Decennale di

HIGHLIGHTS in RADIOTERAPIA

Update degli Studi Practice Changing 2024

Undicesima Edizione

In memoria di Renzo Corvò

ROMA

30-31 gennaio 2025

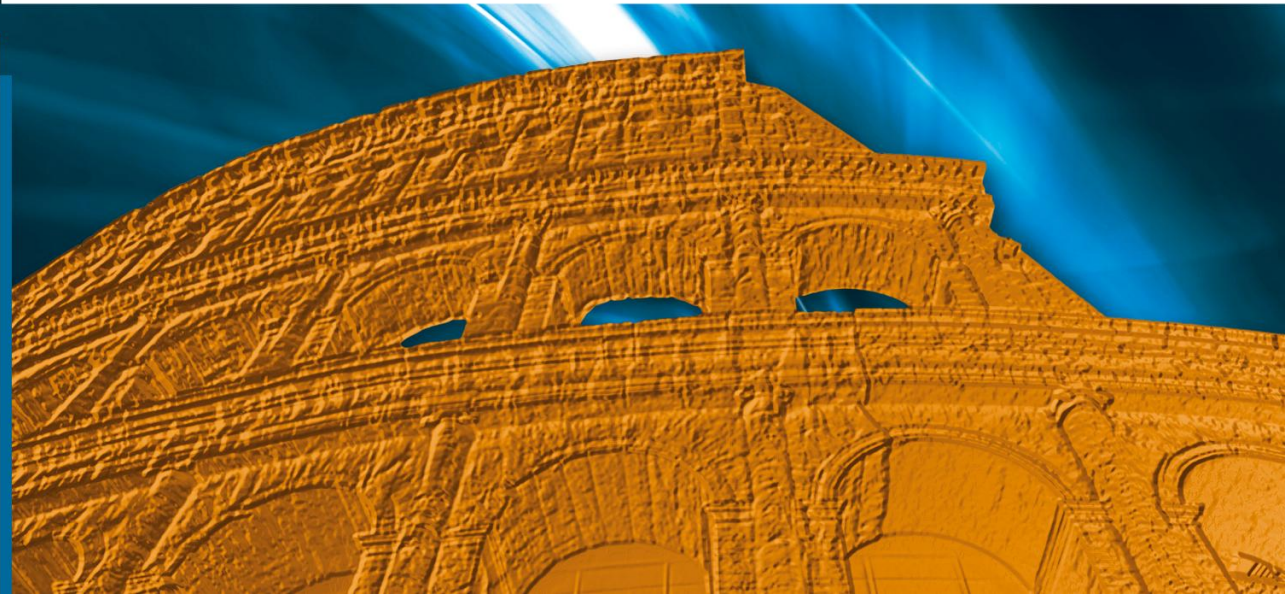
Starhotels Metropole

NEW EVIDENCE AND PRACTICE CHANGING TREATMENTS IN GENITO-URINARY TUMORS (LOCALIZED PROSTATE)

Filippo Alongi

Professor of Radiation Oncology, University of Brescia

Chair of Advanced Radiation Oncology Department
IRCCS, Sacro Cuore Don Calabria Cancer Care Center,
Negrar-Verona, Italy



DECENNALE di
HIGHLIGHTS IN RADIOTERAPIA
Update degli Studi Practice Changing 2024
Roma, 30-31 gennaio 2025

NEW EVIDENCE AND PRACTICE CHANGING TREATMENTS IN GENITO-URINARY TUMORS (LOCALIZED PROSTATE)

Filippo Alongi

Professor of Radiation Oncology, University of Brescia

Chair of *Advanced Radiation Oncology Department*
IRCCS, Sacro Cuore Don Calabria Cancer Care Center,
Negrar-Verona, Italy

DISCLOSURES & CONFLICTS OF INTERESTS

Speaker Honoraria:
- ASTELLAS
- ASTRA ZENECA
- BOSTON SCIENTIFIC
- BRAINLAB
- C-RAD
- ELEKTA
- IPSEN
- RECORDATI
- VARIAN
- TAKEDA

Advisory Board:
- ASTRA ZENECA
- ASTELLAS
- FERRING
- IPSEN
- JANSEEN
- ERGEA

Consultant:
- ELEKTA
- VARIAN

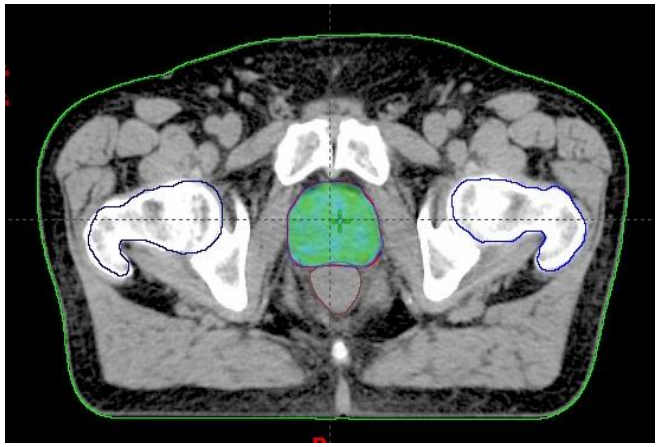
Research Grant:
- ASTELLAS
- ASTRA ZENECA
- JANSEEN
- BRAINLAB

HYPOFRACTIONATION & PROSTATE CANCER:

TECHNOLOGY

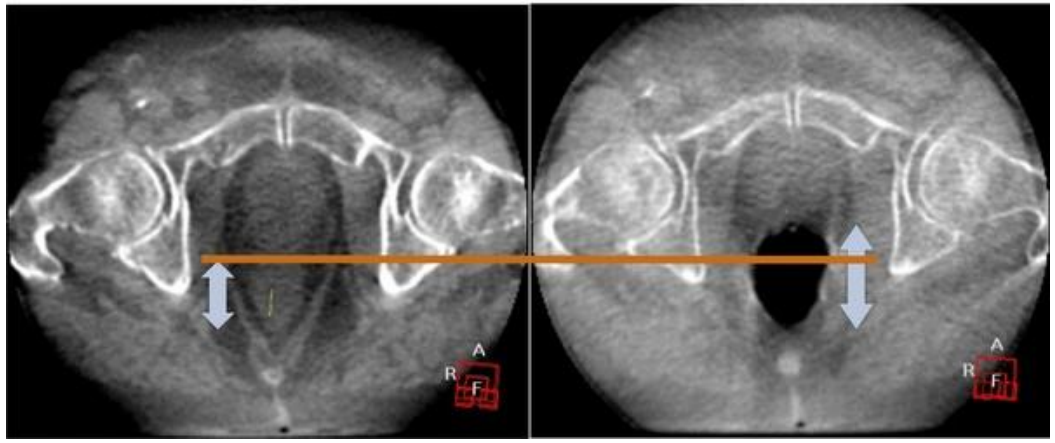
HIGH CONFORMAL DOSE & IMAGING ON BOARD

Planning



Treatment day one

Treatment day two



IMRT and similar

> TARGET DOSE
< OARs TOXICITY
DURING ***PRESCRIPTION***

DAILY IGRT

> TARGET DOSE
< OARs TOXICITY
DURING ***DELIVERY***

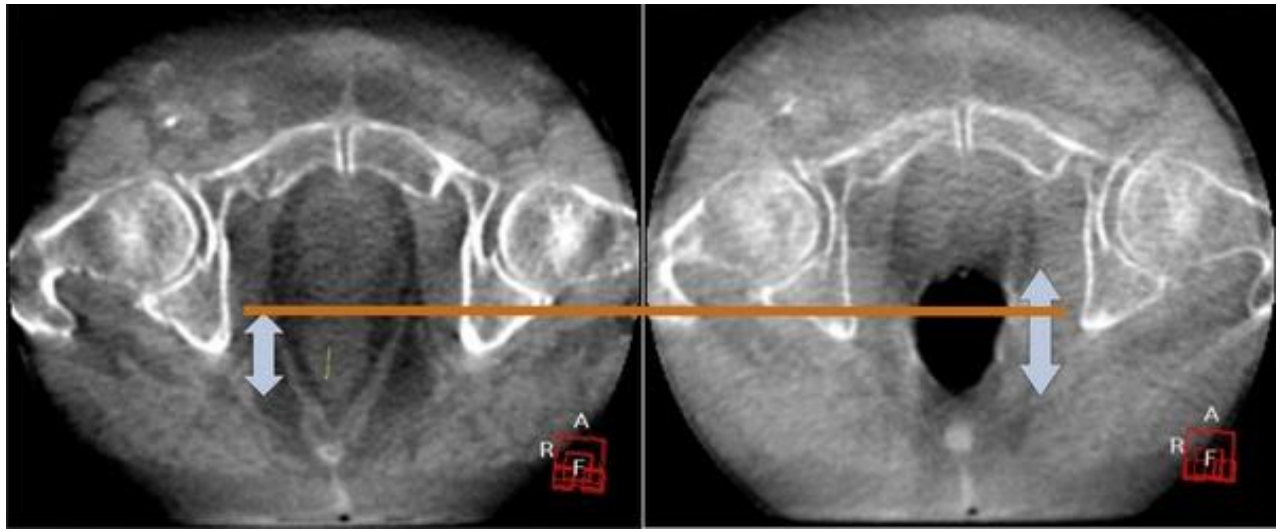
HYPOFRACTIONATION & PROSTATE CANCER:

