

BOLOGNA, 27-29 OTTOBRE 2023 PALAZZO DEI CONGRESSI

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Grandangolo in radioterapia oncologica: nuove evidenze e pratica clinica RETTO-CANALE ANALE

Maria Antonietta Gambacorta

Fondazione policlinico Universitario A. Gemelli IRCCS Università Cattolica del sacro Cuore





Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

No disclosure



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Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

RETTO

TOPICS

CANALE ANALE





Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

TOPICS

RETTO

Total Neoadjuvant Treatment

- Earlier use of systemic therapy: micrometastases
- Maximal downsizing primary tumor for good local control





Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

TNT: published randomized trials





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TNT: published randomized trials





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Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Playing With Dynamite? A Cautious Assessment of TNT

Diana D. Shi, MD¹ and Harvey J. Mamon, MD, PhD²

Journal of Clinical Oncology®

2020 Volume 39, Issue 2 103



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TNT: outcomes





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Disease Related Treatment Failure

Overall Survival



Bahadoer RR Lancet 2021

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Disease Related Treatment Failure



Bahadoer RR Lancet 2021

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Locoregional Recurrence





The New York Times

A Cancer Trial's Unexpected Result: Remission in Every Patient

The study was small, and experts say it needs to be replicated. But for 18 people with rectal cancer, the outcome led to "happy tears."



Sascha Roth, the first patient in the trial, unexpectedly learned she had rectal cancer in 2019. Her gastroenterologist, she recalled, told her during a sigmoidoscopy, "Oh no. I was not expecting this!" Shuran Human for The New York Times



mmunotherapy

Immune therapy in rectal cancer







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The New York Times

Rectal Cancer Patients Could Be Spared the Brutal Effects of Radiation

A large "de-escalation" trial suggests that tens of thousands of people annually may be able to rely on only chemotherapy and surgery to treat their illness.

Give this article

Rectal Cancer Patients Could Be Spared the Effects of Radiation

A large "de-escalation" trial suggests that tens of thousands of people annually may be able to rely on only chemotherapy and surgery to treat their illness Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

PELVIC CHEMORADIOTHERAPY FOR LOcally advanced rectal cancer reduces the risk of disease recurrence in the pelvis to less than 10% and has been standard care in North America since 1990.¹⁻⁶ However, it is associated with short-term and long-term toxic effects⁷⁻⁹ that can adversely affect quality of life and physical function.⁸

These findings motivated us to investigate whether neoadjuvant treatment with FOLFOX could allow the <u>elimination</u> of chemoradiotherapy without increasing the risk of recurrence.





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Neoadiuvant

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Neuropathy

12 Months

250 277

Neoadjuvant

447 492





Diarrhea

12 Months

12 Months

251 279

Appetite Loss

12 Months

100





12 Months

252

Pain

SFUCRT FOLFOX SFUCRT FOLFOX

Randomized Treatment Assignment

Neoadiuvant

446

100

ts (%)

493 250 278

12 Months



100

Randomized Treatment Assignment

SFUCRT FOLFOX SFUCRT FOLFOX Randomized Treatment Assignment





Neoadiuvant

Randomized Treatment Assignment





Neoadiuvant

447 493

100



Dysphagia

12 Months

251 277







SFUCRT FOLFOX SFUCRT FOLFOX

Randomized Treatment Assignment

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Neoadjuvant

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Neuropathy

12 Months





Diarrhea

Appetite Loss

12 Months



12 Months

251 277

Dysphagia

Neoadiuvant

447 493



Pain

5FUCRT FOLFOX 5FUCRT FOLFOX

Randomized Treatment Assignment

Neoadiuvant

446

100

ents (%)

493 250 278

12 Months

SFUCRT FOLFOX SFUCRT FOLFOX

12 Months

251 274

Randomized Treatment Assignment



Neoadjuvant

Depression Neoadiuvant 12 Months 443 493 249 279 100 Patients (%) 50 25 SFUCRT FOLFOX SFUCRT FOLFOX Randomized Treatment Assignment

atients (%)



