Decennale di

HIGHLIGHTS in RADIOTERAPIA

Update degli Studi Practice Changing 2024

Undicesima Edizione

In memoria di Renzo Corvò

ROMA

30-31 gennaio 2025

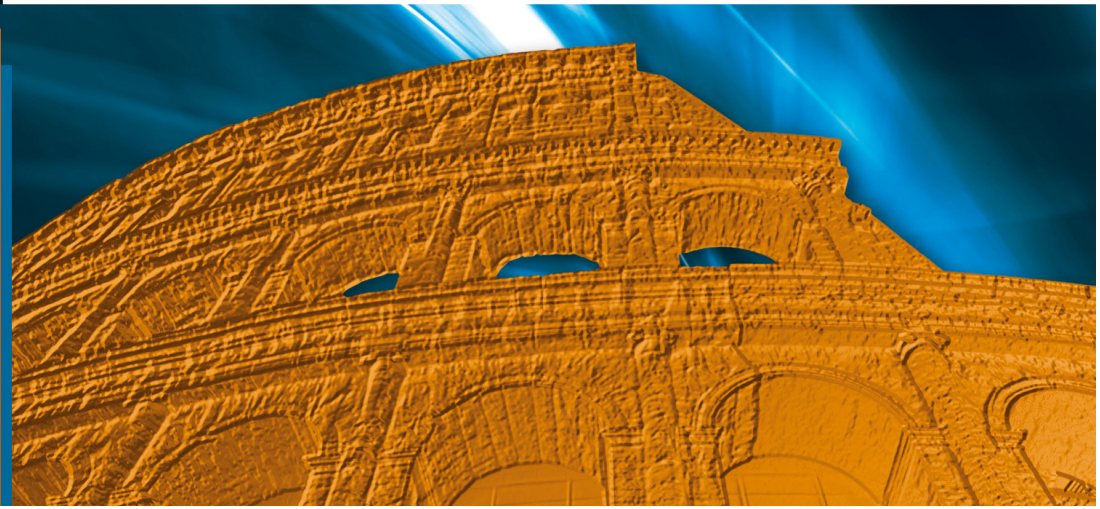
Starhotels Metropole

NEW EVIDENCE AND PRACTICE CHANGING TREATMENTS IN GENITO-URINARY TUMORS

Metastatic prostate and other sites

Dott.ssa Giorgia Timon

IRCCS Policlinico San Martino, Genova



Disclosures

Recordati (advisory board)

Agenda

- Metastatic prostate
  - Primary tumor
- Bladder
- Kidney
- Seminoma
- Closing remarks

- Low metastatic burden, castration-sensitive disease
  - RT to the prostate should be considered in patients with lower metastatic burden castration-sensitive metastatic disease according to CT, MRI, and bone scans when added to ADT. The definition of this cohort is evolving with study updates, concurrent use of intensified systemic therapies, and the introduction of advanced PET imaging. The strongest data are for a benefit of adding RT in patients receiving either ADT alone, ADT+ docetaxel, or ADT + abiraterone for those with <4 bony metastases but should be noted to favor a benefit for up to 7 bony metastases, as reviewed:
    - High metastatic burden originally was defined according to the CHAARTED trial using CT, MRI, and bone scans by presence of visceral metastasis OR ≥4 bone metastasis with at least one outside the vertebral bodies or pelvis. Low metastatic burden disease is defined by lesser volume or extent of disease than high burden. Metastatic burden thus is defined by CT, MRI, and bone scans, whereas PET imaging should not be used to exclude a patient from treatment of the primary tumor.
    - This recommendation is based on the STAMPEDE phase 3 randomized trial's Arm H, which randomized 2061 patients to standard systemic therapy with or without radiotherapy to the primary. The overall cohort had a significant improvement from the addition of radiotherapy to the primary in failure-free survival (FFS), but not OS. The prespecified low-volume subset had a significant improvement in both FFS and OS.[5] A meta-analysis with two other studies confirmed this benefit for primary RT to the primary tumor in lower volume disease.[6]
    - A subsequent update of the STAMPEDE study delineated with more granularity who benefits from treatment of the primary more simply based on number of bone metastases,[7] given the practical challenges with using the CHAARTED definition. In this analysis, the survival benefit of primary RT added to ADT continuously decreased with increasing bone lesion number for up to 7 metastases, with the strongest statistical association remaining for those with <4 metastases. Thus, CT, MRI, and bone scans defined number of bony metastases without visceral involvement may be preferred to define candidacy for treatment of the primary tumor.
  - Minimizing toxicity is paramount when delivering RT to the primary in patients with metastatic disease. As such, it is unclear if routine treatment of regional nodes in addition to the primary tumor or if substantial dose escalation beyond regimens used in prospective studies such as STAMPEDE Arm H improves outcomes; nodal treatment should be performed in the context of a clinical trial.
- High-metastatic burden
  - RT to the prostate should NOT be used in patients with high-volume metastatic disease outside the context of a clinical trial unless for palliative intent.
  - This recommendation is based on two randomized trials, HORRAD and STAMPEDE, neither of which showed an improvement in OS from the addition of radiotherapy to the primary when combined with standard systemic therapy.

Prostate Radiotherapy for Metastatic Hormone-sensitive Prostate Cancer: A STOPCAP Systematic Review and Meta-analysis

Sarah Burdett[a,*], *Liselotte M. Boevé*[b,c,†], *Fiona C. Ingleby*[d,†], *David J. Fisher*[a], *Larysa H. Rydzewska*[a], *Claire L. Vale*[a], *George van Andel*[c], *Noel W. Clarke*[e], *Maarten C. Hulshof*[f], *Nicholas D. James*[g], *Christopher C. Parker*[h], *Mahesh K. Parmar*[d], *Christopher J. Sweeney*[i], *Matthew R. Sydes*[d], *Bertrand Tombal*[j], *Paul C. Verhagen*[k], *Jayne F. Tierney*[a], *the STOPCAP M1 Radiotherapy Collaborators*

Quesito 8 GRADE. **Nei pazienti affetti da carcinoma prostatico metastatico all'esordio, asintomatici, con basso numero di metastasi all'imaging convenzionale (malattia oligometastatica o *low volume* secondo i criteri CHAARTED), l'aggiunta della radioterapia sul volume prostatico alla terapia androgeno-soppressiva (ADT) è raccomandabile in alternativa alla sola ADT in termini di mortalità globale, mortalità cancro-specifica e tossicità?**
Raccomandazione clinica: Nei pazienti affetti da carcinoma prostatico metastatico all'esordio con basso numero di metastasi (malattia oligometastatica o *low volume* secondo i criteri CHAARTED), l'aggiunta della radioterapia sul volume prostatico alla terapia androgeno-soppressiva (ADT) dovrebbe essere presa in considerazione.
Forza della raccomandazione: Forte a favore
Qualità globale delle prove La qualità globale delle prove è da considerarsi **MODERATA** come effetto di un *downgrade* di 1 livello per elevato rischio di *selection bias* (sottogruppo in esame non definito da randomizzazione stratificata) e *performance bias* legato al disegno in aperto degli studi considerati; un ulteriore *downgrade* di 1 livello è stato applicato allo studio HORRAD per imprecisione della stima di OS (IC95% coerenti con interpretazioni cliniche di segno opposto).

mHSPC – RT of the primary tumor

Efficacy and safety of prostate radiotherapy in de novo metastatic castration-sensitive prostate cancer (PEACE-1): a multicentre, open-label, randomised, phase 3 study with a 2 × 2 factorial design

2024

Patient-reported Quality of Life in Patients with Primary Metastatic Prostate Cancer Treated with Androgen Deprivation Therapy with and Without Concurrent Radiation Therapy to the Prostate in a Prospective Randomised Clinical Trial; Data from the HORRAD Trial

2021

Radiotherapy to the primary tumour for newly diagnosed, metastatic prostate cancer (STAMPEDE): a randomised controlled phase 3 trial

2018

Assessment of treatment outcomes: cytoreductive surgery compared to radiotherapy in oligometastatic prostate cancer – an in-depth quantitative evaluation and retrospective cohort analysis

Prostate Radiotherapy in Low-volume Metastatic Hormone-sensitive Prostate Cancer: A Network Meta-analysis

A Systematic Review and Meta-analysis of the Impact of Local Therapies on Local Event Suppression in Metastatic Hormone-sensitive Prostate Cancer

The prognostic significance of additional localized treatment to primary lesion in patients undergoing hormone therapy for metastatic hormone-sensitive prostate cancer: A systematic review and meta-analysis