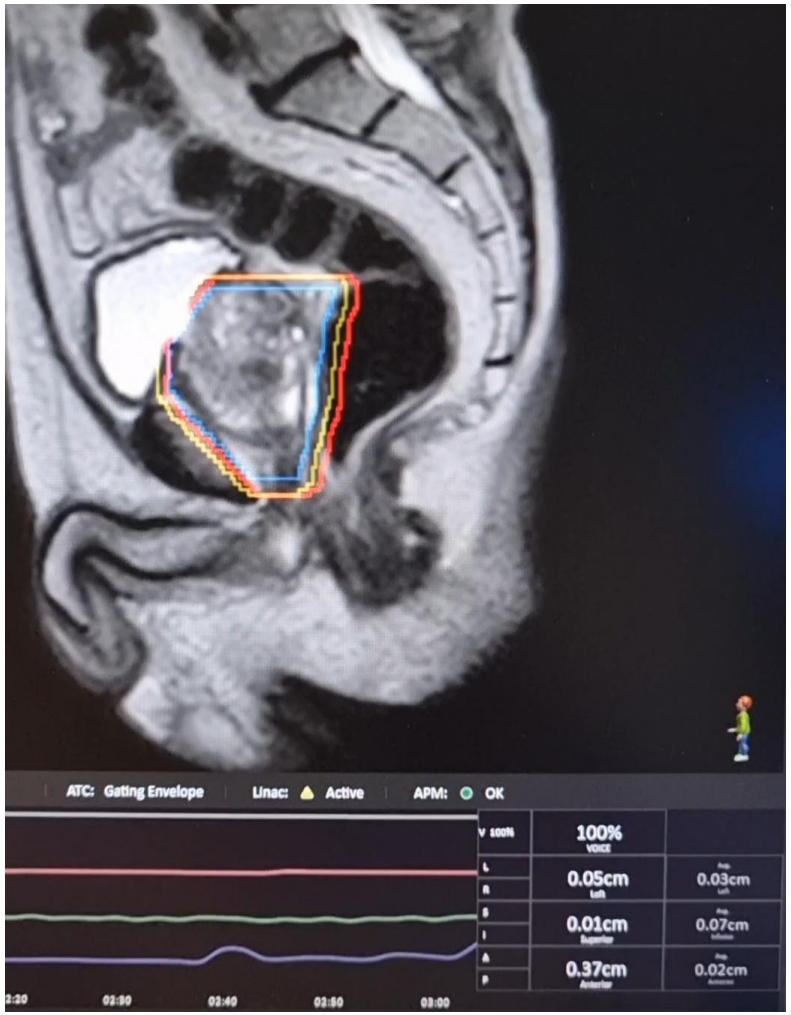
TECHNOLOGY

ADAPTIVE & MOTION MANAGEMENT

Unexpected Movements:

- Patient repositioning
- Peristalsis / passing of gas





AGENDA

1. *News in radical approach for prostate cancer patients*
2. *News in post-radical setting for prostate cancer patients*

AGENDA

1. *News in radical approach for prostate cancer patients*
2. *News in post-radical setting for prostate cancer patients*

EVIDENCE & INDICATIONS

EAU - EANM - ESTRO - ESUR - ISUP - SIOG Guidelines on

Prostate Cancer

P. Cornford (Chair), D. Tilki (Vice-chair), R.C.N. van den Bergh, E. Briers, Patient Advocate (European Prostate Cancer Coalition/Europa UOMO), D. Eberli, G. De Meerleer, M. De Santis, S. Gillessen, A.M. Henry, G.J.L.H. van Leenders, J. Oldenburg, I.M. van Oort, D.E. Oprea-Lager, G. Ploussard, M. Roberts, O. Rouvière, I.G. Schoots, J. Stranne, T. Wiegel
Guidelines Associates: T. Van den Broeck, O. Brunckhorst, A. Farolfi, G. Gandaglia, N. Grivas, M. Lardas, M. Liew, E. Linares Espinós, P-P.M. Willemse
Guidelines Office: J. Darraugh, E. Smith, N. Schouten

*6.3.1.3 Summary of evidence and guidelines for the management of low-risk disease**

Summary of evidence	LE
WW or AS is SOC, based on life expectancy.	2a
All active treatment options present a risk of over-treatment.	1a

Recommendations	Strength rating
Watchful Waiting	
Manage patients with a life expectancy < ten years by watchful waiting.	Strong
Active surveillance (AS)	
Manage patients with a life expectancy > ten years and low-risk disease by AS.	Strong
Selection of patients	
Patients with cribriform or intraductal histology on biopsy should be excluded from AS.	Strong
Perform magnetic resonance imaging (MRI) before a confirmatory biopsy if no MRI has been performed before the initial biopsy.	Strong
Take both targeted biopsy (of any PI-RADS ≥ 3 lesion) and systematic biopsy if a confirmatory biopsy is performed.	Strong
If MRI is not available, per-protocol confirmatory prostate biopsies should be performed.	Weak

NO MORE LOW RISK PATIENTS WILL BE UP FRONT TREATED ?

European Association of Urology

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS

National Comprehensive Cancer Network®

NCCN Guidelines Version 4.2024
Prostate Cancer

NCCN Guidelines Index
Table of Contents
Discussion

PRINCIPLES OF RADIATION THERAPY

Table 1: Below are examples of regimens that have shown acceptable efficacy and toxicity. The optimal regimen for an individual patient warrants evaluation of comorbid conditions, voiding symptoms and toxicity of therapy. Additional fractionation schemes may be used as long as sound oncologic principles and appropriate estimate of BED are considered.
See PROS-3, PROS-4, PROS-5, PROS-6, PROS-7, PROS-8, PROS-13, and PROS-I for other recommendations, including recommendations for neoadjuvant/concomitant/adjuvant ADT.

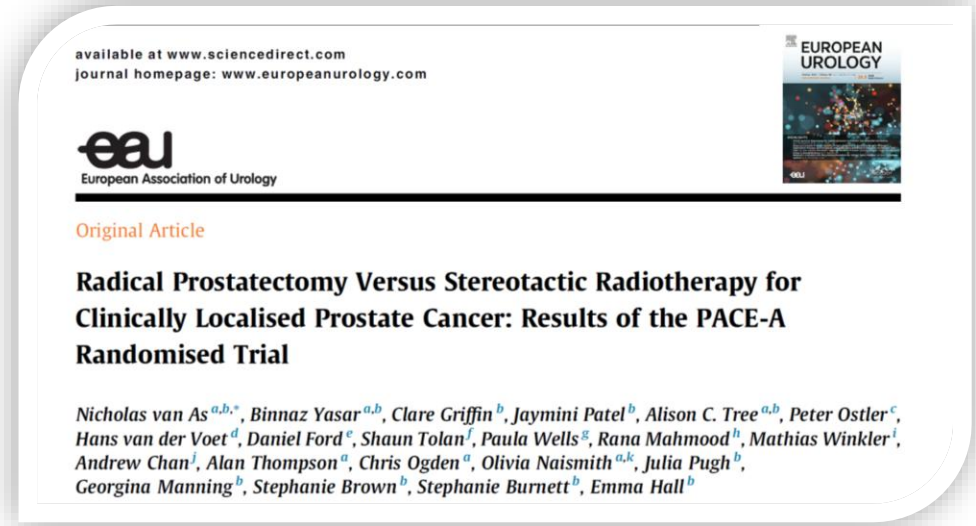
Regimen	Preferred Dose/Fractionation	NCCN Risk Group (✓ indicates an appropriate regimen option if RT is given)					
		Very Low and Low	Favorable Intermediate	Unfavorable Intermediate	High and Very High	Regional N1[e]	Low Metastatic Burden M1[e]
EBRT							
Moderate Hypofractionation[c]	3 Gy x 20 fx 2.7 Gy x 26 fx 2.5 Gy x 28 fx	✓	✓	✓	✓	✓	
	2.75 Gy x 20 fx						✓
Conventional Fractionation[c]	1.8–2 Gy x 37–45 fx	✓	✓	✓	✓	✓	
	2.2 Gy x 35 fx + micro-boost[d] to MRI-dominant lesion to up to 95 Gy (fractions up to 2.7 Gy)		✓	✓	✓		
SBRT Ultra-Hypofractionation	9.5 Gy x 4 fx 7.25–8 Gy x 5 fx[c] 6.1 Gy x 7 fx[c]	✓	✓	✓	✓		
	6 Gy x 6 fx[c]						✓
Brachytherapy Monotherapy							
LDR Iodine 125[c] Palladium 103[c] Cesium 131	145 Gy[c] 125 Gy[c] 115 Gy	✓	✓				
HDR Iridium-192	13.5 Gy x 2 implants 9.5 Gy BID x 2 implants	✓	✓				
Boost Brachytherapy or SBRT with EBRT (combined with 1.8 Gy x 25-28 fx or 2.5 Gy x 15 fx)							
LDR Iodine 125[c] Palladium 103 Cesium 131	110–115 Gy 90–100 Gy 85 Gy			✓	✓		
HDR Iridium-192	15 Gy x 1 fx[c] 10.75 Gy x 2 fx			✓	✓		
EBRT + SBRT Boost	9.5 Gy x 2 fx for SBRT boost			✓	✓		