Randomized Treatment Assignment





12 Months

251

5FUCRT FOLFOX 5FUCRT FOLFOX Randomized Treatment Assignment



Physical Function 12 months





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67

97

5FUCRT

122

88



51

38

5FUCRT

34

27

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70 -

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Relative importance of treatment outcomes

patients' and oncologists' treatment preferences





Pieterse AH, et al Br J Can 2007



FUNCTION SPARING RADIOTHERAPY



Dose levels





HUmanistic Guided Oncology

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti

Art4ART, il Policlinico Gemelli unisce arte e digitale per migliorare la cura dei pazienti oncologici

Salute 29 ottobre 2021, di lg

Franceschini, Art4ART Gemelli esperienza da imitare che apre nuove strade







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Ongoing trials

- **DECREASE:** De-escalation RT-Dose in T1-2N0
- **PLATO**: De-escalation/Escalation RT-Dose based on TNM-Risk
- SWANCA: Proton vs Photon

- **CORINTH** Phase IB: Best integration of **ICI** into CRT
- **RADIANCE**: CRT +/- ICI before, during, and after CRT
- US NCT03233711: CRT +/- consolidation ICI

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PLATO - PersonaLising Anal cancer radioTherapy dOse -Incorporating Anal Cancer Trials ACT3, ACT4 and ACT5



Phase II trial Non randomised N=90





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PLATO - ACT4



Randomised 2:1 Phase II trial N=162 May extend to ph III

T1,T2 < 4 cm N0



DECREASE



(De-intensified ChemoRadiation for Early-stage ASCC) ECOG-ACRIN Cancer Research Group/NCI; NCT04166318)

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PLATO - ACT4

T1,T2 < 4 cm N0



Randomised 2:1 Phase II trial N=162 May extend to ph III

TREATMENT

- sd-IMRT (IMRT; T 50.4Gy in 28F; ENI 40Gy in 28F)

Radioterapia Oncologica:

- dr-IMRT (T 41.4Gy in 23F; ENI 34.5Gy in 23F)

concurrent mitomycin 12mg/m2 day (D)1 and capecitabine (CAP) 825mg/m2 twice daily on days of RT.

PRIMARY OUTCOME

- 3-year locoregional control

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Table 1: 6-month MRI TRG response assessment

6 months end-point analysis

TRG Grade	Standard dose IMRT (50.4 Gy 28F) N (%)	Reduced dose IMRT (41.4 Gy 23F) N (%)	Total N (%)
Grade 1	26 (47.3%)	49 (46.7%)	75 (46.9%)
Grade 2	19 (34.5%)	36 (34.3%)	55 (34.4%)
Grade 3	4 (7.3%)	5 (4.8%)	9 (5.6%)
Grade 4	0 (0.0%)	1 (1.0%)	1 (0.6%)
Grade 5	1 (1.8%)	1 (1.0%)	2 (1.3%)
No imaging data	5 (9.1%)*	13 (12.4%)**	18 (11.3%)
Total	55 (100%)	105 (100%)	160 (100%)

TRG 1: Complete response with no evidence of tumour and normal appearances of the anus; TRG 2: Excellent response with only low signal post treatment fibrotic change and no evidence of tumour; TRG 3: Moderate response with reduction in size but evidence of intermediate tumour signal in keeping with residual disease; TRG 4: Minimal response with reduction in size but evidence of intermediate tumour signal in keeping with residual disease; TRG 5: No response of the primary tumour or frank tumour progression

T1,T2 < 4 cm N0

PLATO - ACT4



Randomised 2:1 Phase II trial N=162 May extend to ph III

Gilbert A. ESTRO 2023

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≥G3 ACUTE TOXICITY

45.5% sd-IMRT (n=25) vs 35.2% dr-IMRT (n=37)

PROs

Sexual function improved to baseline levels by 6 weeks for men and 6 months for women in dr-IMRT

Poorer sexual function was maintained to 6 months in **sd-IMRT** for both men and women.