2024

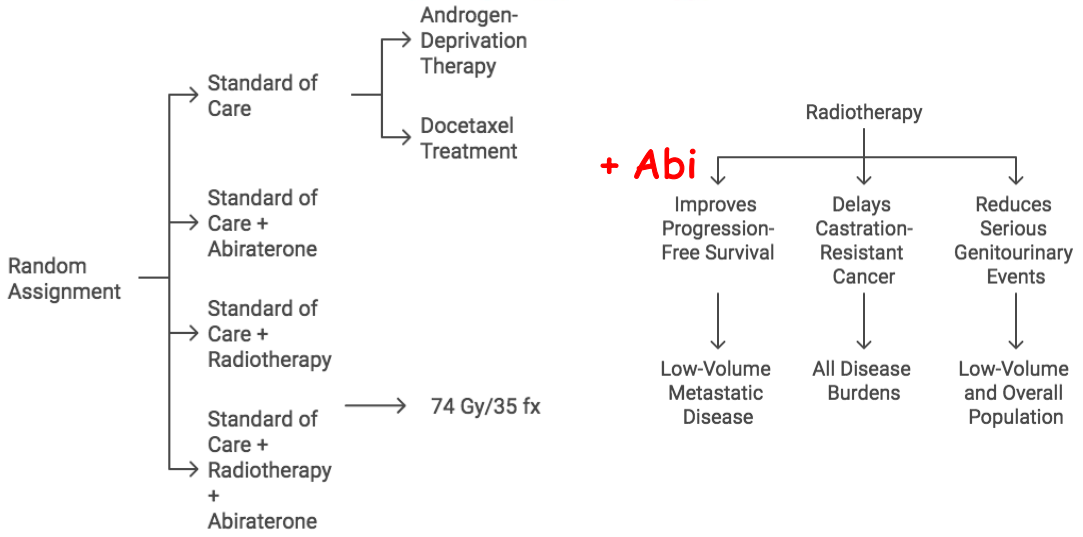
PEACE-1

Efficacy and safety of prostate radiotherapy in de novo metastatic castration-sensitive prostate cancer (PEACE-1): a multicentre, open-label, randomised, phase 3 study with a 2 × 2 factorial design

*Alberto Bossi, Stéphanie Foulon, Xavier Maldonado, Paul Sargos, Ray MacDermott, Paul Kelly, Aude Fléchon, Bertrand Tombal, Stephane Supiot, Dominik Berthold, Philippe Ronchin, Gabriel Kacso, Naji Salem, Fabio Calabro, Jean-François Berdah, Ali Hasbini, Marlon Silva, Jihane Boustani, Hélène Ribault, Karim Fizazi, on behalf of the PEACE-1 investigators**

- randomised, controlled, phase 3 trial with a 2 × 2 factorial design
- de novo mCSPC, ECOG 0-1
- coprimary endpoints: radiographic PFS, OS.
- secondary endpoints:
- castration resistance-free survival
- survival free from serious genitourinary events
- survival free from prostate cancer specifically
- time to next skeletal-related event
- response rate of PSA
- time to pain progression
- time to chemotherapy
- quality of life
- changes in bone mineral density
- correlations between biomarkers and outcomes
- event rate per 100 person-years of treatment and toxicity

1172 pts

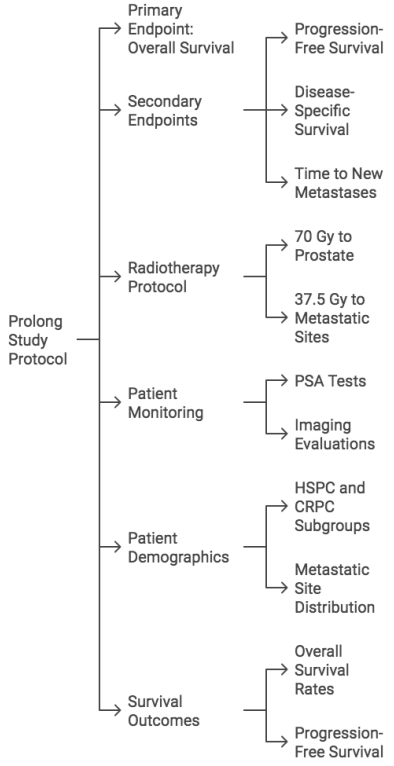


Interpretation Combining radiotherapy with standard of care plus abiraterone improves radiographic progression-free survival and castration resistance-free survival, but not overall survival in patients with low-volume de novo metastatic castration-sensitive prostate cancer. Radiotherapy reduces the occurrence of serious genitourinary events, regardless of metastatic burden and without increasing the overall toxicity, and could become a component of standard of care in patients with both high-volume and low-volume de novo metastatic castration-sensitive prostate cancer.

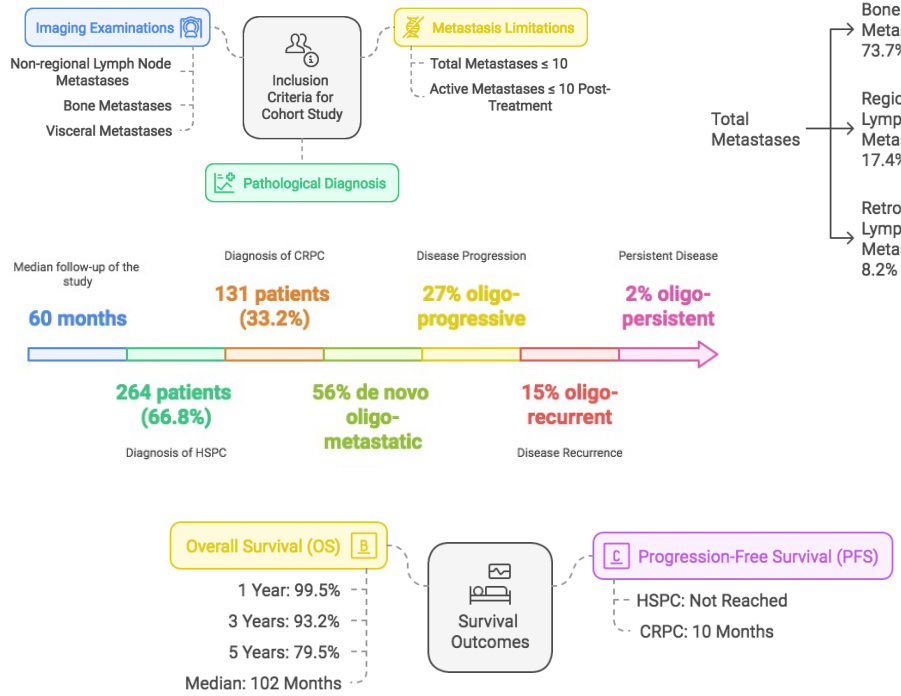
Bossi A et al, Lancet 2024

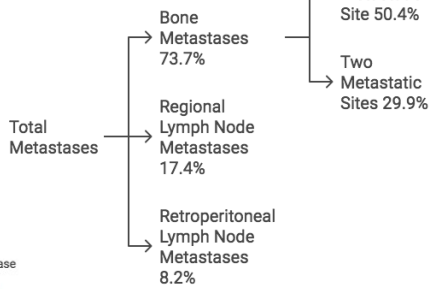
PROLONG

ASTRO 2024 Targeting Provider Wellness FOR EXCEPTIONAL PATIENT CARE
September 29 – October 2, 2024 Walter E. Washington Convention Center - Washington, DC



- patients with oligometastatic prostate cancer
- RT targeting both the primary tumor and all metastatic lesions
- in combination with ADT and ARPI



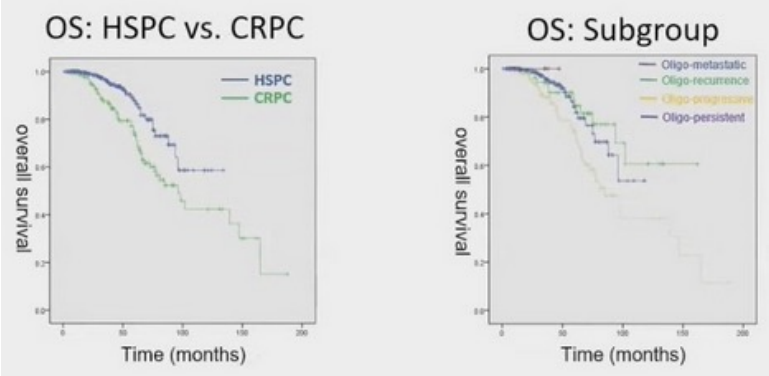


395 pts

Univariate analysis for improved PFS in HSPC:

- HSPC
- lower metastatic volume
- shorter interval between diagnosis and RT
- higher PSA at diagnosis
- the use of WPRT
- lower pre-RT PSA
- type of ADT used
- lower Gleason scores
- use of chemotherapy

Median BED 121.3 Gy



Qi Xin, ASTRO 2024

Agenda

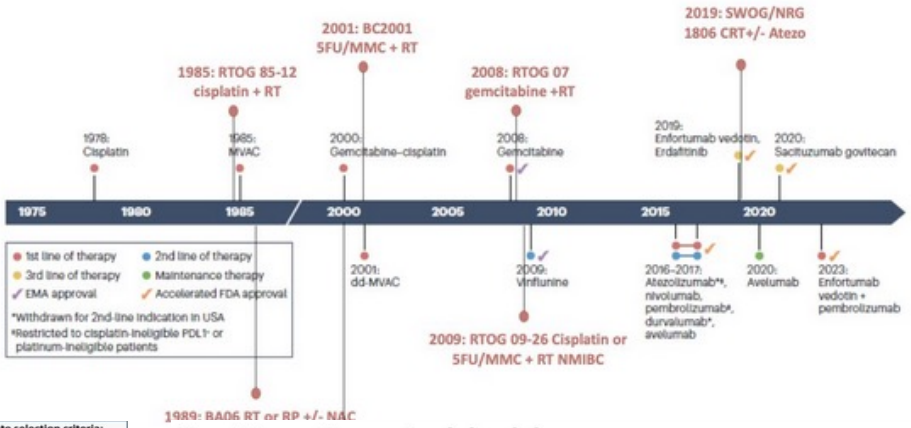
- Metastatic prostate
  - Primary tumor
- **Bladder**
- Kidney
- Seminoma
- Closing remarks

