in metastatic disease.

Estimated 5-year survival for limited disease is approximately 71%, 39% for locally advanced disease (nearby lymph nodes affected), and only 8% for disseminated disease (distant metastases to other organs).

The majority (90%) of all bladder tumors are urothelial carcinomas. Risk factors for bladder cancer are cigarette smoking, age, male sex, exposure to chemicals. About 50-65% of bladder cancers in men and 20-30% in women are related to smoking.

The most common symptom of bladder cancer is hematuria, which is painless. Other symptoms can be invisible hematuria, urinary urgency, dysuria and increased frequency of urination. Symptoms of advanced disease are pelvic pain and urinary retention.

When bladder cancer is suspected, diagnostic processing and treatment are required as quickly as possible, depending on the stage of the disease and patient's performance status.

**Keywords:** bladder cancer, incidence, survival, risk factors, clinical symptoms

**Viri/Sources:**

1. Rak v Sloveniji 2020. Ljubljana: Onkološki inštitut Ljubljana, Epidemiologija in register raka, Register raka Republike Slovenije, 2023.
2. *EAU Guidelines. Edn. presented at the EAU Annual Congress Milan 2023. ISBN 978-94-92671-19-6.*
3. Surveillance, Epidemiology, and End Results (SEER) Program Populations (1969-2020) ([www.seer.cancer.gov/popdata](http://www.seer.cancer.gov/popdata)), National Cancer Institute, DCCPS, Surveillance Research Program, released February 2022.

# **Multiparametrična magnetna resonanca (mpMR) sečnega mehurja za oceno invazije karcinoma v mišično steno mehurja**

***Multiparametric magnetic resonance imaging (mpMRI) of urinary bladder in predicting muscular involvement in bladder carcinoma***

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<sup>1</sup>Radiološki oddelok, UKC Maribor, Slovenija

## **Povzetek**

Najpogostejši rak sečnega mehurja je urotelijski karcinom in predstavlja 90% vseh primerov. Ocena globine invazije tumorja v mišično steno mehurja je najpomembnejši dejavnik v izbiri načina zdravljenja tumorja ter v prognozni bolezni. 70% primerov tumorjev mehurja so neinvazivni karcinomi mehurja (NMIBC), ki zajemajo urotelij in lamino proprio. Mišično invazivni karcinomi mehurja (MIBC) zajemajo mišično plast stene mehurja, so višjega gradusa in imajo večji potencial metastaziranja. Pristop k zdravljenju karcinoma se glede na globino invazije stene mehurja bistveno razlikuje, zato je v prvi vrsti pomembno določiti T stadij bolezni. Multiparametrična magnetna resonanca (mpMR) sečnega mehurja je namenjena oceni globine invazije tumorja v steno sečnega mehurja oz. oceni verjetnosti zajetosti mišične plasti stene mehurja. V ta namen so leta 2018 razvili standardiziran sistem ocene globine mišične invazije poimenovan s kratico VI-RADS (Vesical Imaging Reporting and Data System). VI-RADS s pomočjo 5-točkovnega sistema oz. lestvice oceni verjetnost infiltracije tumorja v mišično steno mehurja, kjer ocena 1 pomeni zelo malo verjetnost mišične invazije tumorja, ocena 5 zelo verjetno invazijo v mišično steno mehurja in ocena 3 kot neopredeljiva. Za razliko od histološko štirih plasti stene mehurja, radiološko z MR razlikujemo le tri plasti in sicer notranjo plast, ki zajema urotelij in lamino proprio - stadij T1, mišično plast - stadij T2 in perivezikalno maščevje - stadij T3. Globino invazije najprej ocenimo na T2 sekvenci visoke ločljivosti z natančnim prikazom anatomskih struktur. T2 sekvenca določa tako imenovano struktурno kategorijo (SC) in je dominantna sekvenca za razvrstitev tumorjev z majhno verjetnostjo prisotnosti invazije v mišično steno - VI-RADS od 1 do 3. Za oceno prisotnosti mišične invazije tumorja sta dominantni dinamični sekvenci, v prvi vrsti difuzija (DWI), in kadar je kvaliteta le-te suboptimalna, dinamična kontrastna sekvenca (DCE).

Sistem VI-RADS je tako namenjen določitvi T-stadija bolezni karcinoma sečnega mehurja, vendar njegova široka uporaba v vsakodnevni klinični praksi še ni jasno definirana.

**Ključne besede:** karcinom sečnega mehurja, multiparametrični MR sečnega mehurja, VI-RADS

## **Abstract**

Urothelial carcinoma is the most common type of bladder cancer and accounts for approximately 90% of all neoplasms. Evaluating the depth of tumour invasion in the bladder wall is essential for determining the treatment and prognosis in patients with bladder cancer. The majority of patients (70%) present with non-muscle-invasive bladder cancer (NMIBC) which is confined to the urothelium and lamina propria. Muscle-invasive bladder cancer (MIBC) invades muscularis propria and are high-grade tumours and strongly associated with metastasis. Bladder cancer treatment approaches vary greatly depending on tumour T stage. To determine presence of muscle invasion multiparametric bladder MRI has increasingly been incorporated into practice for the delineation of muscle invasion. Thus, in 2018, the Vesical Imaging

Reporting and Data System (VI-RADS) was developed to standardise the MRI acquisition and reporting of bladder cancer. The VI-RADS scale ranges from 1 to 5, where 1 indicates that muscle invasion is highly unlikely, 5 suggests that muscle invasion is highly likely, and 3 is equivocal. From a radiological perspective, only three layers may be identified on MRI, the inner layer comprising the urothelium and lamina propria - stage T1, the muscularis propria - stage T2 and the perivesical fat - stage T3 disease. High-resolution T2-weighted (T2W) MR images are particularly useful as an initial guide being crucial anatomic sequence and define so called structural category (SC). T2W should be the first sequence to be considered in assignment of VI-RADS score and dominates with VI-RADS scores between 1 and 3. The presence of muscular invasion is determined with diffusion-weighted (DWI) and dynamic contrast-enhanced sequences (DCE). DWI being dominant when optimal image quality is achieved. VI-RADS is an imaging tool in preoperative T-staging of bladder cancer but specific clinical scenarios in which bladder mpMRI should be used are yet not clear.