Gilbert A. ESTRO 2023

T1,T2 < 4 cm N0

PLATO - ACT4



Randomised 2:1 Phase II trial N=162 May extend to ph III

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Basic Original Report

ECOG-ACRIN Guideline for Contouring and **Treatment of Early Stage Anal Cancer Using IMRT/IGRT**



DECREASE

Nicholas Damico, MD,^a Joshua Meyer, MD,^b Prajnan Das, MD,^c James Murphy, MD,^d Eric Miller, MD,^e Bridget Koontz, MD,^f William Hall, MD,^g Mary McBride, BA,^a Gisele Pereira, PhD,^a Paul Catalano, PhD,^h A. Bapsi Chakravarthy, MD,ⁱ Peter J. O'Dwyer, MD,^j and Jennifer Dorth, MD^{a,*}

Practical Radiation Oncology® (2022) 12, 335-347

Table 2 Target volume definitions

	ECOG-ACRIN guideline	RTOG 0529
GTVp	Primary tumor gross disease as defined by clinical examination, endoscopy, and imaging. Include entire thickness and circumference of the anal complex on axial slices at the level of the tumor. Anal complex = anal canal (including internal and external sphincters) + puborectalis muscle where it adheres to the sphincter muscles laterally and posteriorly.	Primary tumor gross disease as defined by clinical examination, endoscopy, and imaging.
CTVp	GTVp + 1 cm + entire anal complex	GTVp + entire anal canal + 2.5 cm
CTVn	Mesorectum, presacral region, inguinal and iliac lymph node regions with customized expansions defined in Table 3	Mesorectum, presacral region, inguinal nodes, and iliac nodal regions + 1,cm
PTV	Combination of CTVp and CTVn with a 0.5-1-cm expansion based on institutional and patient setup uncertainty	Combination of CTVp and CTVn with >= 1-cm expansion





















Associazione Italiana Radioterapia e Oncologia clinica 33

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ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ionc20

Nordic anal cancer (NOAC) group consensus guidelines for risk-adapted delineation of the elective clinical target volume in anal cancer

Martin P. Nilsson, Christine Undseth, Per Albertsson, Monika Eidem, Birgitte Mayland Havelund, Jakob Johannsson, Anders Johnsson, Calin Radu, Eva Serup-Hansen, Karen-Lise Spindler, Björn Zakrisson, Marianne G. Guren & Camilla Kronborg

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti



Figure 1. Cranial border of the CTVe according to 'Alternative B'. Orange, arteries; blue, left renal vein; yellow, inferior mesenteric artery; purple, internal iliac artery.



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5y OS based on TNM AJCC v.08



TABLE 1 AJCC Version 9 and 8th Edition Clinical Stage Groups based on Survival Data.

AJCC	Version	9			AJCC 8th Edition			
т	Ν	м	Stage	e Group	т	Ν	м	Stage Group
T1	N0	M0	I		T1	N0	M0	I
T2	N0	M0	IIA IIB IIIA	Т2	N0	M0	IIA	
T1	N1	M0		Т3	N0	M0	IIB	
Т2	N1	M0		T1	N1	M0	IIIA	
Т3	N0	M0		Т2	N1	M0	IIIA	
Т3	N1	M0	IIIA		T4	N0	M0	IIIB
T4	N0	M0	IIIB		Т3	N1	M0	IIIC
T4	N1	M0	IIIC	с	T4	N1	M0	IIIC
Any T	Any N	M1	IV		Any T	Any N	M1	IV



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ATOM-CAT consortium

Theophanous et al. Diagnostic and Prognostic Research (2022) 6:14 https://doi.org/10.1186/s41512-022-00128-8 Diagnostic and Prognostic Research

PROTOCOL

Open Access

Development and validation of prognostic models for anal cancer outcomes using distributed learning: protocol for the international multi-centre atomCAT2 study

Stelios Theophanous^{1*}, Per-Ivar Lønne², Ananya Choudhury³, Maaike Berbee³, Andre Dekker³, Kristopher Dennis⁴, Alice Dewdney⁵, Maria Antonietta Gambacorta⁶, Alexandra Gilbert¹, Marianne Grønlie Guren⁷, Lois Holloway⁸, Rashmi Jadon⁹, Rohit Kochhar¹⁰, Ahmed Allam Mohamed¹¹, Rebecca Muirhead¹², Oriol Parés¹³, Lukasz Raszewski¹⁴, Rajarshi Roy¹⁵, Andrew Scarsbrook^{1,16}, David Sebag-Montefiore¹, Emiliano Spezi¹⁷, Karen-Lise Garm Spindler¹⁸, Baukellien van Triest¹⁹, Vassillos Vassiliou²⁰, Eirik Malinen²¹, Leonard Wea³, Ane L. Appelt^{1,16†} and on behalf of the atomCAT consortium