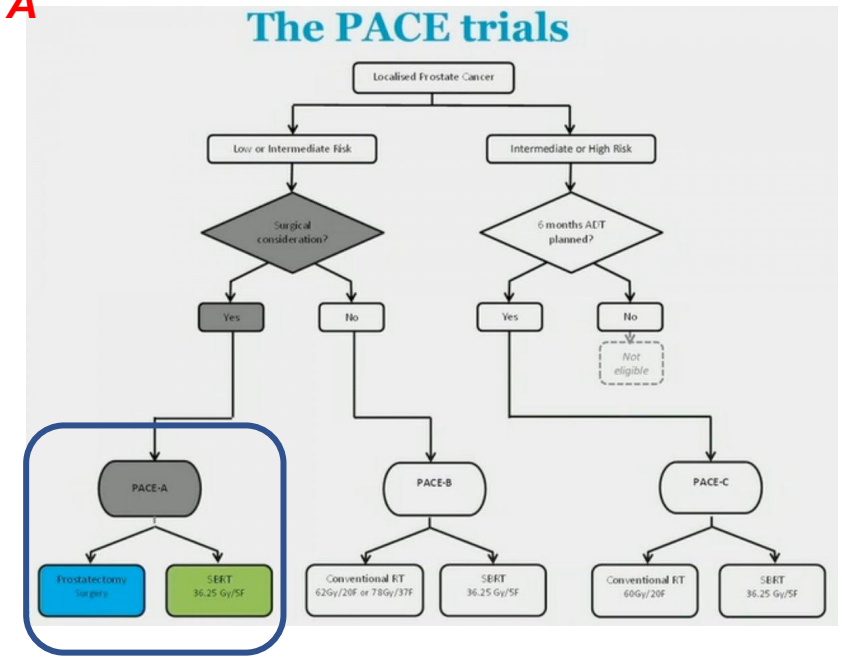
Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Footnotes (PROS-I 7 of 8)
Continued

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS

RCT: PACE A





- **Phase 3** open-label multiple-cohort RCT. In PACE-A, people with LPCa, T1-T2, Gleason≤3+4, PSA≤20ng/mL & suitable for surgery were randomised (1:1) to SBRT or surgery. SBRT dose was 36.25Gy/5 fractions in 1-2 weeks; surgery was laparoscopic or robotically assisted prostatectomy
- From Aug 2012 to Feb 2022, 123 men from 10 UK centres were randomised
- **Compared to surgery, pts receiving SBRT had better urinary continence & sexual bother score;** clinician reported GI toxicity was low but SBRT pts reported more bowel bother at 2 years

The results suggest that stereotactic body radiotherapy may lead to lower rates of urinary incontinence and sexual dysfunction compared to radical prostatectomy, albeit with a potential increase in bowel dysfunction.

Van As N, et al. JCO suppl 2024
Van As N, Eur Urol 2024

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS

PACE-A CRITICISMS??....

"Can we therefore, on the basis of PACE-A, state the superiority of SBRT as the "best" local treatment for intermediate-risk prostate cancer?"

We do not believe that the present study provides sufficient evidence for such a statement, as many questions and relevant doubts remain, which in our opinion call into question the generalizability of these data

1. ***INCONTINENCE***: the rate of 50% pad use at 2 yr after RP recorded here is difficult to understand, substantially higher than results from multiple RP series. The incontinence rates of 25–34% in the ProtecT trial after open RP were already regarded by many high-volume centers as no longer representative of a modern surgical approach.

2. ***SEXUAL ACTIVITY***: In the cohort of men who were potent before RP, erectile function was preserved in 74% of men in the NeuroSAFE Group and in 46% of those in the non-Neuro- SAFE group ($p < 0.01$). Again, such data are strikingly different to the post-RP potency data reported for PACE-A.

3. ***RECRUITMENT AND END POINT CHANGING***: Finally, PACE-A did not reach its initial goal of recruiting 234 patients and was closed early after including approximately half of the study population initially planned.