**Keywords:** bladder cancer, multiparametric MRI, VI-RADS

**Viri/Sources:**

1. Lai AL, Law YM. VI-RADS in bladder cancer: Overview, pearls and pitfalls. European Journal of Radiology. 2023 Mar;160:110666.
2. Panebianco V, Narumi Y, Altun E, Bochner BH, Efstatihou JA, Hafeez S, et al. Multiparametric Magnetic Resonance Imaging for Bladder Cancer: Development of VI-RADS. European urology [Internet]. 2018 Sep 1 [cited 2022 Apr 15];74(3):294–306. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6690492/>
3. Santos, Lorenzoni C, Ivan Morzoletto Pedrollo, Ítalo Ribeiro Cruz, Fernando O, Maurício Zapparoli, et al. Practical Guide to VI-RADS: MRI Protocols, Lesion Characterization, and Pitfalls. Radiographics. 2024 Mar 1;44(3).

# Urotelni karcinom z vidika patologa

***Urothelial Carcinoma from the Pathologist's Point of View***

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## Povzetek

Sodelovanje med kliniki in patologi je ključnega pomena pri natančni diagnozi in nadaljnji obravnavi bolnika s karcinomom mehurja. Za kvalitetni končni histopatološki izvid ni pomembna le adekvatna pridobitev tkiva, temveč tudi posredovanje ključnih in uporabnih kliničnih informacij.

## Histopatološka obdelava

Medtem ko je tkivo pridobljeno z biopsijo ali transuretralno resekcijo (TUR) lahko v celoti pregledano, je proces pri cistektomiji zaradi velikosti resekcije drugačen.

Pri cistektomijah je resektate po fiksaciji s formalinom potrebno kvalitetno makroskopsko opisati. Makroskopski opis vključuje tudi lokalizacijo, velikost in globino invazije tumorja. Nato sledi adekvatno vzorčenje tkiva za mikroskopski pregled. Pri bolnikih z neoadjuvantno terapijo je lokalizacija tumorja lahko otežena, zaradi česar je nujno potreben klinični podatek slikovne diagnostike z informacijo o lokaciji tumorja pred terapijo.

## Histopatološki izvid

Histopatološki izvid med drugim zajema tudi opredelitev urotelnega karcinoma, ki temelji na 2022 WHO klasifikaciji. Ta opredeljuje urotelne karcinome na ne-invazivne in invazivne. Pri ne-invazivnih karcinomih so le-ti lahko s ploščato (karcinom in situ) ali papilarno morfologijo (ne-invazivni papilarni karcinom).

Eden izmed ključnih histopatoloških dejavnikov je tumorski gradus oziroma maligni potencial, ki ne-invazivne papilarne urotelne karcinome in invazivne urotelne karcinome gradira v karcinome z nizkim in visokim malignim potencialom.

Zaradi morebitnega prognostičnega in/ali prediktivnega pomena mora izvid vsebovati tudi podatek o histološkem podtipu urotelnega karcinoma.

Patološki stadij pri urotelnih karcinomih mehurja je osnovan na obsegu invazije. Medtem ko lahko pri biopsijah in TUR potrdimo le prisotnost invazije v lamino proprio in muskularis proprio, je natančnejša opredelitev globine invazije v muskularis proprio in invazija v globlja tkiva mogoča le pri cistektomiji.

**Ključne besede:** urotelni karcinom, histopatološka obdelava, histopatološki izvid

## **Abstract**

Clinicians and pathologists should closely collaborate in order to achieve the most accurate diagnosis and appropriate management for a patient with bladder cancer. Therefore, for the pathologist to sum up an accurate pathologic report, not only adequate tissue samples but also useful clinical information should be provided.

## **Histopathologic specimen handling**

The tissue sampling differs based on the surgical specimen. Biopsy and transurethral resection (TUR) specimens can be fully paraffin embedded and afterwards microscopically examined.

Cystectomy specimens are firstly adequately fixated and afterwards grossly examined. The macroscopic description should include the site, size, appearance and the depth of invasion of the tumour. After it, the tumour should be adequately sampled. Because of neoadjuvant therapy, the tumour is not always grossly visible. In such cases the radiological or cystoscopic information taken before the treatment is pivotal.

## **Histopathologic reporting**

Histopathologic reporting is based on the 2022 WHO classification of urinary bladder tumours, that divides urothelial carcinomas into non-invasive and invasive categories. The non-invasive are further categorised into flat and papillary lesions.

One of the crucial histopathologic parameters is the tumour grade. According to it the non-invasive papillary urothelial carcinomas and invasive urothelial carcinomas are further divided into low and high grade.

There are also different histological subtypes of the urothelial carcinoma. Some of these have prognostic and therapeutic implications and therefore should be reported.

The reporting of pathologic stage is based on the extent of the invasion and differs based on the surgical specimen type. In biopsies and TUR specimen invasion into lamina propria and muscularis propria can be identified, but substaging on the basis of depth of muscularis propria invasion and invasion into deeper tissues is only possible in cystectomy specimen.