Prediction CLINICAL based

Table 3 Specification of the primary models for overall survival, locoregional control and freedom from distant metastasis

Prognostic factors to be included in the primary models

Overall survival model		Locoregional control model	Freedom from distant metastasis model	
1	N stage: N0 vs N+	Sex: female vs male	N stage: N0 vs N+	
2	T stage: T1-2 vs T3-4	N stage: N0 vs N+	T stage: T1-2 vs T3-4	
3	Sex: female vs Male	T stage: T1-2 vs T3-4	Sex: female vs male	
4	Age: modelled as a continuous, linear factor	Age: modelled as a continuous, linear factor	Age: modelled as a continuous, linear factor	
5	Primary tumour GTV (cm ³): modelled as a continuous, log-transformed factor	Primary tumour GTV (cm ³): modelled as a continuous, log-transformed factor	Primary turnour GTV (cm ³): modelled as a con- tinuous, log-transformed factor	
6	Primary tumour dose (EQD2): modelled as a continuous, linear factor	Primary tumour dose (EQD2): modelled as a continuous, linear factor	Primary tumour dose (EQD2): modelled as a continuous, linear factor	
7	Histology: SCC vs basaloid SCC	Histology: SCC vs basaloid SCC	Histology: SCC vs basaloid SCC	
8	Chemotherapy regimen: [no chemotherapy] vs [mitomycin C-based regimen] vs [cisplatin- based regimen]	Chemotherapy regimen: [no chemotherapy] vs [mitomycin C-based regimen] vs [icsplatin- based regimen];	Chemotherapy regimen: [no chemotherapy] vs [mitomycin C-based regimen] vs [cisplatin-based regimen];	
9	RT technique: [3D-CRT] vs [IMRT] vs [VMAT]	RT technique: 3D-CRT vs IMRT vs VMAT	RT technique: 3D-CRT vs IMRT vs VMAT	

N stage nodal stage, T stage tumour stage, GTV Gross tumour volume, EQD2 Equivalent dose in 2 Gy fractions ($\alpha/\beta = 10$ Gy), SCC Squamous cell carcinoma, 3D-CRT Three-dimensional conformal radiation therapy, IMRT intensity-modulated radiation therapy, VMAT Volumetric modulated arc therapy

The analysis aims to provide information on current international clinical practice outcomes and may aid the **personalization** and design of future anal cancer clinical trials through contributing to a better understanding of **patient risk stratifcation**.



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Review > J Natl Compr Canc Netw. 2023 Jun;21(6):678-684. doi: 10.6004/jnccn.2023.7031.

Prognostic and Predictive Markers for Patients With Anal Cancer

Emma B Holliday ¹, Arjun Peddireddy ², Van K Morris ³

Prognostic Biomarkers for Localized SCCA

- Tissue-Based
- Blood-Based: Circulating Tumor DNA
- Serum-Based: Absolute Lymphocyte Count

Biomarkers Predictive to Immunotherapy Benefit

Table 1. Tissue-Based Biomarkers for Anal Cancer				
Biomarker Clinical Relevance				
HPV	 HPV-positive status is prognostically favorable relative to HPV-negative status HPV-negative status may be associated with greater prevalence for actionable somatic mutations 			
Somatic mutations	 PIK3CA is the most commonly mutated gene in multiple series profiling anal cancer Genomic profiling may identify matched targets for clinical trials in rare occasions 			
тмв	 TMB >10 mutations/megabase is relatively uncommon in advanced anal cancer In small series, high TMB has not definitively been linked to benefit with immunotherapy 			
PD-L1 expression	 Higher PD-L1 expression has been linked to improved clinical outcomes with immunotherapy in correlative analyses of small series from single-arm clinical trials Pending further evaluation, a low PD-L1 expression status should not exclude offering immune checkpoint blockade therapy to patients with incurable anal cancer, either for standard treatment or for determination of clinical trial 			
	eligibility			

Abbreviation: TMB, tumor mutational burden.