Graefen, Bossi. Eur Urol 2024

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS

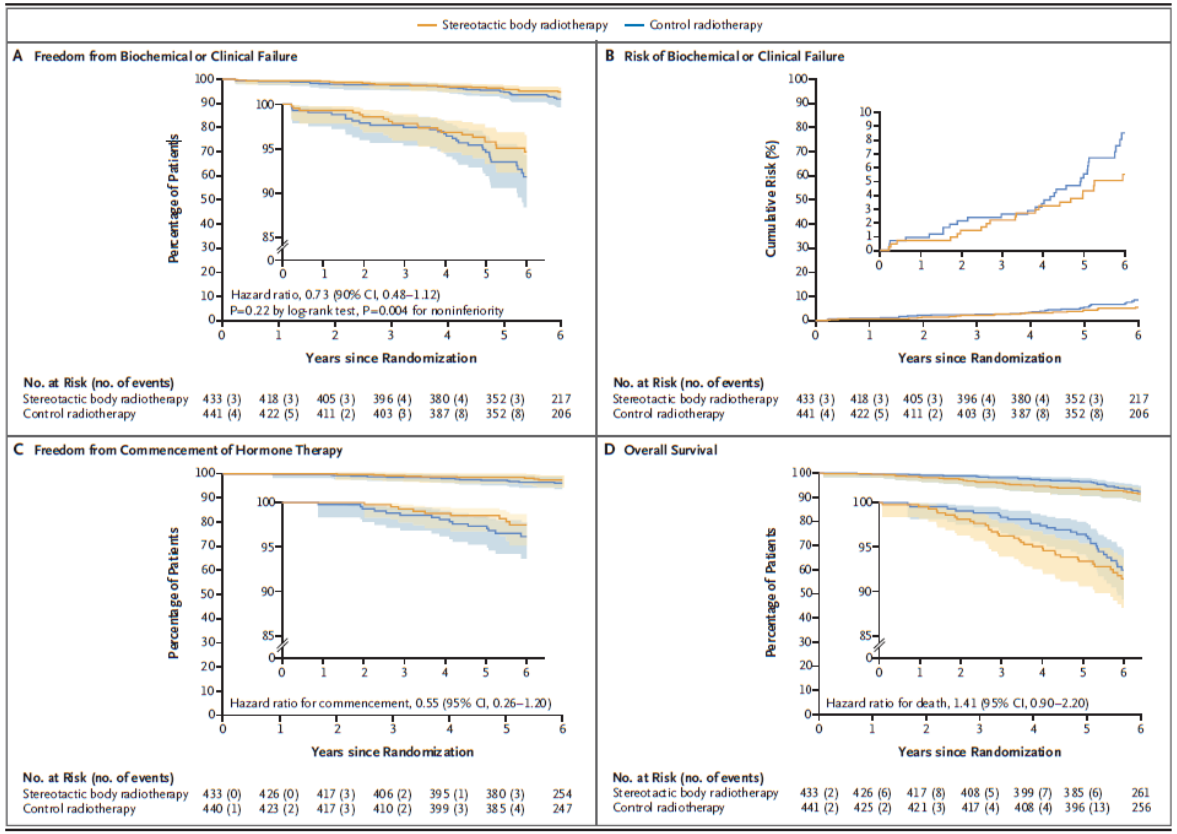
RCT: PACE B

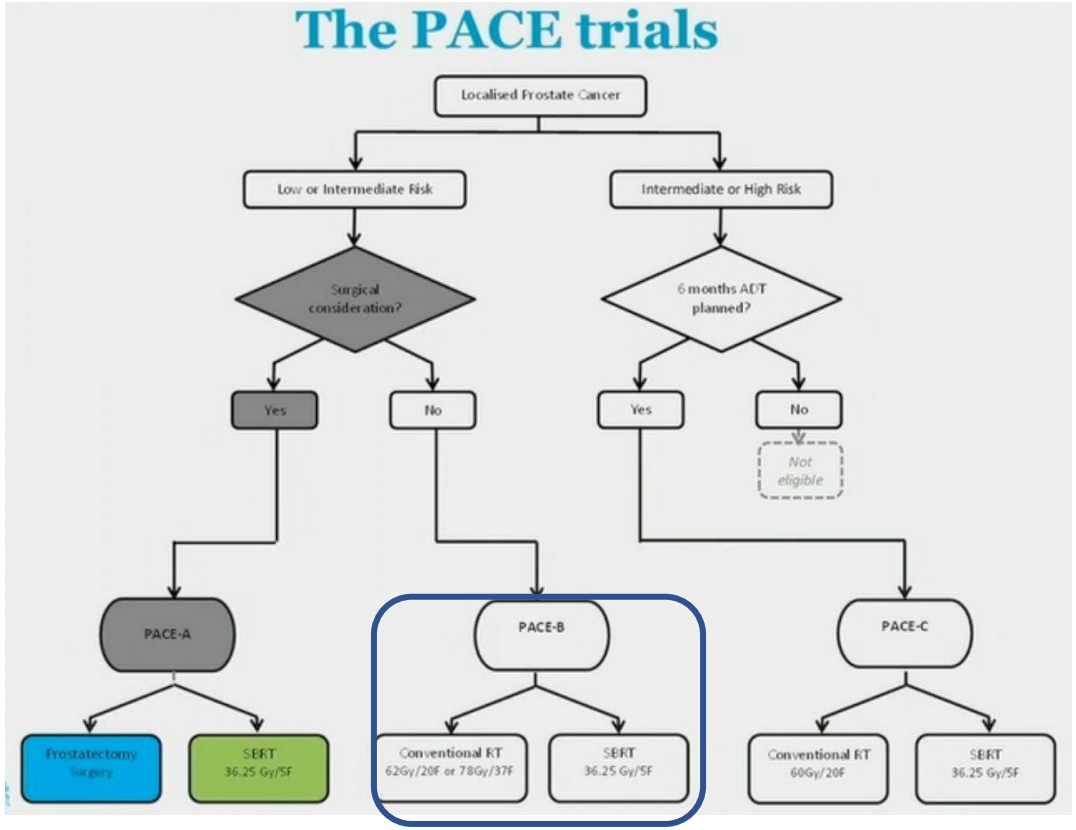
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Phase 3 Trial of Stereotactic Body Radiotherapy in Localized Prostate Cancer

N. van As, C. Griffin, A. Tree, J. Patel, P. Ostler, H. van der Voet, A. Loblaw, W. Chu, D. Ford, S. Tolan, S. Jain, P. Camilleri, K. Kancherla, J. Frew, A. Chan, O. Naismith, J. Armstrong, J. Staffurth, A. Martin, I. Dayes, P. Wells, D. Price, E. Williamson, J. Pugh, G. Manning, S. Brown, S. Burnett, and E. Hall





CONCLUSIONS: Five-fraction SBRT was non inferior to control radiotherapy with respect to biochemical or clinical failure and may be an efficacious treatment option for patients with low-to-intermediate-risk localized prostate cancer as defined in this trial.

Van As N, et al. NEJM 2024

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS
RCT: PACE C

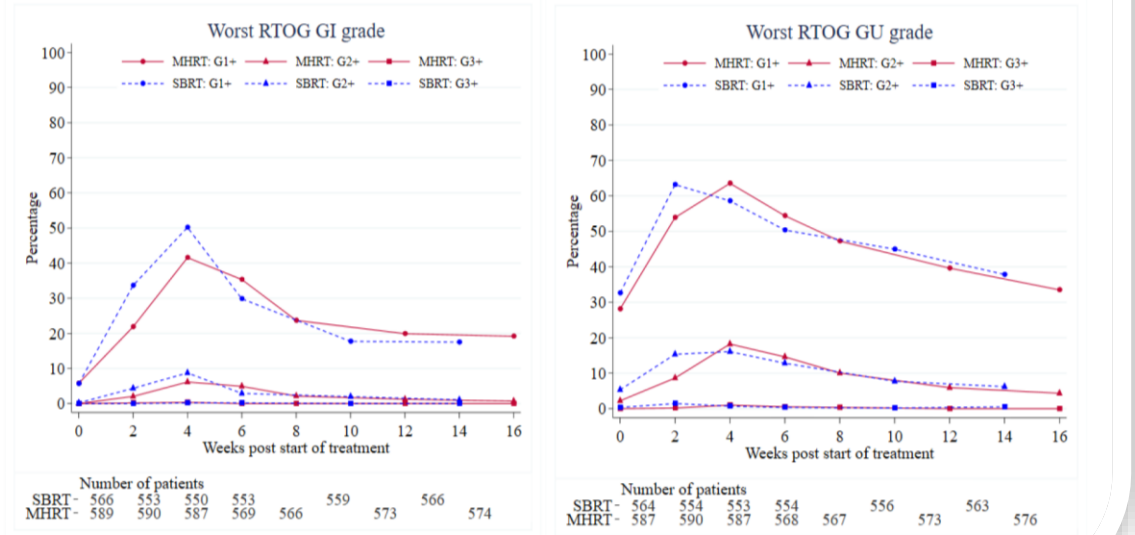
CLINICAL - UROLOGY | PROFFERED PAPER · Volume 194, Supplement 1, S2645-S2647, May 2024

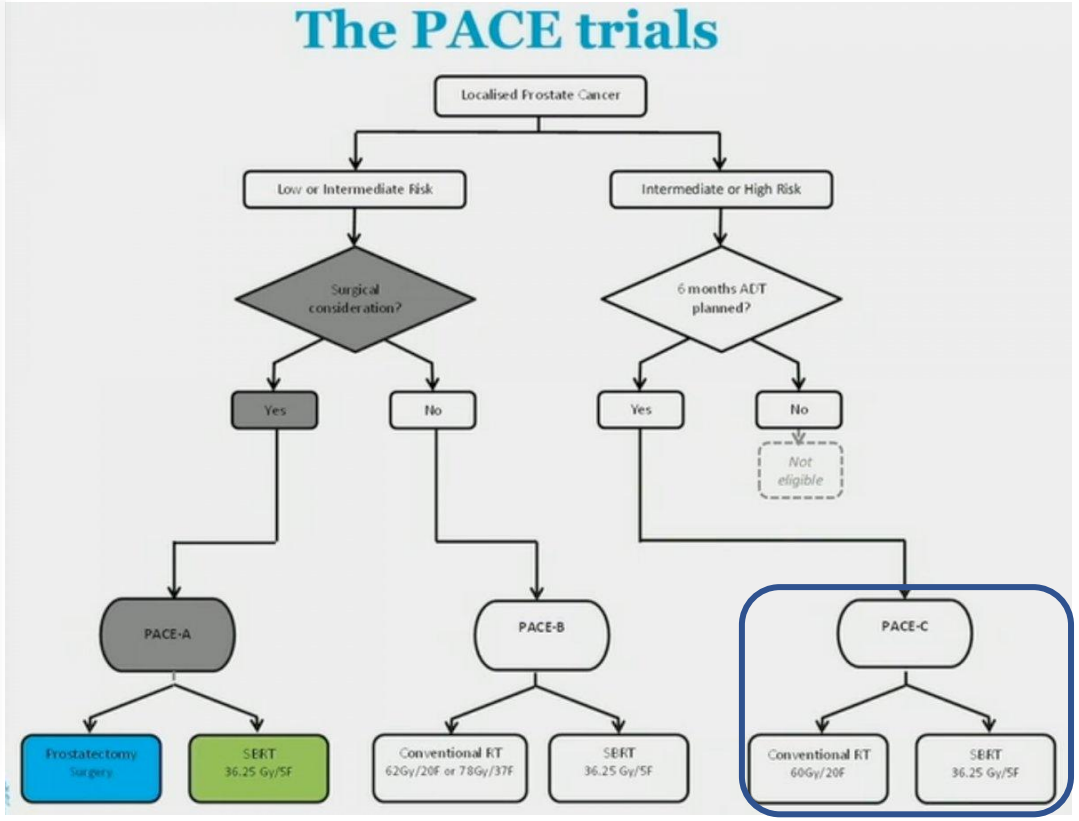
3395: Acute toxicity from PACE-C comparing Stereotactic Body Radiotherapy (SBRT) with moderate hypofractionation (MHRT)

Alison Tree · Victoria Hinder · Andrew Chan · ... · Clare Griffin · Emma Hall · Nicholas van As... Show more

Article Info

Figure 1: RTOG toxicity (GI and GU) by time post-radiotherapy





CONCLUSIONS:
SBRT may offer a convenient option for patients with similar acute toxicity profiles to conventional fractionation.
(ONLY ACUTE TOX WAS REPORTED)

Tree, et al. Radioth Oncol suppl. 2024 (ESTRO 2024)

EVIDENCE & INDICATIONS OF IN FAVOUR OF (SIB-)SBRT IN 5-SESSIONS HYPO-FLAME

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

ELSEVIER

Original Article

Stereotactic body radiotherapy with a focal boost to the intraprostatic tumor for intermediate and high risk prostate cancer: 5-year efficacy and toxicity in the hypo-FLAME trial