**Keywords:** urothelial carcinoma, histopathologic handling, histopathologic reporting

## **Viri/Sources:**

- 1) Mazzucchelli R, Marzoni D, Tossetta G, Pepi L, Montironi R. Bladder Cancer Sample Handling and Reporting: Pathologist's Point of View. *Front Surg.* 2021 Dec 2;8:754741. doi: 10.3389/fsurg.2021.754741. PMID: 34926567; PMCID: PMC8674620.
- 2) WHO Classification of Tumours Editorial Board. WHO classification of tumours. Urinary and male genital tumours. Lyon: International Agency for Research on Cancer; 2022.

# Kirurška Diagnostika - TURB

## ***Surgical diagnostics - TURBT***

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### **Povzetek**

Karcinom mehurja je sedmi najpogosteji karcinom med moškimi in deseti najpogosteji karcinom v splošni populaciji(1) Kajenje tobačnih izdelkov je glavni dejavnik tveganja za pojav karcinoma(1,2).

Karcinome mehurja delimo po TNM klasifikaciji. Tumorji, ki zajemajo sluznico in lamino proprio se klasificirajo kot Ta (ne-invazivni papilarni karcinom) in T1 glede na TNM klasifikacijo. Visoko rizične karcinome omejene na sluznico, brez infiltracije v muscularis proprio klasificiramo kot Tis (karcinom in situ)(1).

Hematurija je najpogosteji klinični znak karcinoma mehurja. Bolniki, z mikro- ali makrohameturijo, pri katerih je izključeno ledvično obolenje, potrebujejo diagnostično obravnavo. Ultrazvok trebuha in sečil je prva diagnostična preiskava pri sumu na tumorje mehurja(1,2). Ambulantna cistoskopija ali cistoskopija v splošni anesteziji predstavlja najbolj natančno preiskavo pri sumu na tumorje spodnjih sečil. Citološka preiskava urina ima visoko občutljivost pri visoko rizičnih (HG) in G3 tumorjih (84%), medtem ko pri nizkorizičnih in karcinomih in situ (LG/G1) občutljivost znaša 16%(1,2).

Tranuretralna resekcija tumorjev mehurja (TUR) je kirurški poseg v splošni ali regionalni anesteziji. Predstavlja glavno diagnostično metodo za pridobitev vzorcev tkiva mehurja, pri neinvazivnih karcinomih Ta in T1 pa tudi dokončno kirurško tehniko za odstranitev tumorjev(1).

Celotna resekcija tumorja pri kateri uporabimo *en-block* resekcijo ali resekcijo po kosih je ključna za dobro prognozo. Kirurška tehnika, ki se uporablja za resekcijo je odvisna od lege tumorja, velikosti tumorja in makroskopskega videza. Pri resekcijah v večih kosih dobimo dobre podatke o globini tumorja. *En-block* resekcija omogoča celotno odstranitev tumorja v enem kosu z zajeto mišico detruzor v 96-100% primerov(1). Prav tako je pri en-block resekciji manjša možnost perforacije mehurja(1).

Pomembno je, da je v vzorcu tkiva zajet tudi mišični del (detruzor). Odsotnost mišice v patohistološkem vzorcu predstavlja pomebno tveganje za ponovitev bolezni in potrebo po ponovnem TUR-u mehurja(1).

**Ključne besede:** Transuretralna resekcija tumorjev mehurja, ne-invazivni karcinom, kirurška diagnostika

## **Abstract**

Bladder carcinoma is the seventh most common cancer among men and the tenth most common cancer in the general population(1). Tobacco smoking is the main risk factor for the development of bladder cancer(2).

Bladder carcinomas are classified according to the TNM classification. Tumors involving the mucosa and lamina propria are classified as Ta (non-invasive papillary carcinoma) and T1 according to the TNM classification. High-risk carcinomas limited to the mucosa, without infiltration into the muscularis propria, are classified as Tis (carcinoma in situ)(1).

Hematuria is the most common clinical sign of bladder cancer. Patients with micro- or macrohematuria, where renal disease is excluded, require diagnostic evaluation. Abdominal and pelvic ultrasound is the first diagnostic test in cases of suspected bladder tumors(1,2). Outpatient cystoscopy or cystoscopy under general anesthesia is the most accurate examination for suspected lower urinary tract tumors. Urine cytology has high sensitivity for high-risk (HG) and G3 tumors (84%), while its sensitivity for low-grade and carcinoma in situ (LG/G1) tumors is 16%(1,2).

Transurethral resection of bladder tumors (TURBT) is a surgical procedure performed under general or regional anesthesia. It is the main diagnostic method for obtaining bladder tissue samples, and for non-invasive Ta and T1 carcinomas, it is also the definitive surgical technique for tumor removal(1).

Complete tumor resection using en-bloc resection or piecemeal resection is crucial for a good prognosis. The surgical technique used for resection depends on the tumor's location, size, and macroscopic appearance. Piecemeal resections provide good data on tumor depth. En-bloc resection allows for complete removal of the tumor in one piece with the involved detrusor muscle in 96-100% of cases. En-bloc resection also reduces the risk of bladder perforation(1).

It is important that the muscle part (detrusor) is included in the tissue sample. Absence of muscle in the histopathological sample represents a significant risk for disease recurrence and the need for repeat TURBT(1).

**Keywords:** Transurethral resection of bladder tumors, non-invasive carcinoma, surgical diagnostics.

## **Viri/Sources:**

1. EAU Guidelines. Edn. presented at the EAU Annual Congress Milan, Italy 2023. ISBN 978-94-92671-19-6.
2. Kim LHC, Patel MI. Transurethral resection of bladder tumour (TURBT). Transl Androl Urol. 2020 Dec;9(6):3056–72.