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journal homepage: www.thegreenjournal.com

Original Article

External validation of a composite bio-humoral index in anal cancer patients undergoing concurrent chemoradiation

Pierfrancesco Franco^{a,*}, Annamaria Porreca^b, Giovanna Mantello^c, Francesca Valvo^d, Lucrezia Gasparini^e, Najla Slim^{*}, Stefania Manfrida^{*}, Francesca De Felice^h, Marianna A. Gerardi[†], Stefano Vagge[‡], Marco Krengli[†], Elisa Palazzari^k, Mattia Falchetto Osti[†], Alessandra Gonnelli^m, Gianpiero Catalanoⁿ, Patrizia Pittoni[°], Giovani B. Ivaldi[®], Marco Lupattelli[¶], Maria Elena Rosetto[†], Rita Marina Niespolo^{*}, Alessandra Guido[†], Oreste Durante[®], Gabriella Macchia^{*}, Fernando Munzo[®], Badr El Khouzai^{*}, Maria Rosaria Lucido[®], Francesca Arcadipane^{*}, Andrea Casadei Gardini^{*a}, Rolando Maria D'Angelillo^{ab}, Maria Antonietta Gambacorta[®], Domenico Genovesi^{*a, ©}, Marta Di Nicola[®], Luciana Caravatta[®]

Prediction PATIENTS based



Fig. 1. Kaplan-Meier curves for overall (OS) and disease-free survival (DFS) and survival in high- and low-risk groups according to the HEI Index in the validation dataset.



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Anal squamous cell carcinoma: Impact of radiochemotherapy evolution over years and an explorative analysis of MRI prediction of tumor response in a mono-institutional series of 131 patients

Marco Lorenzo Bonù^{1*}, Salvatore La Mattina¹, Navdeep Singh¹, Cristian Toraci², Luigi Spiazzi², Fabrizia Terraneo¹, Fernando Barbera¹, Paola Vitali¹, Francesco Frassine¹, Andrea Guerini¹, Luca Triggiani¹, Davide Tomasini¹, Vittorio Morelli¹, Jessica Imbrescia¹, Jacopo Andreuccetti³, Barbara Frittoli⁴, Frida Pittiani⁴, Luigi Grazioli⁴, Nazario Portolani⁵, Luca Nicosia⁶, Domenico Albano⁷, Francesco Bertagna⁷, Stefano Maria Magrini¹ and Michela Buglione¹

Prediction rOMICS based



Relapse is a combination of GTV volume; Signal Intensity; Areas of hyper-intense signal inside the GTV





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Consorti-arno



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IMACC 2023 INTERNATIONAL MULTIDISCIPLINARY ANAL CANCER CONFERENCE – ROMA 9-10 NOVEMBRE 2023

Iome / Events / IMACC 2023 International Multidisciplinary Anal Cancer Conference – Roma 9-10 Novembre 2023

« Tutti gli Eventi

IMACC 2023 International Multidisciplinary Anal Cancer Conference - Roma 9-10 Novembre 2023

9 novembre @ 8:30 - 10 novembre @ 15:00



The 2nd International Multidisciplinary Anal Cancer Conference

9-10 November, 2023 at Catholic University of Sacred Heart - Policlinico Agostino Gemelli, Rome, Italy



https://fopecomrm.unicatt.it/fopecomonline/default_eng. aspx?Edizione=1&IdEvento=9958

Registration deadline October 31st



THE 2nd INTERNATIONAL MULTIDISCIPLINARY ANAL CANCER CONFERENCE

9-10 November, 2023 Centro Congressi Europa Sala Italia Largo Francesco Vito 1

Catholic University of Sacred Heart -Policlinico Agostino Gemelli, Rome, Italy

> Endorsed by Associations Italiana FSTRO



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- Vincenzo Valentini
- Stefania Manfrida
- Giuditta Chiloiro
- Angela Romano