Cédric Draulans [a,*], Karin Haustermans [a,b], Floris J. Pos [c], Uulke A. van der Heide [c], Lisa De Cock [a], Jochem van der Voort van Zyp [d], Hans De Boer [d], Robert J. Smeenk [e], Martina Kunze-Busch [e], Evelyn M. Monninkhof [f], Robin De Roover [b], Sofie Isebaert [b], Linda G.W. Kerkmeijer [d,e]

[a] Department of Oncology, KU Leuven, Leuven, Belgium
[b] Department of Radiation Oncology, University Hospitals Leuven, Leuven, Belgium
[c] Department of Radiation Oncology, The Netherlands Cancer Institute, Amsterdam, the Netherlands
[d] Department of Radiation Oncology, University Medical Center Utrecht, the Netherlands
[e] Department of Radiation Oncology, Radboud University Medical Center, Nijmegen, the Netherlands
[f] Julius Centre for Health Sciences and Primary Care, University Medical Center Utrecht, the Netherlands

- 100 Patients with intermediate-high-risk PCa were enrolled in the phase II hypo-FLAME trial.
- All were treated with 35 Gy in 5 weekly fractions to the whole prostate gland with an integrated boost up to 50 Gy to the multiparametric MRI-defined tumor(s).
- If the dose constraints to the normal tissues would be exceeded, these were prioritised over the focal boost dose.
- F-up 61 months

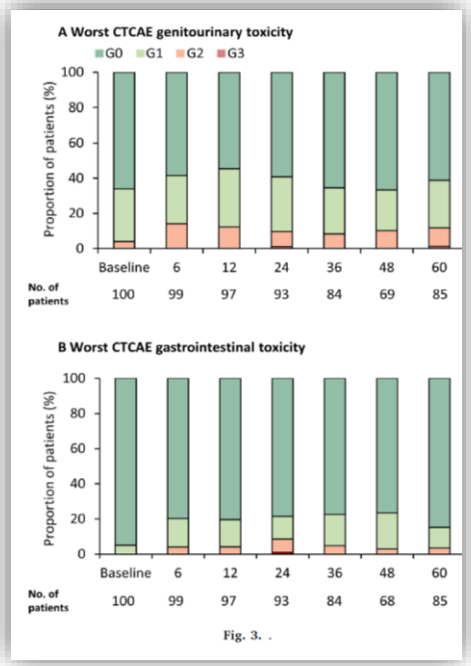


Fig. 3. .

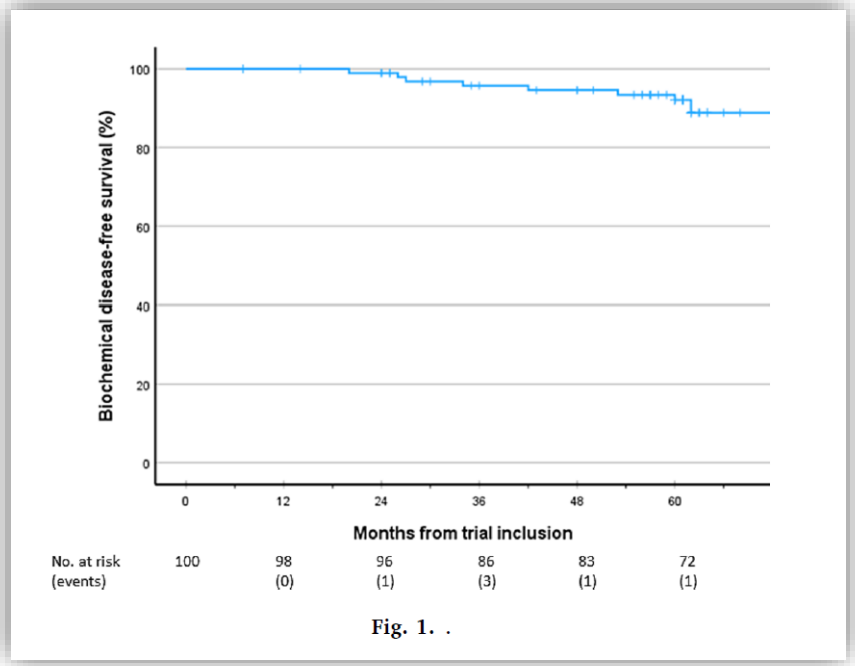


Fig. 1. .

- ✓ At 5 years, the prevalence of grade 2 + GU and GI toxicity was 12 % and 4 %, respectively.
- ✓ The estimated 5-year bDFS was 93 %.

Ultra-hypofractionated focal boost SBRT is associated with encouraging biochemical control up to 5-year follow-up in pts with intermediate and high-risk PCa

Draulans et al, Radioth Oncol 2024

EVIDENCE & INDICATIONS OF IN FAVOUR OF SBRT IN 5-SESSIONS

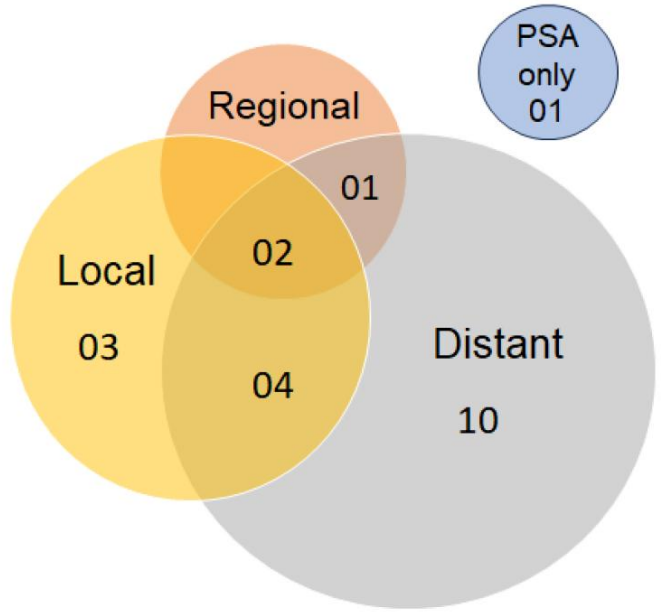
HIGH RISK (PELVIS SBRT) !!!!!!

SHARP

Journal Pre-proof

Pelvic regional control with 25Gy in 5 fractions in SBRT for high risk prostate cancer: Pooled prospective outcomes from the SHARP consortium

Vedang Murthy MD , Indranil Mallick MD,DNB , Priyamvada Maitre MD , Gargee Mulye MD , Moses Arunsingh MD,FRCR , Luca Valle MD , Michael Steinberg MD , Thomas Kennedy MD , Andrew Loblaw MD , Amar U Kishan MD



- A total of 171 patients
- 35-26.25 Gy or 40 Gy in 5#
- Median ADT duration was 15 months
- Median follow up of 51 months
- Biochemical relapse in 11%(PETPSMA:3 pelvic relapses, other distant mets)
- Pelvic control was 98.2%, with 5-year BFFS and OS being 86.1% and 89.3%

Conclusion: For high-risk prostate cancer treated with SBRT, prophylactic pelvic nodal RTwith 25Gy/5# achieved near universal regional control

Vedang M , et al Red J 2025 in press

EVIDENCE & INDICATIONS OF IN FAVOUR OF (MR GUIDED) SBRT IN 5-SESSIONS

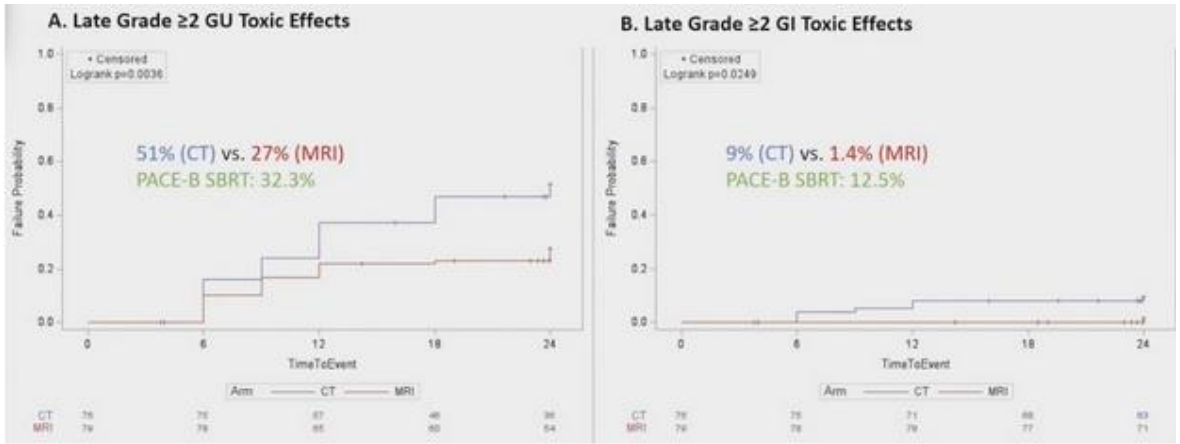
RCT: MIRAGE UPDATE

ASTRO 2024: MRI-Guided versus CT-Guided SBRT for Prostate Cancer: 2-Year Outcomes from the MIRAGE Randomized Clinical Trial

Previously, the MIRAGE trial showed in a randomized trial (156 pts) that margin reduction using MRI guidance has been shown to reduce acute grade 2+ GU and GI following prostate SBRT

PTV Margins of 4 mm (CT-arm) and 2 mm (MRI-arm) were placed around the prostate and proximal seminal vesicles, and this volume received 40 Gy in 5#.