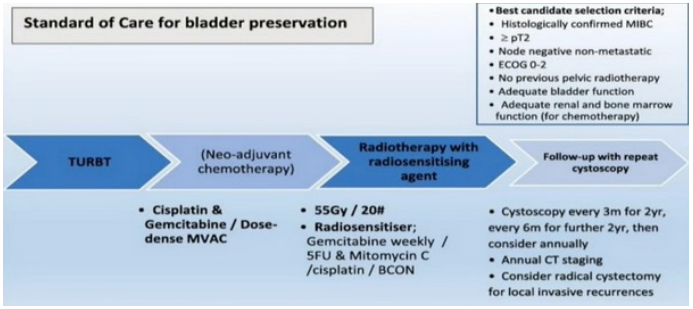
CLINICAL STAGING[h]	ADDITIONAL WORKUP[c]	PRIMARY TREATMENT
Stage II (cT2, N0)	• Abdomen/pelvis CT or MRI[c,x] if not previously done • Chest imaging (CT chest) • Bone scan or MRI[c,x] if clinical suspicion or symptoms of bone metastases • Estimate glomerular filtration rate (GFR) to assess eligibility for cisplatin[y]	Neoadjuvant cisplatin-based combination chemotherapy[z] followed by radical cystectomy[d] (category 1) or Neoadjuvant cisplatin-based combination chemotherapy[z] followed by partial cystectomy[d] (highly selected patients with solitary lesion in a suitable location; no Tis) or Cystectomy alone for those not eligible to receive cisplatin-based chemotherapy or Bladder preservation with concurrent chemoradiotherapy[aa,bb,cc] (category 1) and maximal TURBT or If patient is not a candidate for cystectomy or definitive chemoradiotherapy: RT[bb] or TURBT[d]

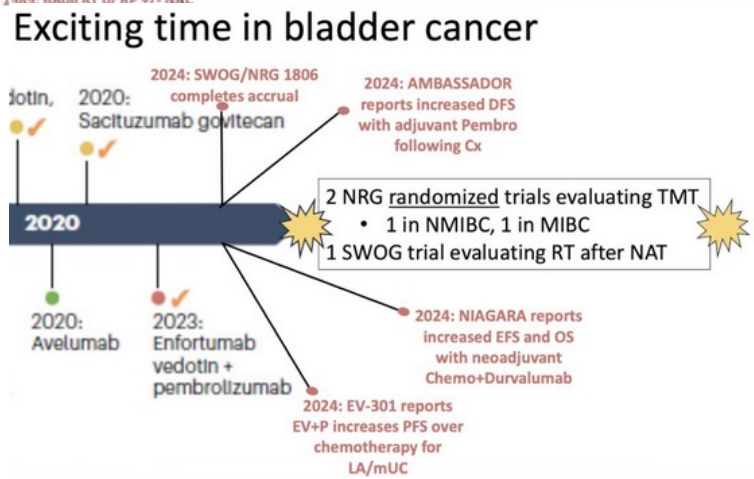
ADJUVANT TREATMENT

Following cystectomy →

- Based on pathologic risk,
  - If no cisplatin neoadjuvant treatment given and pT3, pT4a, or pN+
    - ◊ Adjuvant cisplatin-based chemotherapy should be discussed (preferred)[z]
    - or
    - ◊ Consider adjuvant nivolumab[z,ee]
  - or
  - If cisplatin neoadjuvant chemotherapy given and ypT2–ypT4a or ypN+, consider nivolumab[z,ee]
  - or
  - Consider adjuvant RT in selected patients (pT3–4, positive nodes/margins at the time of surgery)[bb] (category 2B)







Ballas L, ASTRO 2024

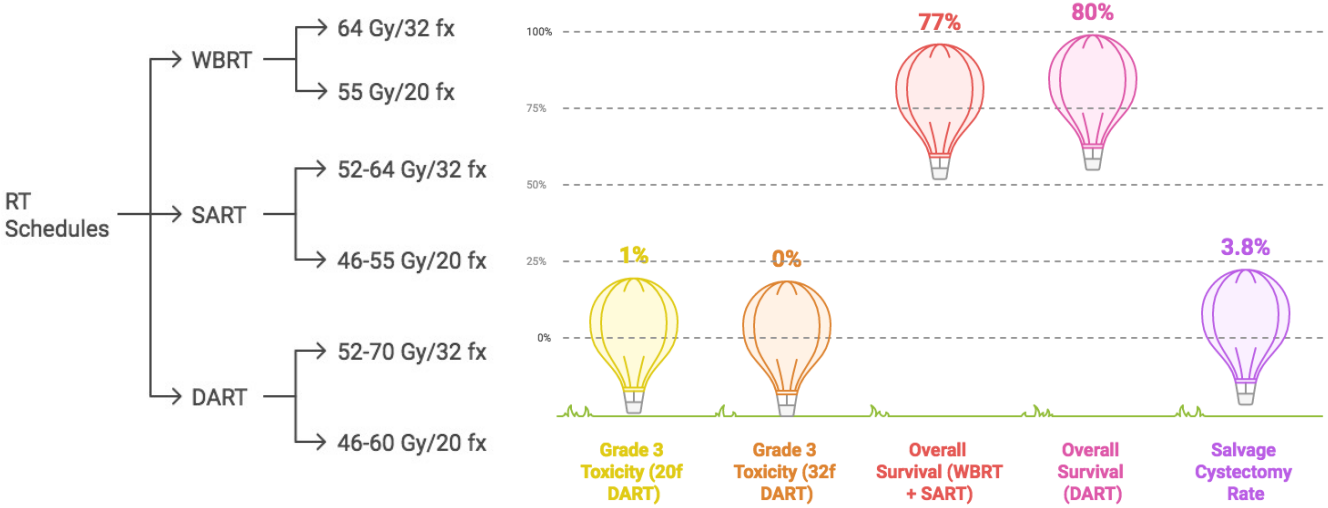
RAIDER

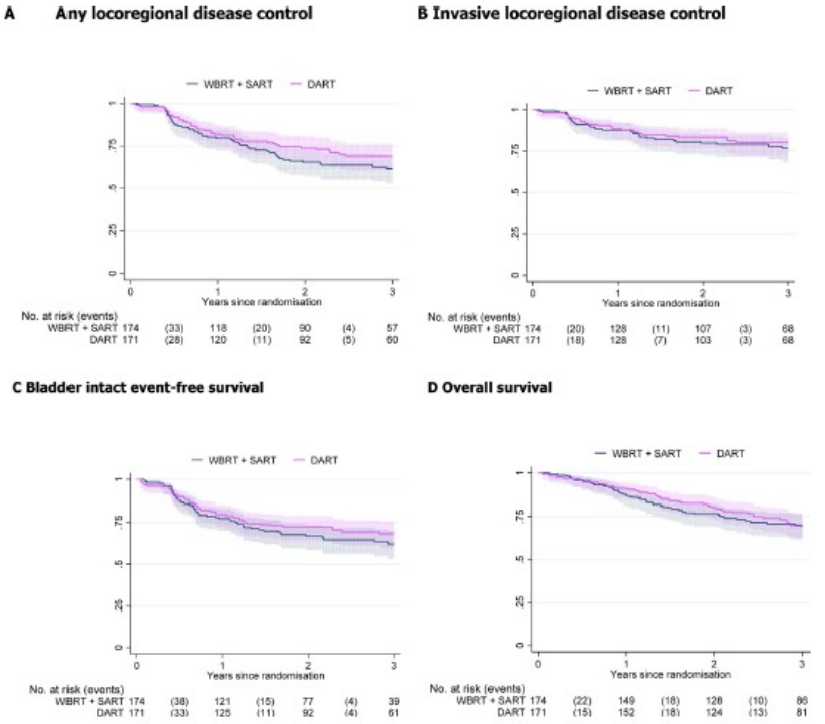
Dose-escalated Adaptive Radiotherapy for Bladder Cancer: Results of the Phase 2 RAIDER Randomised Controlled Trial

Robert Huddart [a,b,*], Shaista Hafeez [a,b], Clare Griffin [a], Ananya Choudhury [c], Farshad Foroudi [d], Isabel Syndikus [e], Benjamin Hindson [f], Amanda Webster [g,h], Helen McNair [a,b], Alison Birtle [i,j,k], Mohini Varughese [l], Ann Henry [m,n], Duncan B McLaren [o], Omi Parikh [i], Ashok Nikapota [p], Colin Tang [q], Emma Patel [r], Elizabeth Miles [r], Karole Warren-Oseni [a,b], Tomas Kron [s], Courtney Hill [t], Lara Philipps [a], Catalina Vassallo-Bonner [a], Ka Ching Cheung [a], Hannah Gribble [a], Rebecca Lewis [a], Emma Hall [a]

- phase 2 noncomparative randomised controlled trial
- unifocal T2-T4a urothelial bladder cancer
- randomized (1:1:2) to WBRT, SART, or DART
- a radiotherapy plan (small, medium, or large) was chosen daily
- primary endpoint: proportion of patients with radiotherapy-related late CTCAE G3 toxicity