# **Radikalna cistektomija**

## ***Radical cystectomy***

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### **Povzetek**

Radikalna cistektomija je kirurški poseg, ki se večinoma uporablja pri zdravljenju napredovalega raka mehurja. Ta zapleten poseg vključuje radikalno odstranitev mehurja, pogosto pa tudi izrez pridruženih bezgavk in drugih priležnih organov, kar je odvisno od spola pacienta. Odločitev za radikalno cistektomijo se običajno sprejme, ko rak napreduje v fazo, kjer manj invazivni načini zdravljenja niso učinkoviti ali ko obstaja visoko tveganje za ponovitev raka.

Postopek radikalne cistektomije zahteva skrbno načrtovanje in izvedbo s strani izkušene kirurške ekipe. Začne se s temeljito predoperativno pripravo, ki vključuje slikovne preiskave in oceno splošnega zdravja ter telesne pripravljenosti pacienta za operacijo.

Po operaciji se pacienti soočajo s pomembnimi prilagoditvami v svojem vsakodnevnu življenju. Ker je mehur odstranjen, je treba vzpostaviti alternativne metode za shranjevanje in izločanje urina. To vključuje ustvarjanje urinske derivacije, kjer se večinoma z uporabo črevesnih segmentov oblikuje novo pot za odvod urina. Čeprav to pacientom omogoča ohranitev urinske funkcije, zahteva prilagoditev in skrbno samopomoč, da se preprečijo zapleti, kot so okužbe sečil ali presnovna neravnošč.

Klub izzivom, povezanim z radikalno cistektomijo, ta poseg ponuja možnost za ozdravitev raka mehurja in lahko znatno izboljša dolgoročne preživetje pacientov. Napredki v kirurških tehnikah in perioperativni oskrbi so priveli do zmanjšanja obolenosti in izboljšanja kakovosti življenja pacientov.

Vendar radikalna cistektomija, ni poseg brez zapletov. Kirurški zapleti, kot so okužbe, krvavitve ali poškodbe sosednjih organov, se lahko zgodi. Poleg tega je lahko psihični vpliv življenja brez mehurja precejšen, kar zahteva celovito podporo s strani zdravstvenega osebja in svojcev med celotnim procesom okrevanja.

Zaključno, radikalna cistektomija igra ključno vlogo pri zdravljenju napredovalega raka mehurja. Z razumevanjem zapletenosti tega posega in zagotavljanjem celovite oskrbe lahko pomagamo pacientom premagati izzive in doseči najboljše možne izide pri zdravljenju raka.

### **Abstract**

Radical cystectomy is a surgical procedure primarily employed in the treatment of advanced bladder cancer. This intricate operation involves the complete removal of the bladder, often accompanied by the excision of adjacent lymph nodes and other affected tissues, depends on the sex of the patient. The

decision to undergo radical cystectomy is typically made when cancer has progressed to a stage where less invasive treatments are ineffective or when there is a high risk of cancer recurrence.

The procedure of radical cystectomy requires meticulous planning and execution by a skilled surgical team. It begins with thorough preoperative evaluation, including imaging studies and assessment of the patient's overall health and fitness for surgery. Depending on the extent of cancer spread, the surgeon may need to consider additional measures such as pelvic lymph node dissection to ensure optimal cancer removal.

Post-surgery, patients face significant adjustments in their daily lives. Since the bladder is removed, alternative methods for urine storage and elimination must be established. This often involves the creation of a urinary diversion, where a new pathway for urine drainage is constructed using segments of the intestines. While this allows patients to maintain urinary function, it requires adaptation and diligent self-care to prevent complications such as urinary tract infections or metabolic imbalances.

Despite the challenges associated with radical cystectomy, it offers a potential cure for bladder cancer and can significantly improve patients' long-term survival outcomes. Moreover, advancements in surgical techniques and perioperative care have led to reduced morbidity and enhanced quality of life for patients undergoing this procedure.

However, radical cystectomy is not without risks. Surgical complications, such as infection, bleeding, or injury to adjacent organs, may occur. Additionally, the psychological impact of living without a bladder can be profound, necessitating comprehensive support from healthcare professionals and loved ones throughout the recovery process.

In conclusion, radical cystectomy plays a crucial role in the management of advanced bladder cancer. By understanding the intricacies of this procedure and providing comprehensive care, healthcare providers can help patients navigate through the challenges and achieve the best possible outcomes in their cancer treatment journey.

#### **Viri/Sources:**

1. Wein, Alan J.; Kavoussi, Louis R.; Partin, Alan W.; and Peters, Craig A., "Campbell-Walsh Urology: 3-Volume (11th Ed.)" (2016).
2. Joseph A. Smith, Jr., Stuart S. Howards, Glenn M. Preminger, and Roger R. Dmochowski "Hinman's Atlas of Urologic Surgery, 4th Edition" (2019).
3. *EAU Guidelines. Edn. presented at the EAU Annual Congress Milan 2023. ISBN 978-94-92671-19-6.*

# Novosti v sistemskem zdravljenju urotelnega raka

## *Update in the systemic treatment of urothelial cancer*

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### Povzetek

Urotelni rak je rak, ki vznikne v celicah urotelijskega epitelija (mehur, sečnica, sečevodi, ledvični meh), prisoten je v 90% diagnosticiranih rakov mehurja. Cca 12% bolnikov ima ob diagnozi lokalno napredovalo bolezen, primarno metastatskih je cca. 5%. Prognoza je slaba, večina bolnikov po prvi liniji zdravljenja doživi progres; 5-letno relativno preživetje lokalno napredovale bolezni je 39% in metastatske 8%. Letno na svetovni ravni umre 200.000 bolnikov.