Parameter	CT (n=77)	MRI (n=79)
Age (median, IQR)	71 (67-77)	71 (68-75)
Risk Group		
Imaging N0		
Favorable Intermediate	15 (19%)	14 (18%)
Unfavorable Intermediate	24 (32%)	40 (51%)
High Risk	21 (27%)	15 (19%)
Very High Risk	9 (12%)	5 (6%)
Imaging N+	7 (9%)	5 (6%)
ADT Use	57 (74%)	49 (62%)
Nodal Radiation	19 (25%)	18 (23%)
GTV Boost	22 (29%)	19 (24%)
Rectal Spacer	32 (42%)	37 (47%)
Prior TURP/HOLEP	3 (4%)	5 (6%)
Prostate Size (mL, median, IQR)	41 (33-59)	39 (30-54)
IPSS (median, IQR)	6 (3-11)	7 (4-12.5)



Compared to CBCT -based SBRT, patients receiving MRI-guided SBRT had significantly lower cumulative incidences of grade 2+ GU and GI through two years

Kishan et al JAMA Oncol 2023 2024 ASTRO

NEWS IN FAVOUR OF SBRT IN SINGLE-SESSIONS

ABRUPT

CLINICAL INVESTIGATION

Ablative Radiation Therapy for Unfavorable Prostate Tumors (ABRUPT): Preliminary Analysis of Toxicity and Quality of Life from a Prospective Study

Stefano Arcangeli, MD,*,† Chiara Chissotti, MD,† Federica Ferrario, MD,† Raffaella Lucchini, MD,† Maria Belmonte, MD,† Giorgio Purrello, MD,† Riccardo Ray Colciago, MD,† Elena De Ponti, MSc,†,‡ Valeria Faccenda, MSc,‡ and Denis Panizza, MSc†,‡

*Radiation Oncology Department, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy; †School of Medicine and Surgery, University of Milan Bicocca, Milan, Italy; and ‡Medical Physics Department, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy

- Thirty patients enrolled in a single arm prospective trial received 24Gy SDRT to the whole prostate with urethra-sparing and organ motion control delivered on a Linac
- Median follow-up was18 months(range,6-31months), with no ≥G3 late side effects observed. G2 late GI and G2 late GU toxicities occurred in 1and 2 patients,respectively

Table 3 Incidences of acute (≤3 months) and late (≥6 months) genitourinary and gastrointestinal highest-grade treatment-related adverse events according to CTCAE v.5.0

	Acute			Late		
Adverse event	Grade 1	Grade 2	Grade ≥3	Grade 1	Grade 2	Grade ≥3
Genitourinary	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Urinary incontinence	–	–	–	–	2 (6.7)	–
Urinary frequency	1 (3.3)	1 (3.3)	–	4 (13.3)	1 (3.3)	–
Urinary urgency	5 (16.7)	2 (6.7)	–	6 (20.0)	2 (6.7)	–
Urinary retention	–	–	–	–	–	–
Dysuria	2 (6.7)	2 (6.7)	–	4 (13.3)	1 (3.3)	–
Hematuria	–	–	–	1 (3.3)	–	–
Any*	6 (20.0)	2 (6.7)	–	8 (26.7)	2 (6.7)	–
Gastrointestinal	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Hematochezia	–	–	–	–	–	–
Tenesmus/Proctitis	1 (3.3)	–	–	2 (6.7)	1 (3.3)	–
Fecal Incontinence	–	–	–	–	–	–
Bowel frequency	–	–	–	–	–	–
Any*	1 (3.3)	–	–	2 (6.7)	1 (3.3)	–

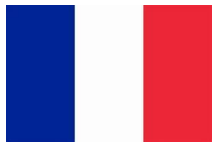
Abbreviations: CTCAE = Common Terminology Criteria for Adverse Events.
* Any genitourinary or gastrointestinal toxic effect indicates the highest-grade adverse event in that domain for all patients. Patients may have experienced more than 1 category of adverse event.

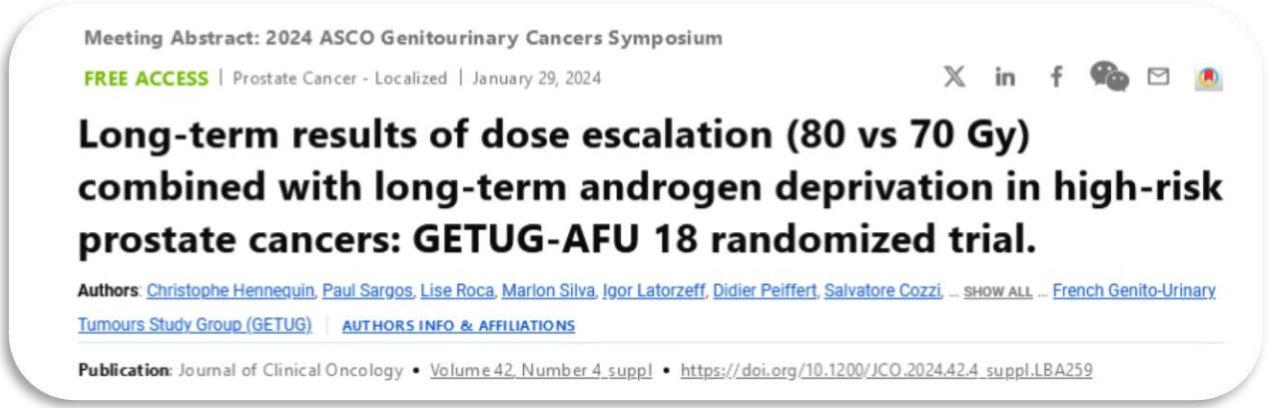
Promising data on the feasibility and safety of 24Gy whole-gland SDRT with urethra-sparing and organ motion control,in association with androgen deprivation therapy and an adequate prophylactic medication,in organ-confined unfavorablePCa

Arcangeli S, Red J 2024

OTHER NEWS IN ADT+RADICAL PROSTATE CONVENTIONAL RT IN HIGH RISK

RCT: GETUG-AFU18





Meeting Abstract: 2024 ASCO Genitourinary Cancers Symposium

FREE ACCESS | Prostate Cancer - Localized | January 29, 2024

Long-term results of dose escalation (80 vs 70 Gy) combined with long-term androgen deprivation in high-risk prostate cancers: GETUG-AFU 18 randomized trial.

Authors: Christophe Hennequin, Paul Sargos, Lise Roca, Marlon Silva, Igor Latorzeff, Didier Peiffert, Salvatore Cozzi, ... SHOW ALL ... French Genito-Urinary Tumours Study Group (GETUG) | AUTHORS INFO & AFFILIATIONS

Publication: Journal of Clinical Oncology • Volume 42, Number 4_suppl • https://doi.org/10.1200/JCO.2024.42.4_suppl.LBA259

505 patients were included between June 2009 and January 2013

Patients were randomly assigned to dose-escalated RT (80 Gy) or conventional-dose (70 Gy) with 3 years of ADT in both arms.

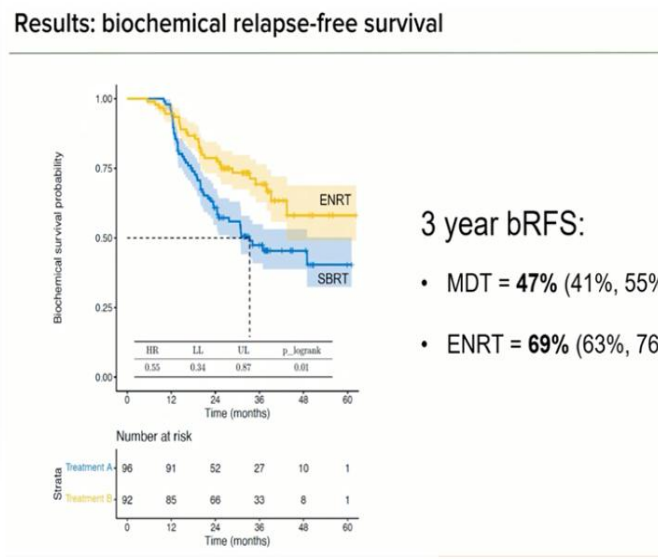
The bcPFS was significantly improved in the dose-escalated RT arm compared with conventional RT arm (HR = 0.56, [95% CI, 0.40-0.76], p = 0.0005). The 5-year bcPFS was 91.4% (95% CI, 87.0-94.4) and 88.1% (95% CI, 83.2-91.6), and the 7-year bcPFS 88.1% (95% CI, 83.1-91.7) and 79.2% (95% CI, 73.1-84.0) in dose-escalated RT and conventional RT, respectively.