345 pts

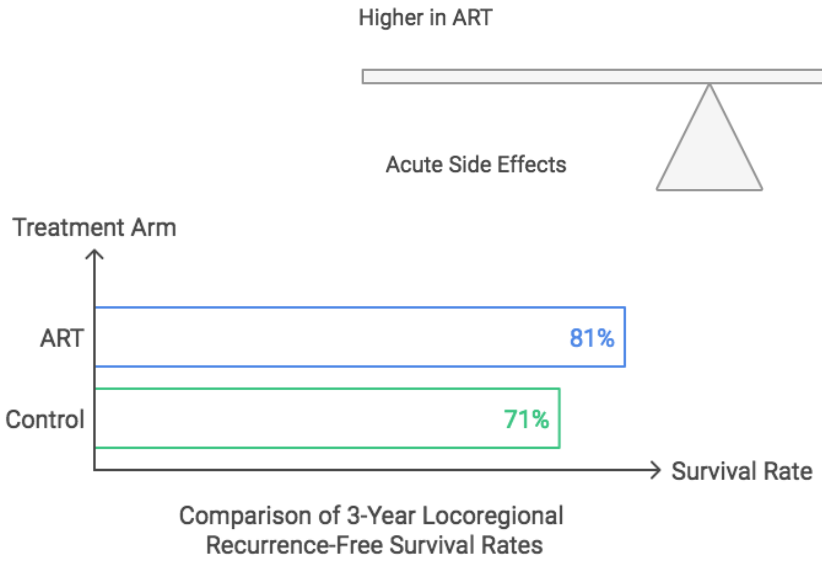




Huddart R et al, Eur Urol 2025

- Controlled phase 2/3 randomized study
- Cystectomy vs cystectomy + ART (50 Gy/25 fx)
- IMRT+IGRT, bladder bed + pelvis
- Primary endpoint: LRRFS
- Secondary endpoints: DFS, DMFS, OS, tox

122 pts



Zaghloul MS, Int J Radiat Oncol Biol Phys 2024

The Value and Safety of Adjuvant Radiation Therapy After Radical Cystectomy in Locally Advanced Urothelial Bladder Cancer: A Controlled Randomized Study

Mohamed S. Zaghloul, MD,*,†,‡,§,‖ Ahmed Khaled Alnagmy, MD,*,† Hatem Aboul Kasem, MD,*
Mohamed M. Abdel Hakim, MD,* Ahmed Abdallah, MD,* Mohamed Kamal, PhB,†
Ayatallah G. Mostafa, MD, PhD,§,‖ and Tarek M. Zaghloul, MD, PhD*,‖

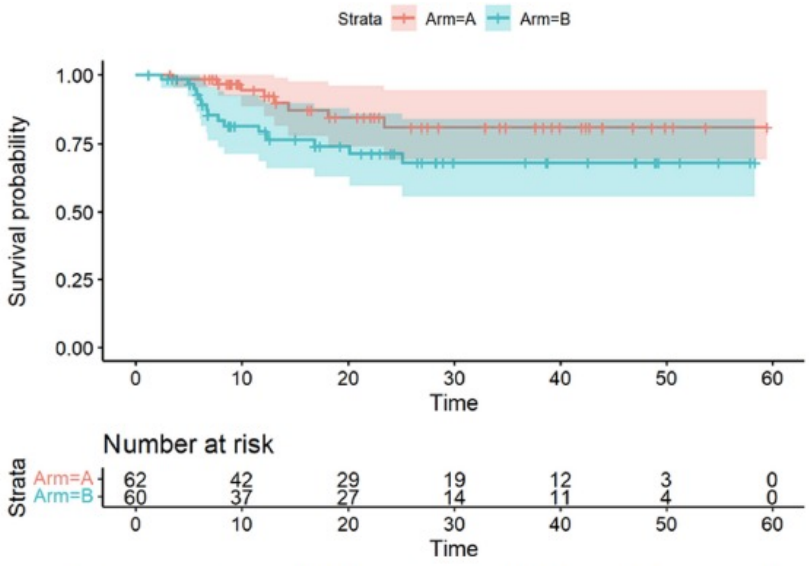


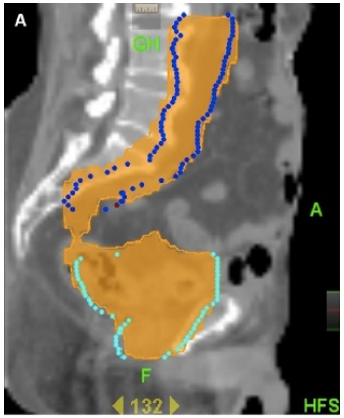
Fig. 2. The locoregional recurrence–free survival in the adjuvant radiation therapy and cystectomy alone arms ($P = .0457$).

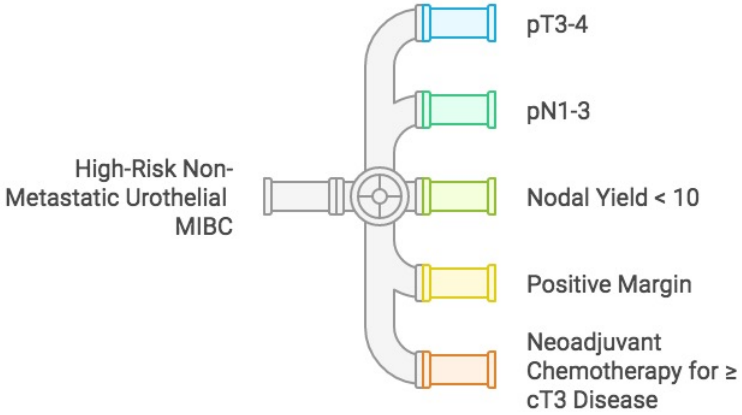
Bladder Adjuvant Radiation Therapy (BART): Acute and Late Toxicity From a Phase III Multicenter Randomized Controlled Trial

Vedang Murthy, MD,[*] Priyamvada Maitre, MD,[*] Ganesh Bakshi, MCh,[†] Mahendra Pal, DNB,[†] Maneesh Singh, MD,[*] Rakesh Sharma, MCh,[‡] Duleep Gudipudi, MD,[‡,§] Lincoln Pujari, MD,[‖] Himanshu Pandey, MCh,[‖,¶] Bhavesh Bandekar, MSc,[‖,#] Deepa Joseph, MD,[**] Rahul Krishnatry, MD,[*] Reena Phurailatpam, MSc,[††] Sadhana Kannan, MSc,[‡‡] Amandeep Arora, MCh,[†] Ankit Misra, MCh,[†] Amit Joshi, DM,[§§] Vanita Noronha, DM,[§§] Kumar Prabhash, DM,[§§] Santosh Menon, MD,[‖‖] and Gagan Prakash, DNB[†]

- Phase 3 randomized superiority study
- Cystectomy vs cystectomy + ART (50.4 Gy/28 fx)
- Stoma-sparing IMRT+IGRT, bladder bed + pelvis
- Primary endpoint: 2-year LRFS

153 pts

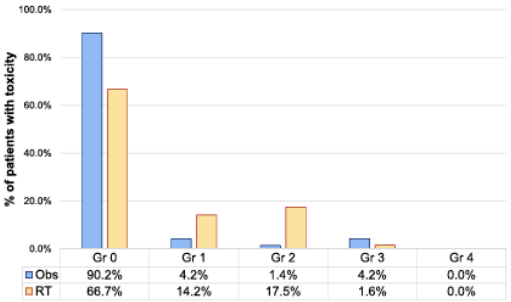




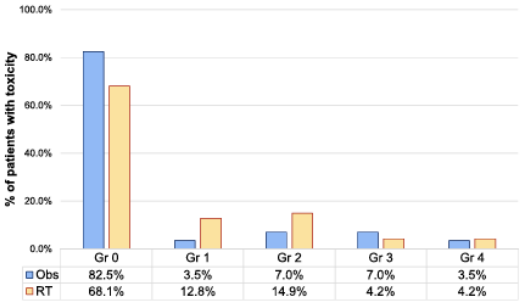
Conclusions

In the largest RCT comparing adjuvant RT to observation for high-risk urothelial MIBC, severe acute and late adverse events were low and similar between the 2 arms. As expected, mild acute bowel toxicity was higher in the RT arm. The oncological outcomes are awaited.