Standard prve linije zdravljenja je bil vrsto let kombinacija KT na osnovi platine, vendar le-ta s sabo prinaša veliko toksičnosti, odgovor je relativno kratek, cca 50% bolnikov pa za zdravljenje s platino niti ni primernih bodisi zaradi slabe ledvične funkcije bodisi zaradi slabega splošnega stanja zmogljivosti. Kombinacije s cisplatinom in carboplatinom imajo sicer primerljivo učinkovitost in do neke mere toksičnost. Imunoterapija je bila do sedaj v prvi liniji omogočena bolnikom, ki so dosegli odgovor ob zdravljenju s platino, v obliki vzdrževalnega zdravljenja z avelumabom oz. kot terapija prvega izbora pri tistih, ki niso bili sposobni zdravljenja s cisplatinom in so njihovi tumorji imeli ustrezan pozitiven PD-L1 status.

Septembra 2023 so bili na ESMO kongresu prvič objavljeni rezultati študije Keynote A-39/EV 302, ki kot nov standard zdravljenja postavlja kombinacijo pembrolizumaba (imunoterapija) in enfortumab vedotina (konjugat protitelo-zdravilo). Celokupno mediano preživetje in preživetje brez progrusa sta bila pri zdravljenju z omenjeno kombinacijo v primerjavi z zdravljenjem s kemoterapijo na osnovi platine podvojena (mOS 16.1m vs. 31.5m, mPFS 6.3m vs. 12.5m), toksični profil pa primerljiv. FDA je kombinacijo odobrila 12/2023, na odobritev EMA še čakamo, s 13.3.2024 je uradno priporočena kot 1. linija zdravljenja napredovalega urotelnega karcinoma v ESMO smernicah.

**Ključne besede:** napredoval urotelni karcinom, pembrolizumab, enfortumab vedotin

### Abstract

Urothelial cancer is a cancer that arises in the cells of the urothelial epithelium (bladder, urethra, ureters, renal pelvis), it is present in 90% of diagnosed bladder cancers. Approximately 12% of patients have locally advanced disease at diagnosis, and approximately 5% of patients are primarily metastatic. The prognosis is poor, most patients experience progression after first-line treatment; The 5-year relative survival of locally advanced disease is 39% and of metastatic 8%. 200,000 patients die annually worldwide.

For many years, the standard of first-line treatment was a platinum-based chemotherapy combination, but this brings with it a lot of toxicity, the response is relatively short, and approx. 50% of patients are not even suitable for platinum treatment, either because of poor kidney function or because of poor general health capacity states. Combinations with cisplatin and carboplatin otherwise have comparable

efficacy and to some extent toxicity. Until now, immunotherapy has been available in the first line for patients who have achieved a response to platinum treatment in the form of maintenance treatment with avelumab or as first-line therapy choice in those who were ineligible for cisplatin and whose tumors had an adequate positive PD-L1 status.

In September 2023, the results of the Keynote A-39/EV 302 study were published for the first time at the ESMO Congress, which sets the combination of pembrolizumab (immunotherapy) and enfortumab vedotin (antibody-drug conjugate) as a new treatment standard. Overall median survival and progression-free survival were doubled in treatment with the mentioned combination compared to treatment with platinum-based chemotherapy (mOS 16.1m vs. 31.5m, mPFS 6.3m vs. 12.5m), and the toxic profile was comparable. The FDA approved the combination in 12/2023, we are still waiting for EMA approval, but from 13/03/2024 it is officially recommended as the 1st line of treatment for advanced urothelial carcinoma in the ESMO guidelines.

**Keywords:** advanced urothelial carcinoma, pembrolizumab, enfortumab vedotin

**Viri/Sources:**

1. Powles T. B. et al. LBA6 EV-302/KEYNOTE-A39: Open-label, randomized phase III study of enfortumab vedotin in combination with pembrolizumab (EV+P) vs chemotherapy (Chemo) in previously untreated locally advanced metastatic urothelial carcinoma (la/mUC). Ann Oncol. 2023; 34: S1340
2. Powles T. B. et al. ESMO clinical practice guideline interim update on first-line therapy in advanced urothelial carcinoma. Pridobljeno 13. 3. 2024 na spletni strani: [https://www.annalsofoncology.org/article/S0923-7534\(24\)00075-9/fulltext](https://www.annalsofoncology.org/article/S0923-7534(24)00075-9/fulltext)

# Vloga obsevanja pri zdravljenju mišično invazivnega raka sečnega mehurja

## ***Role of radiotherapy in treatment of muscular invasive bladder cancer***

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### **Povzetek**

Obsevanje ima pomembno vlogo pri zdravljenju raka sečnega mehurja. Lahko je del primarnega (radikalnega) zdravljenja, v kombinaciji z operacijo kot adjuvantno in v primeru potrebe po lajšanju težav kot paliativno zdravljenje.

Pri omejeni obliki raka sečnega mehurja, ko operacija ni izvedljiva ali si bolnik želi ohranitve sečnega mehurja, se lahko obsevanje ponudi bolnikom kot **radikalno** zdravljenje. Kombinira se z maksimalno transuretralno resekcijo sečnega mehurja in kemoterapijo, kar imenujemo tudi multi-modalno zdravljenje. Takšna oblika zdravljenja je možna le v primerih, ko je tumor omejen na sečni mehur in se ni obsežno razsiril izven njega.

Obsevanje lahko sledi operaciji tumorja sečnega mehurja kot **dopolnilno** zdravljenje, če so prisotni dejavniki tveganja za ponovitev bolezni (npr. R1 resekcija ali prizadetost bezgavk z ektrakapsularnim širjenjem).