Associazione Italiana Radioterapia e Oncologia clinica

- Luciana Caravatta
- Giovanna Mantello

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti





Studi clinici conclusi e pubblicati o under review

Studi clinici in corso

TITOLO DEL PROGETTO/STUDIO	REFERENTE	RIVISTA		REFERENTE (NOME	
RETTO				COGNOME, EMAIL)	
Analisi dei risultati a lungo termine dello Dr. Marco Lupattelli under review alla rivista			RETTO		
studio sulla Intensificazione di dose mediante IMRT SIB nella RTCT preoperatoria per carcinoma del retto	mlupattelli62@gmail.com Dr.ssa Elisa Palazzari elisa.palazzari@cro.it	"Cancers"	Bridge I – studio prospettico randomizzato volto a valutare l'allungamento del tempo alla chirurgia dopo RT-CT nel tumore del retto	Prof.ssa Maria Antonietta Gambacorta mariaantonietta.gambaco @policlinicogemelli.it	
Pattern of care for Re-Irradiation of locally recurrent rectal cancer: a national survey by the AIRO gastrointestinal tumors study	Dr.ssa Giovanna Mantello giovanna.mantello@ospedaliri uniti.marche.it	Radiol Med. 2023 Jul;128(7):869-876.	Bridge 2 – studio prospettico di fase II su TNT nel tumore del retto alto rischio	Dr.ssa Elisa Palazzari elisa.palazzari@cro.it	
group (Endorsement Nr 31/2022). Studio Retrospettivo PILLAR:Predictive and prognostic value of inflammatory markers in patients with locally advanced rectal	Dr.ssa Giuditta Chiloiro giuditta.chiloiro@policlinicoge melli.it	Clin Transl Radiat Oncol. 2023 Jan 12;39:100579.	RETRY – studio prospettico sulla radioterapia e Total Neoadjuvant Therapy nei pazienti con recidiva di carcinoma del retto precedentemente irradiati	Prof.ssa Maria Antonietta Gambacorta mariaantonietta.gambaco @policlinicogemelli.it	
cancer undergoing neoadjuvant chemoradiotherapy (Endorsement Nr. 20/2022)			Analisi retrospettiva multicentrica sui programmi di Total Neoadjuvant Therapy per i pazienti con adenocarcinoma del retto ad alto rischio	Dr. Marco Lupattelli <u>mlupattelli62@gmail.con</u> Dr.ssa Elisa Palazzari	
Freatment Volume, Dose Prescription and Delivery Techniques for Dose-intensification n Rectal Cancer: a national survey	Dr.ssa Luciana Caravatta lcaravatta@hotmail.com	Anticancer Res. 2021 Apr;41(4):1985-1995.	SCARLET - Registro prospettico nazionale sul trattamento dell'adenocarcinoma del retto pT1	elisa.palazzari@cro.it Dott.ssa Giuditta Chiloroi giuditta.chiloiro@policlin	
CANALE ANALE				emelli.it	
Validazione esterna di un indice bio- umorale composito (HEI) in pazienti con carcinoma anale sottoposti a chemioradioterapia concomitante.	Prof. Pierfrancesco Franco pierfrancesco.franco@uniupo.it Dr.ssa Luciana Caravatta Icaravatta@hotmail.com	Radiother Oncol. 2022 Dec;177:9-15	Validazione multicentrica di un modello predittivo di risposta tumorale basato su MRI diagnostica pre- trattamento nel carcinoma squamocellulare del	Dott. Marco L. Bonù marco.bonu@unibs.it	
Pattern of Care sulla gestione dei pazienti con carcinoma a cellule squamose dell'ano.	Prof. Pierfrancesco Franco pierfrancesco.franco@uniupo.it	Medicina (Kaunas). 2021 Dec 9;57(12):1342.	canale anale		
Radioterapia con tecniche ad intensità modulata (IMRT) nel trattamento del carcinoma anale (RAINSTORM): analisi retrosnettiva multicentrica	Dr.ssa Luciana Caravatta lcaravatta@hotmail.com	Cancers (Basel). 2021 Apr 15;13(8):1902.	GRUPPO DI STUDIO PER LI GASTROINTESTINALI	E NEOPLASIE	