Acute CTCAE toxicity



Late CTCAE toxicity



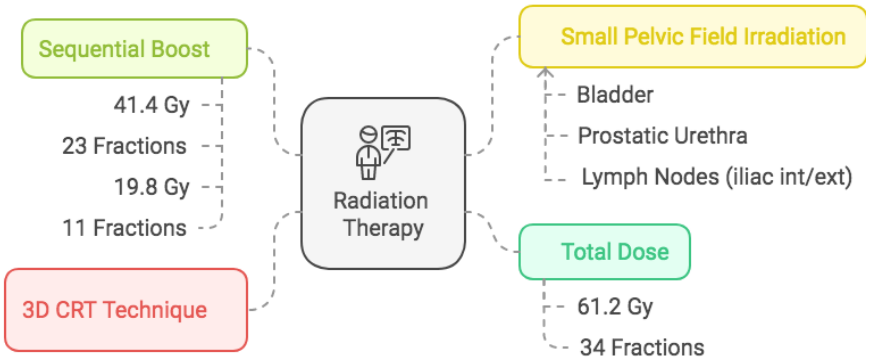
Murthy V et al, Int J Radiat Oncol Biol Phys, 2024

RTOG 0926

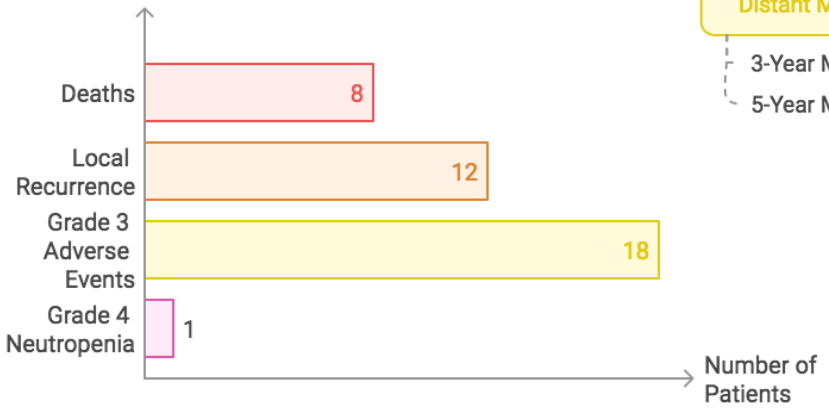
Bladder-Preserving Trimodality Treatment for High-Grade T1 Bladder Cancer: Results From Phase II Protocol NRG Oncology/RTOG 0926

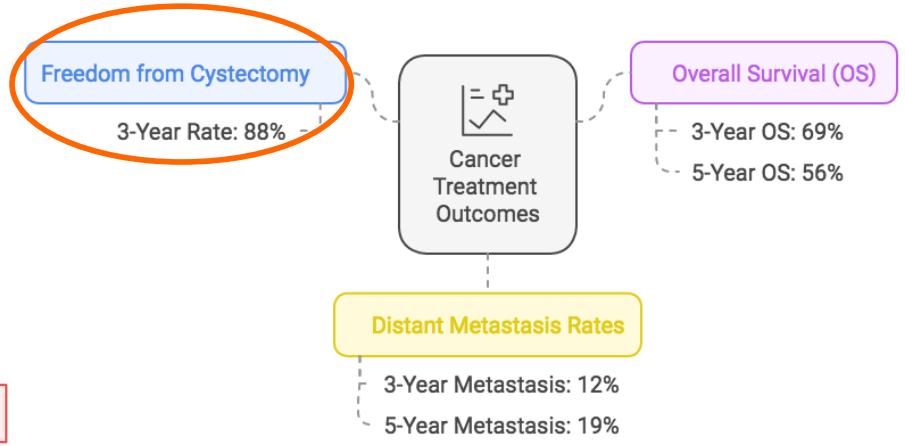
Douglas M. Dahl, MD[1]; Joseph P. Rodgers, MS[2]; William U. Shipley, MD[2]; M. Dror Michaelson, MD, PhD[2]; Chin-Lee Wu, MD, PhD[2]; William Parker, MSc[3]; Ashesh B. Jani, MD[4]; Fabio L. Cury, MD[3]; Richard S. Hudes, MD[5]; Jeff M. Michalski, MD[6]; Alan C. Hartford, MD, PhD[7]; Daniel Song, MD[8]; Deborah E. Citrin, MD[9]; Theodore G. Karrison, PhD[2]; Howard M. Sandler, MD[10]; Felix Y. Feng, MD[11]; and Jason A. Efstathiou, MD[1]

- single-arm phase 2 study
- recurrent T1 bladders who had failed BCG
- primary endpoint: 3-year freedom from cystectomy
- Secondary endpoints: distant metastasis at 3 and 5 years, LR, DSS, OS, safety



34 pts





Dahl DM et al, J Clin Oncol 2024

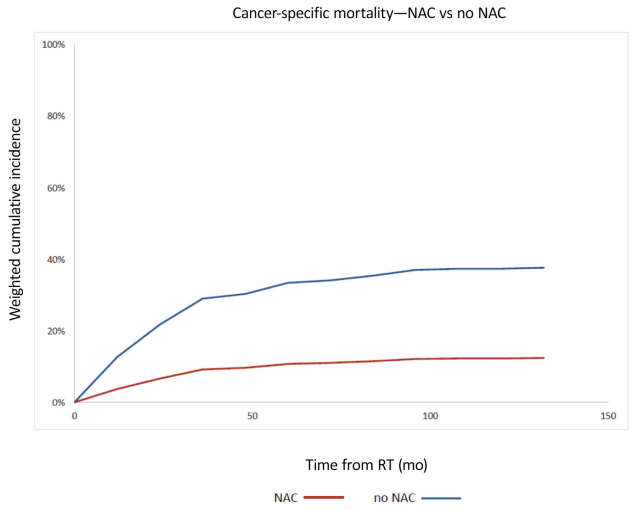
Benefit of Neoadjuvant Cisplatin-based Chemotherapy for Invasive Bladder Cancer Patients Treated with Radiation-based Therapy in a Real-world Setting: An Inverse Probability Treatment Weighted Analysis

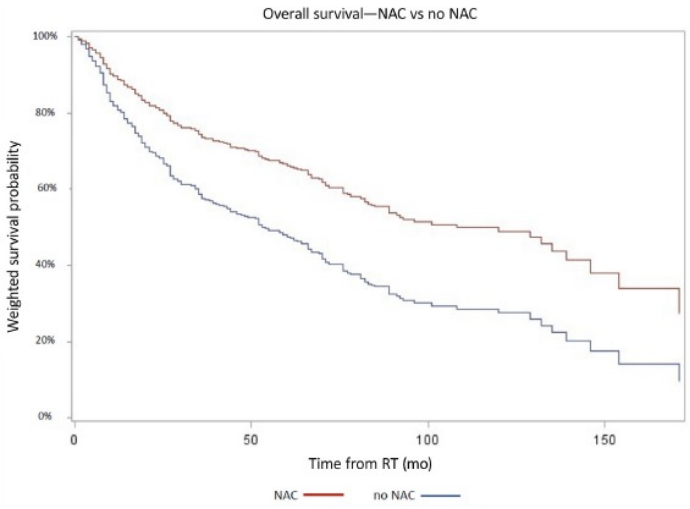
Ronald Kool [a,b], Alice Dragomir [a], Girish S. Kulkarni [c], Gautier Marcq [a,d,e], Rodney H. Breau [f], Michael Kim [c], Ionut Busca [g], Hamidreza Abdi [f], Mark Dawidek [h], Michael Uy [i], Gagan Fervaha [j], Fabio L. Cury [a,k], Nimira Alimohamed [l], Jonathan Izawa [m], Claudio Jeldres [n], Ricardo Rendon [o], Bobby Shayegan [i], Robert Siemens [j], Peter C. Black [h], Wassim Kassouf [a,]*

- retrospective study
- NAC: 4x MVAC/GC
- RT: bladder±pelvis, 64-66 Gy/32-33 fx or 50-55 Gy/20 fx

586 pts

NAC Subgroup
- Younger Patients (66 vs 77 ys)
- Higher ECOG PS 0-1 (87% vs 78%)
- Lymphovascular Invasion (32% vs 20%)
- Higher cT Stage (cT3-4 29% vs 20%)
- Higher cN Stage (cN1-2 32% vs 4%)
- Had Concurrent Chemotherapy (79% vs 67%)



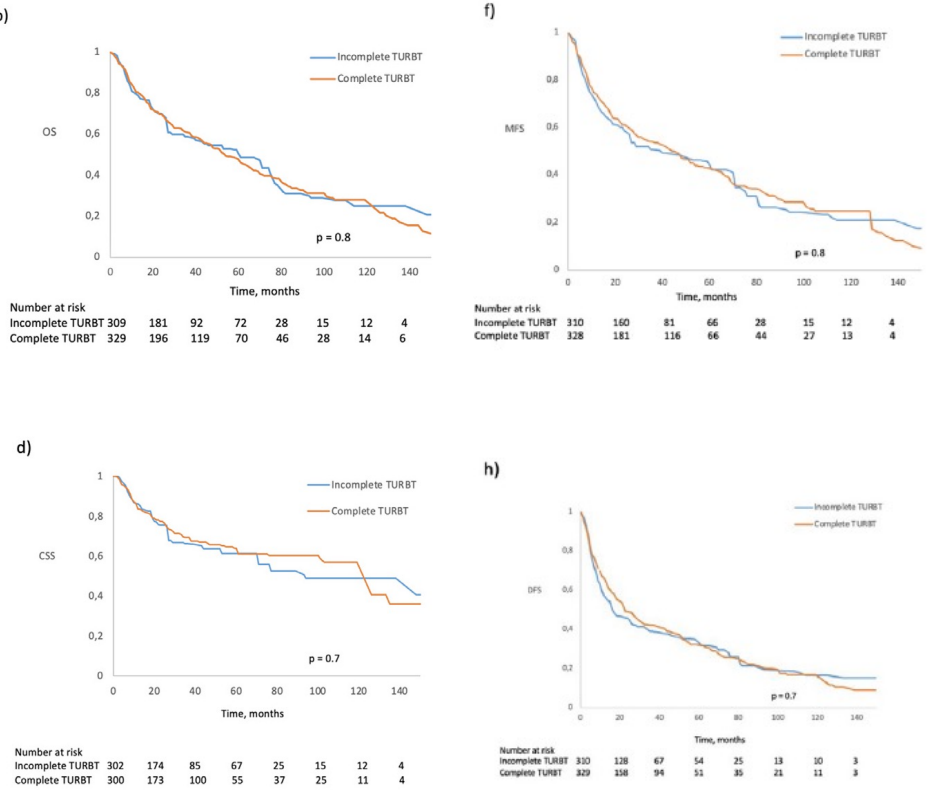


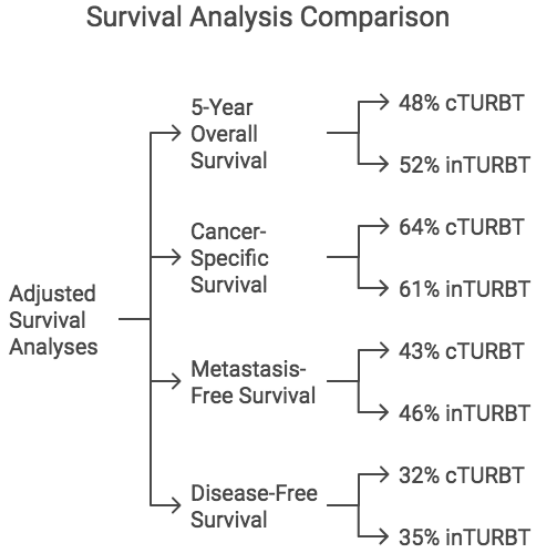
Kool R, Eur Urol Oncol 2024

Effect of Complete Transurethral Resection on Oncologic Outcomes After Radiation Therapy for Muscle-Invasive Bladder Cancer