Pri napredovali obliki raka sečnega mehurja pa ima obsevanje pomembno mesto kot **paliativno** zdravljenje. Predvsem ima vlogo pri zaustavljanju krvavitve (t.i. hemostiptično obsevanje) in lajšanju bolečin pri napredovali bolezni.

Pomembno je, da se zavedamo, da ima obsevanje stranske učinke, ki so lahko takojšnji ali pozni. Najpogosteje se od takojšnjih stranskih učinkov pojavi utrujenost, frekvence inurgence uriniranja ter diareja. Razvoj modernih tehnik obsevanja (IMRT, VMAT) je omogočil natančno dostavo doze in zmanjšanje doze na zdrava tkiva, kar se kaže z zmanjšanjem pojavnosti stranskih učinkov oziroma resnostjo le-teh.

**Ključne besede:** radikalno obsevanje, multimodalno zdravljenje, tehnike obsevanja

### **Abstract**

Radiotherapy plays an important role in the treatment of bladder cancer. It can be part of primary (radical) treatment, in combination with surgery as an adjuvant treatment and in the case of the need to relieve symptoms as a palliative treatment.

In early stage of bladder cancer if surgery is not feasible or the patient wants preservation of the bladder, radiotherapy can be offered to patients as a radical treatment. It is combined with maximal transurethral resection of the bladder and chemotherapy, which is called multi-modal treatment. This form of treatment is possible only in cases where the tumor is limited to the bladder and has not spread extensively outside of it.

Radiotherapy may follow surgery as adjuvant treatment if there are risk factors for disease recurrence (eg. R1 resection or lymph node involvement with extracapsular extension).

In the advanced stages of bladder cancer, radiotherapy plays an important role as a palliative treatment. It mainly plays a role in stopping bleeding (haemostyptic irradiation) and relieving pain in advanced disease.

It is important to be aware that radiation has side effects that can be acute or late. The most common acute side effects are fatigue, urinary frequency and urgency, and diarrhea. The development of modern radiation techniques (IMRT, VMAT) has made it possible to precisely deliver the dose and reduce the dose to healthy tissues, which is manifested by a decrease in the incidence of side effects or their severity.

**Keywords:** radical radiotherapy, multimodal treatment, radiotherapy technics

**Viri/Sources:**

1. Chang SS, Bochner BH, Chou R et al: Treatment of non-metastatic muscle-invasive bladder cancer: AUA/ASCO/ASTRO/SUO guideline. J Urol 2017; 198: 552.
2. National Comprehensive Cancer Network. Bladder Cancer (Version 1.20124). [http://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](http://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed March 19, 2024

# Verifikacija obsevalnega polja pri obsevanju mehurja

## ***Image guided radiation therapy for bladder cancer***

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### **Povzetek**

Namen radioterapije je dostaviti zadostno dozo sevanja v maligni tumor, ki povzroči njegovo uničenje. Hkrati pa želimo zmanjšati izpostavljenost zdravih, okolnih tkiv, z namenom, da preprečimo resne stranske učinke. Ker se tumorji lahko premikajo zaradi dihanja in drugih fizioloških procesov v telesu, se pred vsako frakcijo obsevanja izvede postopek slikanja. Gre za slikovno vodeno radioterapijo (*IGRT – Image Guided Radiotherapy*), geometrično verifikacijo, ki omogoča natančno poravnavo pacienta v izocenter. Preveri se položaj tarčnega volumna (milimetrska natančnost), položaj pacienta in po potrebi izvede korekcija z obsevalno mizo. IGRT nam prav tako dovoljuje zmanjšanje varnostnih robov tarčnega volumna, uporabo modernejših obsevalnih tehnik (IMRT in VMAT), kjer lahko uporabimo višjo dozo na tarčne volumne in s tem zmanjšamo dozo na zdrave organe. Spremljajo se tudi anatomske spremembe tekom vsakdanjega obsevanja, kot so premikanje organov in njihova polnjenost, zmanjšanje ali povečanje tumorja, izguba telesne teže.

Pri verifikaciji slikovnega polja obsevanja mehurja uporabljam CBCT (Cone Beam Computed Tomography). Gre za tridimenzionalno, kilovoltno slikovno tehniko, kjer z enim snopom žarkov stožčaste oblike, v 360° rotaciji zajamemo cel obod pacienta. Dobljeno sliko primerjamo s sliko pridobljeno na CT simulatorju.

### **Priprava in izvedba obsevanja**

Pacientova dokumentacija je najprej predstavljena na onkološkem konziliju. Če je pacientu indicirano obsevanje, medicinska sestra na Enoti za radioterapijo vpše osnovne podatke o pacientu v program Mosaiq, zdravnik specialist radioterapevt naredi triažo, določi področje obsevanja, število frakcij, dozo na frakcijo in celokupno dozo. Radiološki inženir pacienta razvrsti na obsevalni aparat in CT simulator ter določi datum prvega obsevanja.

Lega pacienta, ki se določi na CT pripravi, mora biti čim bolj udobna, fiksna in ponovljiva za vsa nadaljnja obsevanja. Radiološka inženirja pripravita primerne podlage za obsevanje v področju medenice. Opravita pregledno sliko, kjer ocenita velikost mehurja (na približno petnajstih rezih CT slik) in rektuma (ne več kot 5 centimetrov debeline). Določijo se izhodišča s svinčenimi točkami, katera se ob koncu priprave tetovirajo, za potrebe planiranja in vsakdanjega nastavljanja pacienta v položaj za obsevanje. Točke ležijo na sramnici in na lateralni strani medenice v višini kolkov. Področje CT slikanja pri obsevanju mehurja zajema celo medenico.