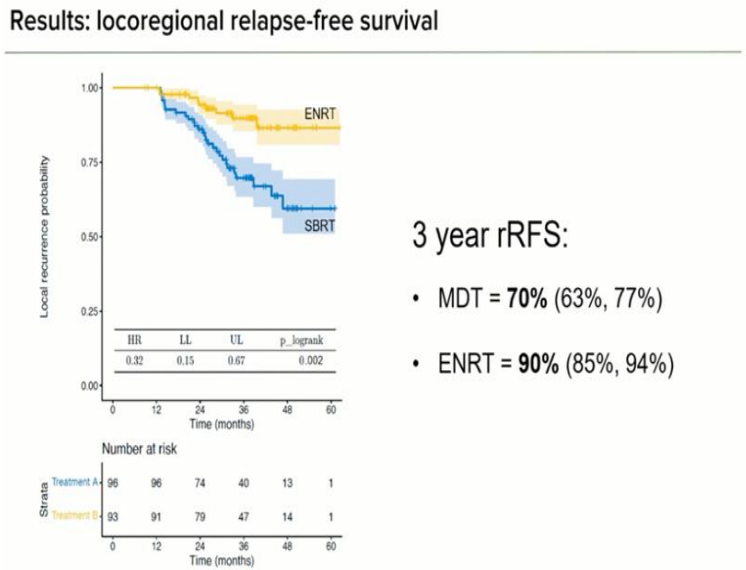
We did observe significant differences in prostate cancer-specific survival (HR = 0.48 [95% CI, 0.27-0.83], p = 0.0090) and overall survival (HR = 0.61 [95% CI, 0.44-0.85], p = 0.0039)

Conclusions:
Dose-escalation RT in combination with long-term ADT is effective and safe, increasing bcPFS rate but also specific survival and overall survival in high-risk prostate cancer patients without increasing long-term toxicity. Clinical trial information: NCT00967863.

OTHER NEWS IN N1 PELVIC DISEASE

RCT: PEACE V -STORM





- ✓ After SBRT, 25% had pelvic nodal relapse compared with 3% in the ENRT arm.
- ✓ Omission of prostate bed radiotherapy trebled the chance of a prostate bed recurrence (14% vs. 5%).
- ✓ On the basis of the data presented, ENRT should be considered optimal care for men who wish to maximise their biochemical and relapse-free survival outcomes.

Ost P, et al Eur Urol 2024
EAU 2024
ESTRO 2024

OTHER NEWS IN RADICAL PROSTATE RT

RCT: PARTIQOL

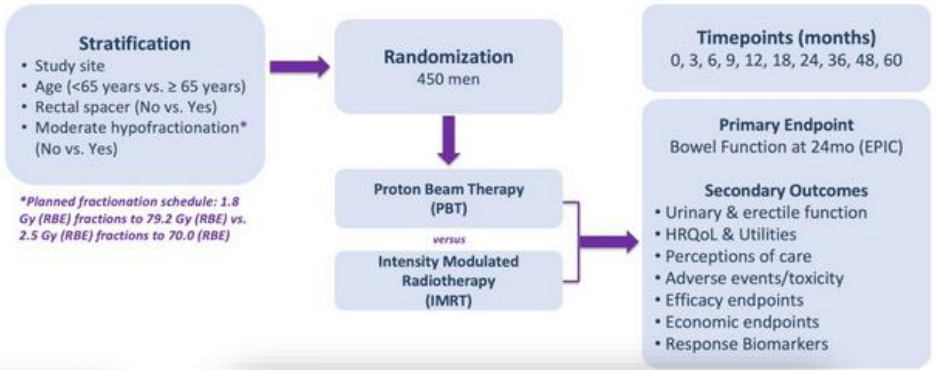
ASTRO 2024: Prostate Advanced Radiation Technologies Investigating Quality of Life (PARTIQoL): Phase III Randomized Clinical Trial of Proton Therapy vs IMRT for Localized Prostate Cancer

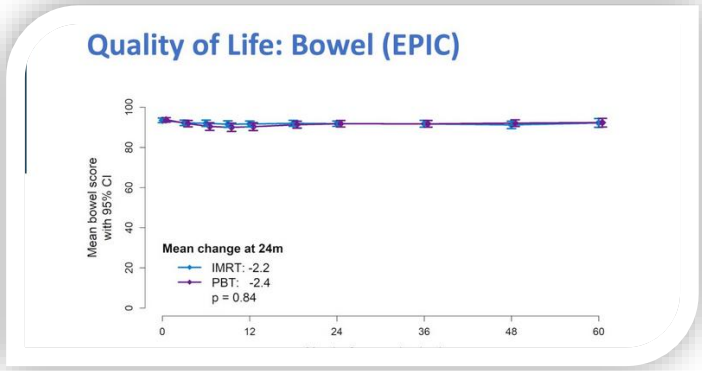
ARTIQoL trial (NCT01617161) is a multi-center phase 3 randomized study compared the two radiation therapy modalities (PBT vs. IMRT) in low-intermediate PC.

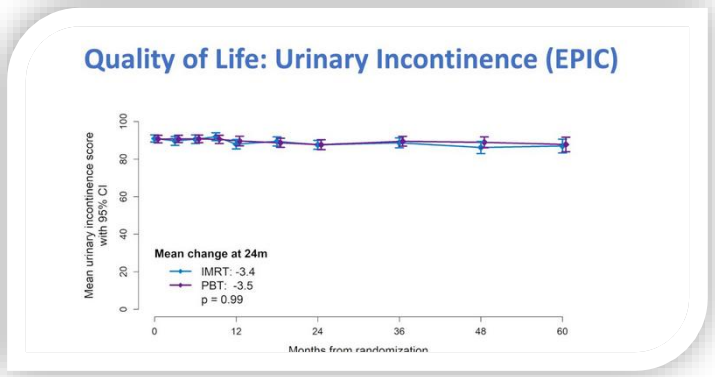
450 men: 221 PBT vs 215 IMRT

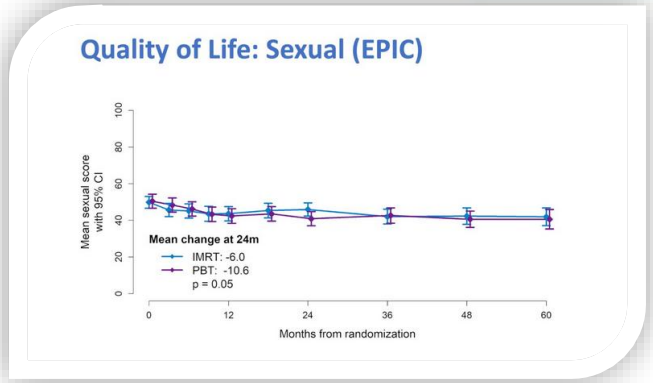
Analysis @24months

Study Design & Aims: Phase III RCT









Patients treated with RT for localized prostate cancer achieve excellent HRQoL alongside highly effective tumor control.

No significant differences were observed in HRQoL endpoints or cancer control outcomes between the two modalities.

The investigators continue to monitor participants for longer-term follow-up and secondary endpoints.