Pier Paolo Avolio, MD,[*,†] Ronald Kool, MD,[*,†] Bobby Shayegan, MD,[§] Gautier Marcq, MD,[*,‖] Peter C. Black, MD,[¶] Rodney H. Breau, MD,[#] Michael Kim, MD,[**] Ionut Busca, MD,[#] Hamidreza Abdi, MD,[#] Mark Dawidek, MD,[¶] Michael Uy, MD,[§] Gagan Fervaha, MD,[††] Fabio L. Cury, MD,[*,‡‡] Rafael Sanchez-Salas, MD,[*] Nimira Alimohamed, MD,[§§] Jonathan Izawa, MD,[‖‖] Claudio Jeldres, MD,[¶¶] Ricardo Rendon, MD,[##] Robert Siemens, MD,[††] Girish S. Kulkami, MD,[**] and Wassim Kassouf, MD[*]

757 pts





Avolio PP et al, Int J Radiat Oncol Biol Phys 2025

TMT+ICI

ASTRO 2024
Targeting Provider Wellness
FOR EXCEPTIONAL PATIENT CARE
September 29 – October 2, 2024
Walter E. Washington Convention Center · Washington, DC

Pembrolizumab with Chemoradiation as Treatment for Muscle-invasive Bladder Cancer: Analysis of Safety and Efficacy of the PCR-MIB Phase 2 Clinical Trial (ANZUP 1502)

Andrew Weickhardt[a,], Farshad Foroudi[a], Nathan Lawrentschuk[b], Jing Xie[c], Mark Sidhom[d], Abhijit Pal[d], Peter Grimison[e], Alison Zhang[e], Siobhan Ng[f], Colin Tang[f], Elizabeth Hovey[g], Colin Chen[g], George Hruby[h], Alexander Guminski[h], Margaret McJannett[i], Ciara Conduit[b,i], Ben Tran[b], Ian D. Davis[i,j,k], Dickon Hayne[l]*

Pembrolizumab Monotherapy Following Tri-Modality Treatment for Selected Patients with Muscle-Invasive Bladder Cancer

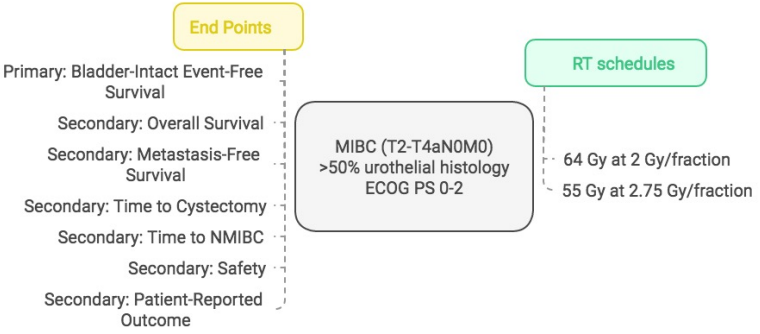
S.B. Qin,[1] W. Yu,[2] Z.S. He,[2] X.S. Gao,[1] H. Hao,[2] H.Z. Li,[1] and Y. Bai[1];
[1]Department of Radiation Oncology, Peking University First Hospital, Beijing, China, [2]Department of Urology, Peking University First Hospital, Beijing, China

ASCO GU SYMPOSIUM 2024

Phase 3 KEYNOTE-992 study of pembrolizumab plus chemoradiotherapy versus placebo plus chemoradiotherapy in patients with muscle-invasive bladder cancer (MIBC).

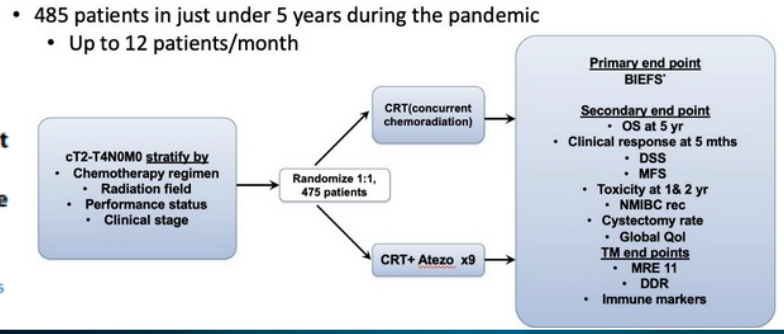
636 pts

Shilpa Gupta, Yasuhisa Fujii, Michiel Simon Van Der Heijden, Andrew James Weickhardt, Nicholas D. James, Shahrokh F. Shariat, Jeff M. Michalski, Kentaro Imai,



INTACT (S/N1806): Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer—Toxicity Update on First 213 Patients

P. Singh,[1] J.A. Efstathiou,[2] M. Plets,[3] S.G. Jhavar,[4] S. Delacroix, Jr[5]



Agenda

- Metastatic prostate
  - Primary tumor
- Bladder
- **Kidney**
- Seminoma
- Closing remarks

Stereotactic body radiotherapy for primary renal cell carcinoma: a systematic review and practice guideline from the International Society of Stereotactic Radiosurgery (ISRS)

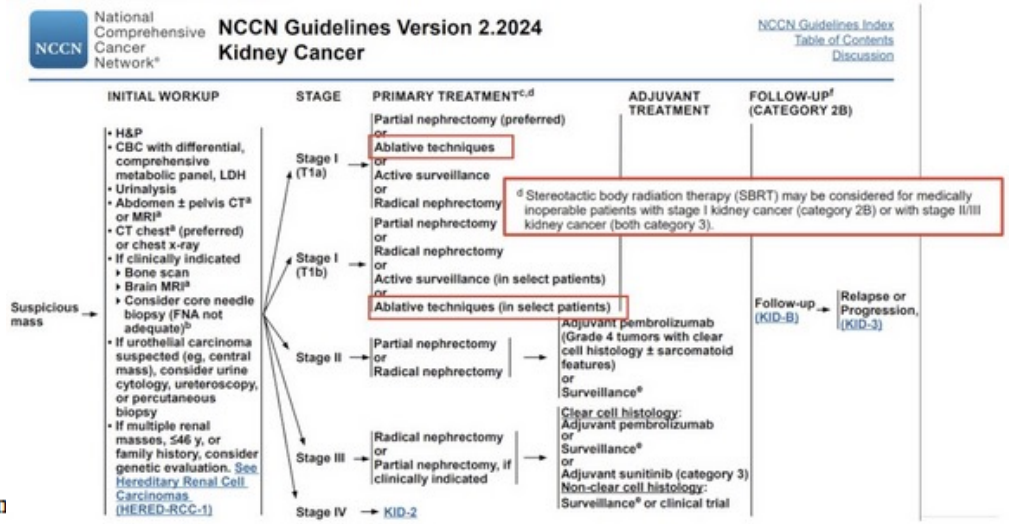
Shankar Siva, Alexander V Louie, Rupesh Kotecha, Melissa N Barber, Muhammad Ali, Zhenwei Zhang, Matthias Guckenberger, Mi-Sook Kim, Marta Scorsetti, Alison C Tree, Ben J Slotman, Arjun Sahgal, Simon S Lo

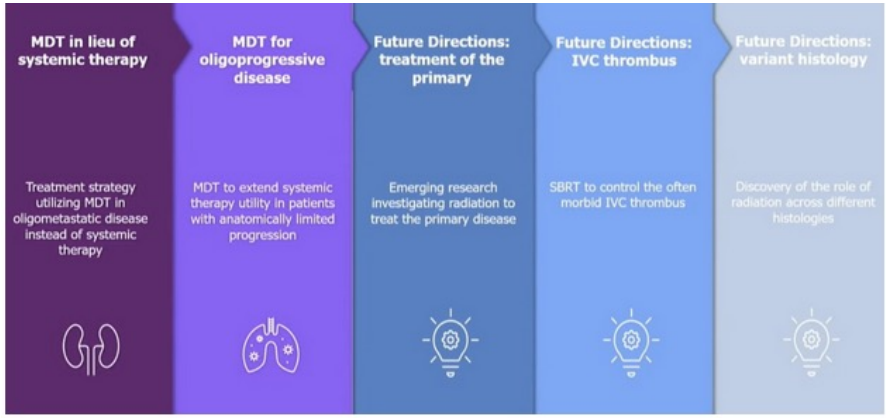
Dose-response of localized renal cell carcinoma after stereotactic body radiation therapy: A meta-analysis