### **Verifikacija obsevalnega polja**

Referenčna CBCT slika (set CT slik) je predhodno uvožena na delovno postajo XVI. Pri tem označimo clipbox okoli področja, ki nas zanima. Pozorni smo, da je znotraj območja le rigidni del medenice, stegnenico skušamo izključiti. Po zajemu slik s CBCT-jem se odpre okno za registracijo (slika1). Dobimo presek pacienta v koronarni, sagitalni in transverzalni ravnini. Ocenujemo polnjenost rektuma, mehurja

in pokritost tarčnega volumna. Poleg tega smo pozorni tudi na rotacijo medenice in odstopanja zunanje konture, ki lahko vplivata na dozno porazdelitev.



Slika1/fig1: Postavitev clipboxa/ Setting the clipbox (rumena črta - področje registracije/ yellow line – region of interest)

## Zaključek

Človeško telo je kompleksno. Maligni tumorji so pogosto blizu kritičnih organov, zato je uporaba IGRT v radioterapiji ključna za natančno obsevanje. Tako lahko zagotavljamo, da bo tumor prejel načrtovano dozo, okolna, zdrava tkiva pa bodo sevanju izpostavljeni minimalno.

**Ključne besede:** Slikovno vodena radioterapija, CBCT, obsevanje mehurja

## Abstract

The aim of radiotherapy is to deliver a sufficient dose of radiation to a malignant tumour to destroy it. At the same time, we want to minimise exposure to healthy, surrounding tissues in order to prevent serious side effects. As tumours can move due to respiration and other physiological processes in the body, each fraction of radiation is performed by an imaging procedure. This is Image Guided Radiotherapy(IGRT), a geometric verification, that helps to precisely align the patient in the isocentre. The position of the target volume (millimetre accuracy) and the patient's position are verified. If necessary, correction with the radiation table is performed. IGRT also allows us to reduce the safety margins of the target volume, using more modern irradiation techniques (IMRT and VMAT), where we can apply a higher dose to the target volumes and so reduce the dose to healthy organs. Anatomical changes during daily irradiation, such as organ displacement and filling, tumour reduction or enlargement, weight loss, are also monitored.

Cone Beam Computed Tomography (CBCT) is a three-dimensional, kilovoltage imaging technique where a single cone beam is used to image the entire circumference of the patient in a 360° rotation. The image obtained is compared with the image obtained on the CT simulator.

### **Preparation and implementation of the patient for radiotherapy**

The patient's record is first presented to the oncology consilium. If the patient is indicated for radiation treatment, the nurse at the Radiotherapy Unit enters the patient's basic data into Mosaiq, the specialist radiotherapist performs a triage, determines the area of radiation treatment, the number of fractions, the dose per fraction and the total dose. The radiotherapy technician assigns the patient to the radiation machine and the CT simulator and sets the date of the first radiation treatment.

The patient's position, which is determined in the CT preparation, should be as comfortable as possible, fixed and reproducible for all further irradiations. The radiotherapy technicians prepare suitable baseplate for irradiation in the pelvic area. They shall perform a review image to assess the size of the bladder (on approximately 15 slices of the CT images) and the rectum (no more than 5 cm thick). Baselines are determined. These are tattooed at the end of the preparation, for planning purposes and for daily positioning of the patient for irradiation. The points shall be located on the pubic bone and on the lateral side of the pelvis at hip level. The CT imaging area for bladder irradiation covers the whole pelvis.

### **Verification of the treatment field**

The reference CBCT image (CT image set) is pre-imported to workstation XVI. Here we mark the clipbox around the area of interest. We make sure that only the rigid part of the pelvis is inside the area, we try to exclude the femur. After capturing the CBCT images, the registration window opens (fig.1). We obtain a cross-section of the patient in the coronal, sagittal and transverse layers. The rectal and bladder filling and target volume coverage are estimated. In addition, we pay attention to pelvic rotation and deviations of the external contour, which may influence the dose distribution.

### **Conclusion**

The human body is complex. Malignant tumours are often close to critical organs, so the use of IGRT in radiotherapy is crucial for precise radiation treatment. This ensures that the tumour receives the planned dose and that surrounding, healthy tissues are minimally exposed to radiation.

**Keywords:** Image guided radiation therapy, Cone Beam Computed Tomography (CBCT), radiation therapy for bladder cancer

### **Viri/Sources:**

1. Nabavizadeh, N., Elliott, D. A., Chen, Y., Kusano, A. S., Mitin, T., Thomas, C. R., & Holland, J. M. (2016). Image guided radiation therapy (IGRT) practice patterns and IGRT's impact on workflow and treatment planning: Results from a national survey of American Society for Radiation Oncology Members. International Journal of Radiation Oncology Biology Physics, 851.
2. Boc N., Brojan D., But Hadžić J., Čemažar M., ... Stereotaktično obsevanje – novi izzivi zdravljenja v radioterapiji. DiRROS - Stereotaktično obsevanje : novi izzivi zdravljenja v radioterapiji : [strokovno srečanje : elektronski zbornik prispevkov : v Ljubljani, 27.11.2020] (openscience.si)

# Rak mehurja – prikaz primera

## *Bladder cancer – case presentation*

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### **Povzetek**

87- letni bolnik je bil v juliju 2022 sprejet v UKC Maribor zaradi oslabelosti in hematurije. CT urografija je pokazala hiperdenzno spremembo sprednje stene mehurja. Glede na bolnikovo splošno slabo stanje, starost in številne pridružene bolezni dodatna diagnostika in verifikacija bolezni nista bili izvedeni. Na oddelku je prejel transfuzijo eritrocitov. Opravljeno je bilo paliativno hemostiptično obsevanje, ki ga je prejel v avgustu 2022 na predel celotnega mehurja s celokupno dozo 20 Gy v 5 frakcijah. Hematurija se je po obsevanju umirila.