2024 ASCO GU

AGENDA

1. *News in radical approach for prostate cancer patients*

2. ***News in post-radical setting for prostate cancer patients***

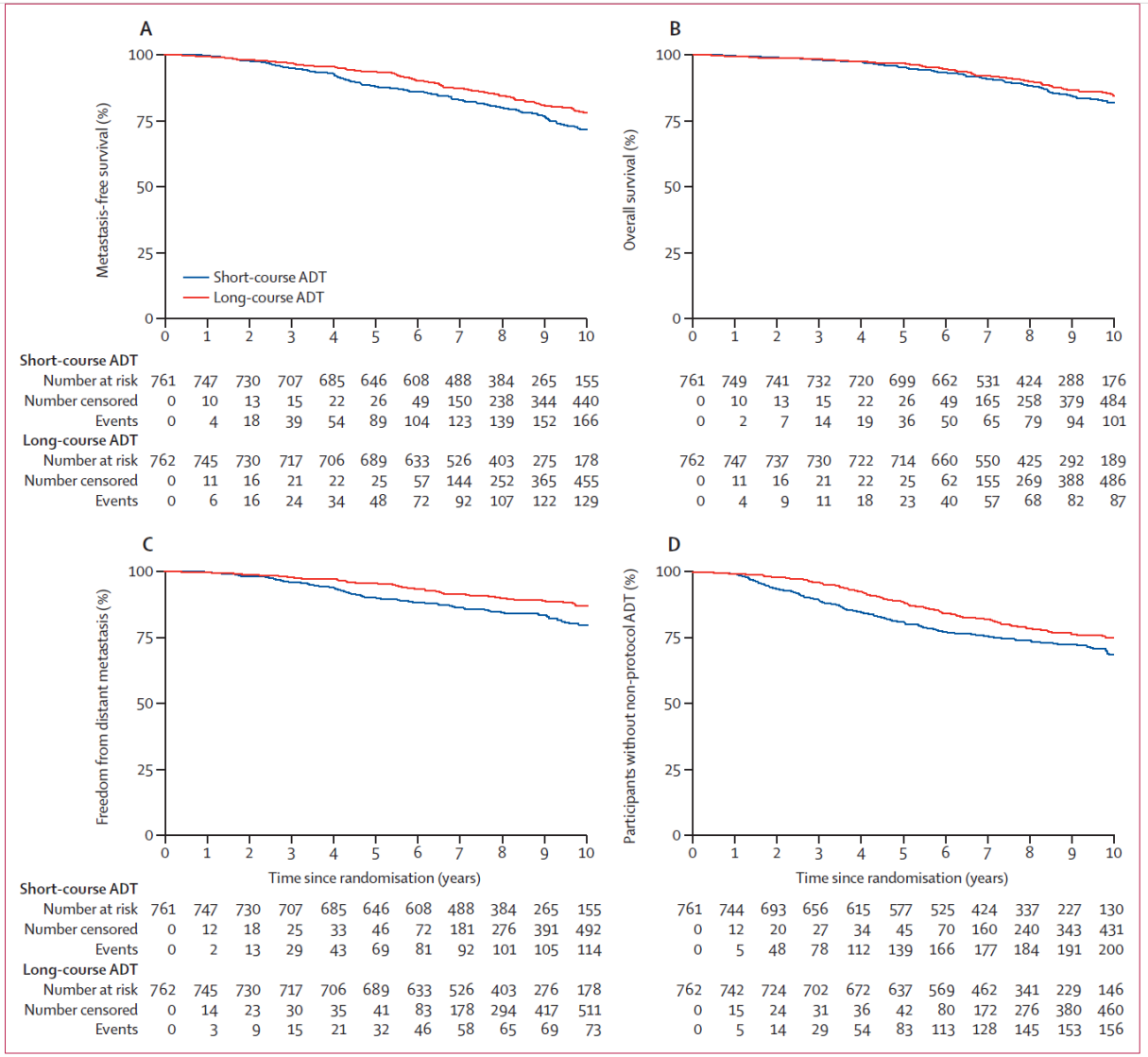
EVIDENCE & INDICATIONS OF IN FAVOUR OF ADT AND POST-OP RT

RCT: RADICALS-HD

Duration of androgen deprivation therapy with postoperative radiotherapy for prostate cancer: a comparison of long-course versus short-course androgen deprivation therapy in the RADICALS-HD randomised trial

Chris C Parker, Howard Kynaston, Adrian D Cook, Noel W Clarke, Charles N Catton, William R Cross, Peter M Petersen, Rajendra A Persad, Cheryl A Pugh, Fred Saad, John Logue, Heather Payne, Lorna C Bower, Chris Brawley, Mary Rauchenberger, Maroie Barkati, David M Bottomley, Klaus Brasso, Hans T Chung, Peter W M Chung, Ruth Conroy, Alison Falconer, Vicky Ford, Chee L Goh, Catherine M Heath, Nicholas D James, Charmaine Kim-Sing, Ravi Kodavatiganti, Shawn C Malone, Stephen L Morris, Abdenour Nabid, Aldrich D Ong, Rakesh Raman, Sree Rodda, Paula Wells, Jane Worlding, Wendy R Parulekar*, Mahesh K B Parmar*, Matthew R Sydes*, on behalf of the RADICALS investigators†

- Randomised controlled trial of ADT duration (short 6 ms vs long 24 ms course) within the RADICALS protocol.
- 1523 patients at 138 centres, median follow-up of 8,9 years
- 10-year metastasis-free survival was 71·9% (95% CI 67·6–75·7) in the short-course ADT group and 78·1% (74·2–81·5) in the long-course ADT group.



- ✓ Compared with adding 6 months of ADT, adding 24 months of ADT improved metastasis-free survival in people receiving postoperative RT.
- ✓ For individuals who can accept the additional duration of adverse effects, long-course ADT should be offered with postoperative radiotherapy.

Parker C et al , The Lancet 2024

PROMISING STUDIES IN FAVOUR OF POST-OP SBRT IN 5-SESSIONS

POPART

Clinical and Translational Radiation Oncology 44 (2024) 100704

Contents lists available at ScienceDirect

Clinical and Translational Radiation Oncology

journal homepage: www.sciencedirect.com/journal/clinical-and-translational-radiation-oncology

Toxicity profile and Patient-Reported outcomes following salvage Stereotactic Ablative Radiation Therapy to the prostate Bed: The POPART multicentric prospective study

Federica Ferrario [a,b,1], Ciro Franzese [c,d,1], Valeria Faccenda [e], Suela Vukcaj [f], Maria Belmonte [a,b], Raffaella Lucchini [a,b], Davide Baldaccini [d], Marco Badalamenti [d], Stefano Andreoli [g], Denis Panizza [a,e,*], Alessandro Magli [b], Marta Scorsetti [c,d], Stefano Arcangeli [a,b]

[a] School of Medicine and Surgery, University of Milan Bicocca, 20126 Milan, Italy
[b] Department of Radiation Oncology, Fondazione IRCCS San Gerardo dei Tintori, 20900 Monza, Italy
[c] Department of Biomedical Sciences, Humanitas University, 20090 Pieve Emanuele (MI), Italy
[d] Radiotherapy and Radiosurgery Department, IRCCS Humanitas Research Hospital, 20089 Rozzano (MI), Italy
[e] Department of Medical Physics, Fondazione IRCCS San Gerardo dei Tintori, 20900 Monza, Italy
[f] Department of Radiation Oncology, ASST Papa Giovanni XXIII, 24127 Bergamo, Italy
[g] Department of Medical Physics, ASST Papa Giovanni XXIII, 24127 Bergamo, Italy
[h] Department of Radiation Oncology, AULSS 1 Dolomiti, 32100 Belluno, Italy

- Fifty patients enrolled in a single arm prospective trial received with PSA levels between 0.1–2.0 ng/mL after radical prostatectomy received Linac-based SBRT to the prostate bed in five fractions every other day for a total dose of 32.5 Gy (EQD21.5 = 74.3 Gy)
- Median follow-up was 12 months(range,3-27months), with no ≥G2 late side effects observed.
- Late G1 urinary and rectal toxicities occurred in 46 % and 4 % of patients, respectively

Our findings show that post-prostatectomy SBRT did not result in increased toxicity nor a significant decline in QoL measures, thus showing that it can be safely extended to the postoperative setting.

6/50 relapses @12 months…

Maximum late toxicity after RT.

	Grade 1	Grade 2	Grade ≥ 3
Late GU toxicity	**N (%)**	**N (%)**	**N (%)**
Hematuria	2 (4 %)	–	–
Urinary incontinence	16 (32 %)	–	–
Urinary tract obstruction	1 (2 %)	–	–
Urinary frequency	3 (6 %)	–	–
Non-infectious Cystitis	1 (2 %)	–	–
Total	*23 (46 %)*	–	–
Late GI toxicity	**N (%)**	**N (%)**	**N (%)**
Hematochezia	–	–	–
Tenesmus/Proctitis	1 (2 %)	–	–
Fecal Incontinence	–	–	–
Bowel frequency	1 (2 %)	–	–
Total	*2 (4 %)*	–	–

Table 4
Median and range of patient-reported QoL using EPIC-CP, ICIQ-SF and IIEF 5.

EPIC-CP	**Median (range)**	
	Baseline	**Last follow-up**
Urinary Incontinence	2 (0 – 8)	2 (0 – 8)
Urinary Irritation/Obstruction	1 (0 – 4)	1 (0 – 5)
Bowel Symptoms	0 (0 – 5)	0 (0 – 7)
Sexual Dysfunctions	5 (0 – 12)	5 (0 – 12)
Hormonal Symptoms	0 (0 – 7)	0 (0 – 6)
Quality of Life	9 (0 – 19)	10 (1 – 37)
ICIQ-SF	**Median (range)**	
	Baseline	**Last follow-up**
Urinary Incontinence	4 (0 – 13)	2 (0 – 16)
IIEF 5	**Median (range)**	
	Baseline	**Last follow-up**
Erectile Function	13 (0 – 25)	10 (0 – 25)

EPIC-CP: Expanded Prostate Cancer Index Composite for Clinical Practice; ICIQ-SF: International Consultation on Incontinence Questionnaire Short Form; IIEF 5: International Index of Erectile Function Questionnaire.

Ferrario F et al , CTRO 2024

GRAZIE!!!!!!!!!!