Ryan S. Huang [a], Ronald Chow [a,b,d,e], Pradnya Chopade [b], Andrew Mihalache [a], Asad Hasan, Gabriel Boldt [d], Rachel Glicksman [b], Charles B. Simone II [e], Michael Lock [d], Srinivas Raman

Long-term Renal Function Outcomes After Stereotactic Ablative Body Radiotherapy for Primary Renal Cell Carcinoma Including Patients with a Solitary Kidney: A Report from the International Radiosurgery Oncology Consortium of the Kidney

Vivian S. Tan [a,†], Rohann J.M. Correa [a,†], Andrew Warner [a], Muhammad Ali [b], Alexander Muacevic [c], Lee Ponsky [d], Rodney J. Ellis [e,f], Simon S. Lo [g], Hiroshi Onishi [h], Anand Swaminath [i], Young Suk Kwon [j], Scott C. Morgan [k], Fabio L. Cury [l], Bin S. Teh [m], Anand Mahadevan [n], Irving D. Kaplan [o], William Chu [p], Raquibul Hannan [j], Michael Staehler [c], Nicholas G. Zaorsky [d], Alexander V. Louie [a,p], Shankar Siva [b,]*

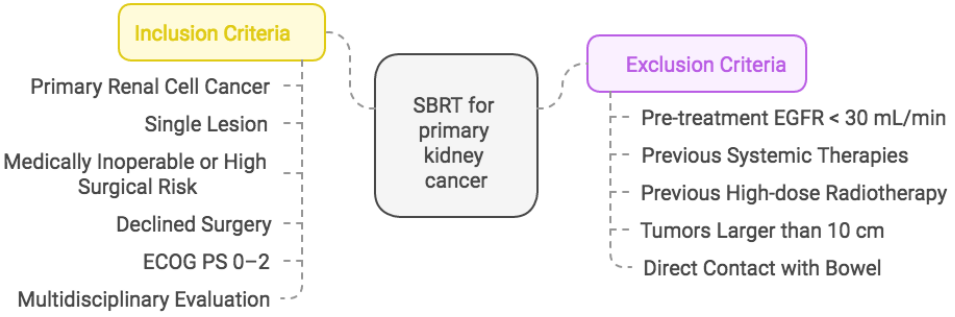


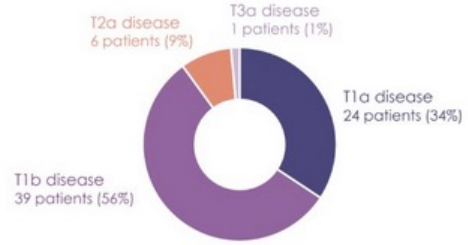


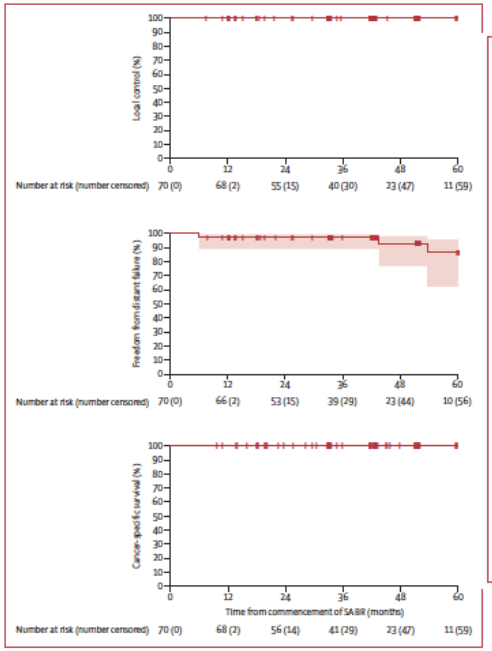
Tang C, ASTRO 2024

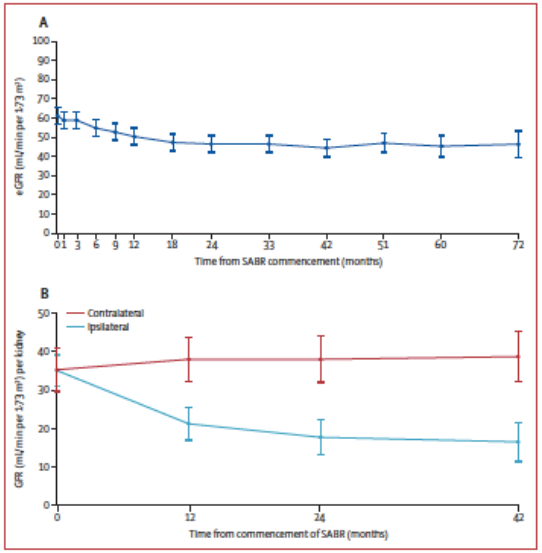
FASTRACK II

- non-randomised, phase 2 study — 70 pts
- Primary endpoint: 12 months local control (RACIST v1.1)
- Secondary endpoints: OS, CSS, FFDF, safety (CTCAE 4.03), renal function change









Siva S et al, Lancet Oncol 2024

kidney – ongoing studies

Cytoreductive stage I

Oligometastatic/ oligoprogressive

Primary in metastatic/poor risk

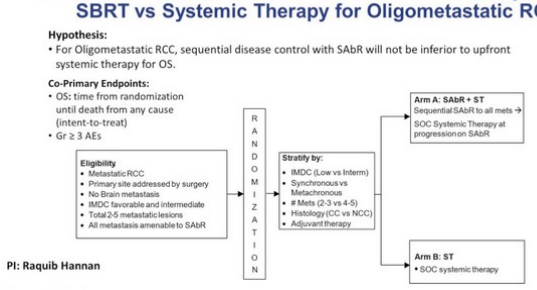
NeoAdjuvant pembrolizumab and STEreotactic radiotherapy prior to nephrectomy for renal cell carcinoma (NAPSTER): A phase II randomised clinical trial

Muhammad Ali[a,b,*], Simon Wood[c,d,e], David Pryor[f,g], Daniel Moon[h], Mathias Bressel[i], Arun A. Azad[b,j], Catherine Mitchell[k], Declan Murphy[l], Homi Zargar[b], Nick Hardcastle[b,m,n], Jamie Kearsley[o], Renu Eapen[l], Lih Ming Wong[b,p], Katharine Cuff[q], Nathan Lawrentschuk[b,l,o], Paul J. Neeson[b,r], Shankar Siva[a,b]

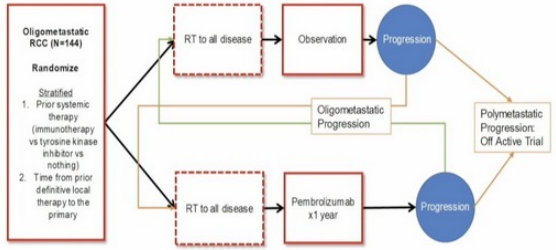
A Pilot Study of Stereotactic Body Radiation Therapy Combined with Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma

Anurag K. Singh[1], Timothy B. Winslow[1], Mohammad Habiby Kermany[2], Vincent Goritz[2], Lilia Heit[2], Austin Miller[3], Nicholas C. Hoffend[2], Leighton C. Stein[4], Lalith K. Kumaraswamy[1], Graham W. Warren[5], Wiam Bshara[4], Kunle Odunsi[6,7,8], Junko Matsuzaki[7], Scott I. Abrams[8], Thomas Schwaab[2,8], and Jason B. Muhitch[2,8]

EA8211 SOAR Randomized Phase III Non-inferiority Trial of SBRT vs Systemic Therapy for Oligometastatic RCC

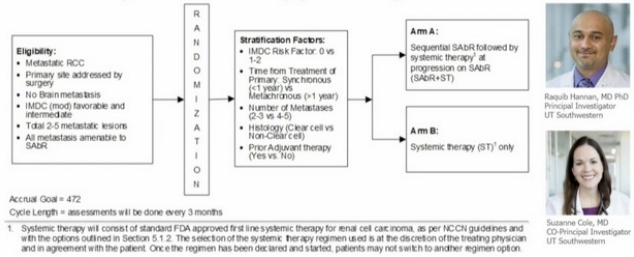


ASTROs trial

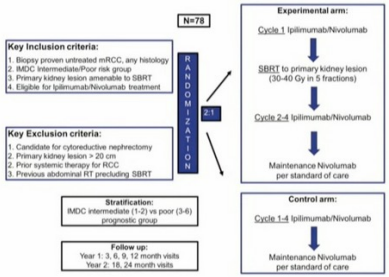


Activated November 2023
Primary Endpoint: PFS

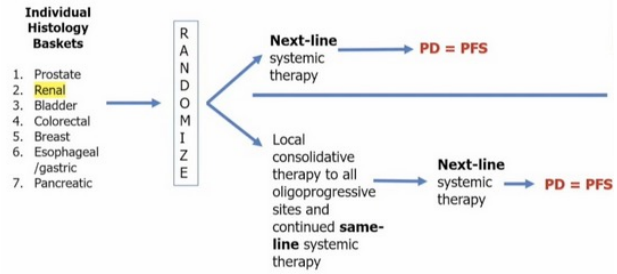
EA8211/SOAR
Randomized Phase III Non-inferiority Trial of SAbR vs Systemic Therapy for Oligometastatic RCC



CYTOSHRINK, NCT04090710



EXTEND-OP trial



NRG-GU012: Randomized phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma Receiving Immunotherapy (SAMURAI) NCT 05327686

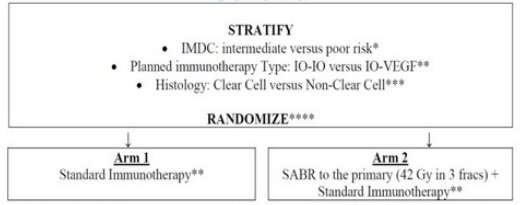
Primary Endpoint: Nephrectomy & radiographic progression-free survival

Secondary Endpoints:
OS
Toxicities
ORR

Target Accrual: 240 patients

PIs: Dr. Rana McKay & Dr. William Hall

Schema



*International Metastatic RCC database consortium (IMDC): Intermediate risk is 1-2 risk factors and poor risk is 3 or more risk factors (See Section 3.1.3).