Bolnik je bil nato ponovno sprejet v UKC Maribor v novembru 2022 zaradi ponovne oslabelosti in hematurije. Dodatno je bil obsevan na celoten mehur s celokupno dozo 8 Gy v eni frakciji. Po obsevanju se je stanje bolnika ponovno izboljšalo.

Do poslabšanja hematurije in oslabelosti je ponovno prišlo v novembru 2023. Ob pogovoru z bolnikom in predstavitvi možnih tveganj, je bil gospod še tretjič paliativno obsevan. Tokrat na celoten mehur s celokupno dozo 7 Gy v enkratni frakciji. Celotna radiobiološka doza na mehur je v vseh treh obsevanjih dosegla približno 60 Gy. Tudi po tretjem obsevanju je prišlo do izboljšanja hematurije za približno 1 mesec.

Gospod je umrl februarja 2024, eno leto in pol po prvem obsevanju. Z obsevanji je bil dosežen zadovoljiv paliativni učinek v smislu zaustavitve hematurije. Poznih stranskih učinkov obsevanja ni bilo zabeleženih.

**Ključne besede:** rak mehurja, hematurija, hemostiptično obsevanje

### **Abstract**

An 87-year-old patient was admitted to UKC Maribor in July 2022 due to weakness and hematuria. CT urography showed a hyperdense change in the anterior wall of the bladder. Considering the patient's general condition, age and many associated diseases, additional diagnostics and verification of the disease was not performed. He received a red blood cell transfusion in the ward. Palliative hemostyptic irradiation was administered, which he received in August 2022 to the area of the entire bladder with a total dose of 20 Gy in 5 fractions. After the radiation hematuria subsided.

The patient was then re-admitted to UKC Maribor in November 2022 due to renewed weakness and hematuria. He was additionally irradiated to the entire bladder with a total dose of 8 Gy in one fraction. After radiation, the patient's condition improved again.

Hematuria and weakness worsened again in November 2023. After talking with the patient and presenting the possible risks, he underwent palliative radiation for the third time. This time to the entire bladder with a total dose of 7 Gy in a single fraction. The total radiobiological dose to the bladder in all

three irradiations reached approximately 60 Gy. Even after the third radiation, the hematuria improved for about 1 month.

The patient died in February 2024, a year and a half after the first radiation. Irradiation achieved a satisfactory palliative effect in terms of stopping hematuria. No late side effects of radiation were noted.

**Keywords:** bladder cancer, hematuria, hemostyptic irradiation

**Viri/Sources:**

- I. Joiner M., van der Kogel A. Basic Clinical Radiobiology 4th. Ed., Hodder Arnold, UK, p. 160-166.

PRI LOKALNO NAPREDOVALEM ALI METASTATSKEM RAKU UROTELJIA

# SMER ZA DALJŠE PREŽIVETJE

PADCEV V PRIMERJAVI S KEMOTERAPIJO PO IZBORU RAZISKOVALCA

Inovativno zdravilo **PADCEV**, ki cilja na nektin-4, je podaljšalo mediano celokupnega preživetja do 12,9 mesecev pri bolnikih, ki so bili predhodno zdravljeni s kemoterapijo s platino in zaviralcem PD-1 ali PD-L1 v primerjavi s kemoterapijo po izboru raziskovalca (mediana celokupnega preživetja 12,9 v primerjavi z 9 meseci; RO za smrt: 0,70, 95% IZ: 0,56-0,89; P = 0,001)<sup>1,2</sup>



## INDIKACIJA

Zdravilo Padcev kot monoterapija je indicirano za zdravljenje odraslih bolnikov z lokalno napredovalim ali metastatskim rakom urotelija, ki so predhodno prejeli kemoterapijo s platino in zaviralca receptorja 1 programirane celične smrti ali liganda 1 programirane celične smrti.<sup>1</sup>



20 mg in 30 mg vlate za raztopno za infundiranje

IZ - interval zaupanja; RO - razmerje ogroženosti; LA/mUC - locally advanced or metastatic urothelial cancer, lokalno napredovali ali metastatski rak urotelija; mOS - median overall survival, mediana celokupnega preživetja; PD-1 - programmed death-1, receptor 1 programirane celične smrti; PD-L1 - programmed death-ligand 1, ligand 1 programirane celične smrti.<sup>1</sup>

Viri: 1. Povzetek glavnih značilnosti zdravila PADCEV (enfortumab vedotin). 2. Powles T, Rosenberg JE, Sonpavde GP, et al. Enfortumab vedotin in previously treated advanced urothelial carcinoma. *N Engl J Med.* 2021;384(12):1125-1135.

## SAMO ZA STROKOVNO JAVNOST

Pred predpisovanjem, prosimo, preberite celoten povzetek glavnih značilnosti zdravila. Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v bolnišnicah.

Za vse dodatne informacije o zdravilih podjetja Astellas se obrnite na: medinfo.AB@astellas.com. Lokalni kontaktni naslov za prijavo neželenih učinkov: farmakovigilanca.si@astellas.com.



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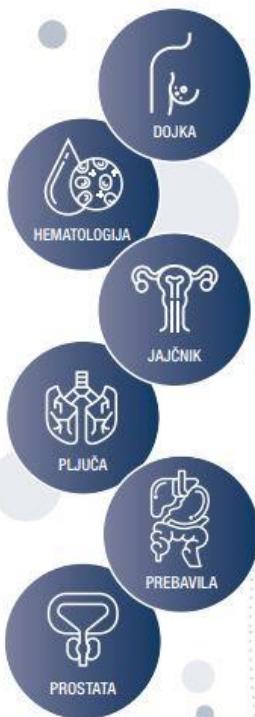


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