VIEWPOINT

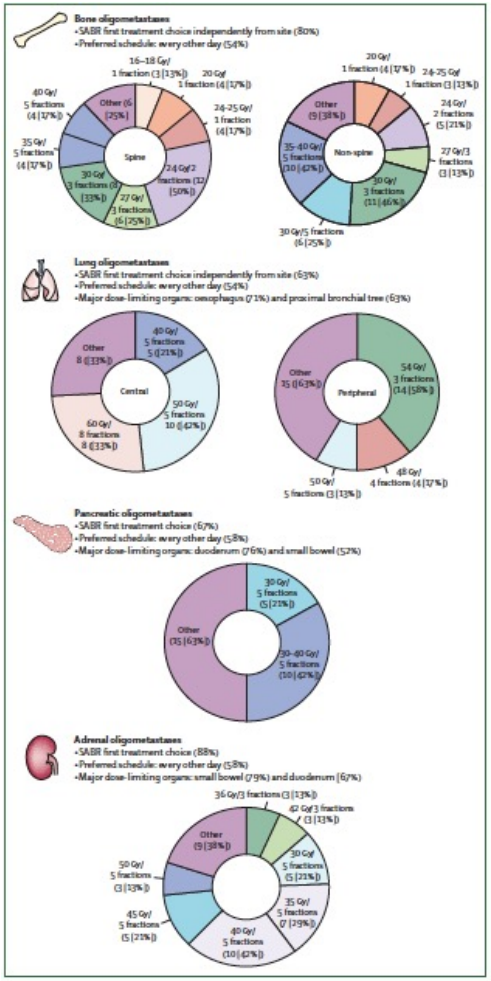
Charting the Path to Systemic Therapy De-escalation—Oligometastatic Kidney Cancer as a Paradigm

Chad Tang, MD
Department of Genitourinary Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston.

Pavlos Msaouel, MD, PhD
Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston.

Database Consortium score) and novel prognostic scores that leverage both traditional and experimental biomarkers including circulating tumor DNA, cell-free DNA methylation, and genomic/transcriptional classifiers. It is unlikely that industry alone will sponsor research into systemic therapy de-escalation or translational studies to understand the oligometastatic state, both of which could potentially reduce pharmaceutical revenues.

Oncology stands at a critical juncture due to treatment cost escalation driven in significant part by pharmaceutical costs. Therefore, it is time for the oncology community, scientific journals, and philanthropic funding sources to advocate for and support research efforts to further define the oligometastatic disease space and carefully investigate systemic therapy de-escalation in the appropriate populations. The recent common sense oncology movement represents one of the first steps of such a paradigm shift by emphasizing patient outcomes that matter while de-emphasizing pharmaceutical company agendas.[7] Although we use kidney cancer as a focus point, we should also note efforts to deintensify systemic therapy are being pursued in other cancers. These include replacement of chemotherapy as a radiation sensitizer for human papillomavirus–positive localized oropharyngeal cancers and MDT to defer hormone therapy in oligometastatic prostate cancer. It is only through such efforts that we may be able to achieve a counterbalance to the prevailing trend of systemic therapy escalation through the development of patient-centric treatment strategies that maintain quality of life without impacting efficacy.



Delphi consensus on stereotactic ablative radiotherapy for oligometastatic and oligoprogressive renal cell carcinoma—a European Society for Radiotherapy and Oncology study endorsed by the European Association of Urology

Giulia Marvaso, Barbara Alicja Jereczek-Fossa*, Mattia Zaffaroni, Maria Giulia Vincini, Giulia Corrao, Nicolaus Andratschke, Ehsan H Balagamwala, Jens Bedke, Oliver Blanck, Umberto Capitanio, Rohann J M Correa, Gert De Meerleer, Ciro Franzese, Aurora Gaeta, Sara Gandini, Cristina Garibaldi, Peter C Gerszten, Silke Gillessen, William R Grubb, Matthias Guckenberger, Raquibul Hannan, Pavan M Jhaveri, Mirjana Josipovic, Linda G W Kerkmeijer, Eric J Lehrer, Magnus Lindskog, Alexander V Louie, Quynh-Nhu Nguyen, Piet Ost, David A Palma, Giuseppe Procopio, Maddalena Rossi, Michael Staehler, Alison C Tree, Yat Man Tsang, Nicholas Van As, Nicholas G Zaorsky, Thomas Zilli, David Pasquier†, Shankar Siva†*

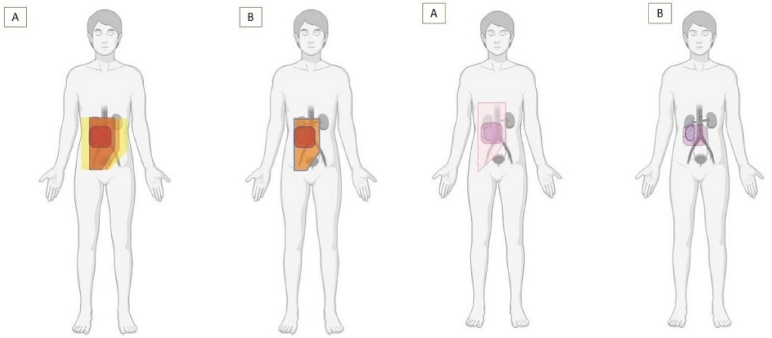
Agenda

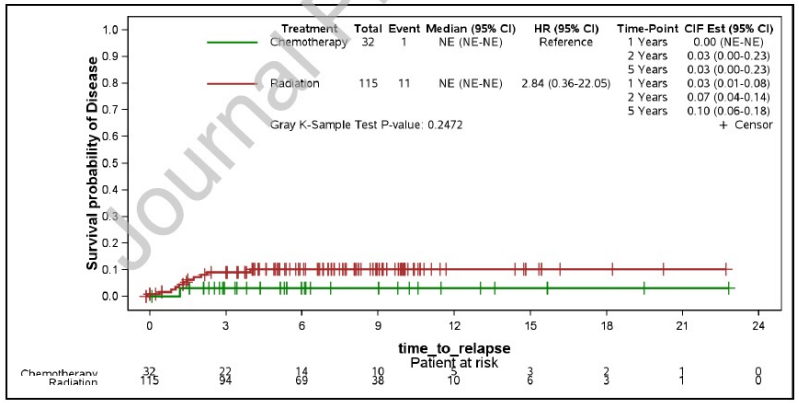
- Metastatic prostate
  - Primary tumor
- Bladder
- Kidney
- Seminoma
- Closing remarks

Short Communication

Radiation therapy for stage IIA/IIB seminomas: Back to the future?

Jennifer Le Guévelou [a,*], Luca Nicosia [b], Pierre Blanchard [c], Flavien Ralite [d], Xavier Durand [e], Vincent Marchesi [f], Guilhem Roubaud [g], Paul Sargos [d,h]





153 pts

Clinical outcomes of stage IIA/IIB seminoma treated with radiotherapy and chemotherapy: should regional therapy be considered the preferred treatment approach?

Rachel M Glicksman MD MSc,[1] Di Maria Jiang MD,[2] Philippe L Bedard MD,[2] Xiang Y Ye MSc,[3] Lynn Anson-Cartwright,[4] Astrid Billfalk-Kelly MBBCh,[5] Satheesh Krishna MD,[6] Martin O'Malley MBBCh,[6] Carol C Cheung MD PhD,[7] Abigail Shin,[1] Robert J Hamilton MD MPH,[4] Padraig Warde MBBCh,[1] Peter Chung MBChB [1]

Agenda

- Metastatic prostate
  - Primary tumor
- Bladder
- Kidney
- Seminoma
- Closing remarks

Primary RT in mHSPC
- Diagnostic imaging issue
- Are more prospective studies needed?

Bladder
- Adjuvant RT, data transferability (age)
- Adaptive RT to increase dose/lower toxicity
- How important really is a maximal TURBT?

Kidney
- Is RCC truely radioresistant?

Seminoma
- Is RT back?
- Is PRT the future?

General
- TT/IT trials to ride
- Difference between guidelines and clinical practice
- Do many retrospective or small non-randomized prospective trials… make a RCT?
- New lendscapes
- Allocation of (limited) resourses