

Organ preservation in early and intermediate risk rectal cancer - New trials strengthen Level 1 evidence

Emmanouil Fokas

Department of Radiotherapy, Cyberknife and
Radiation Oncology
University of Cologne

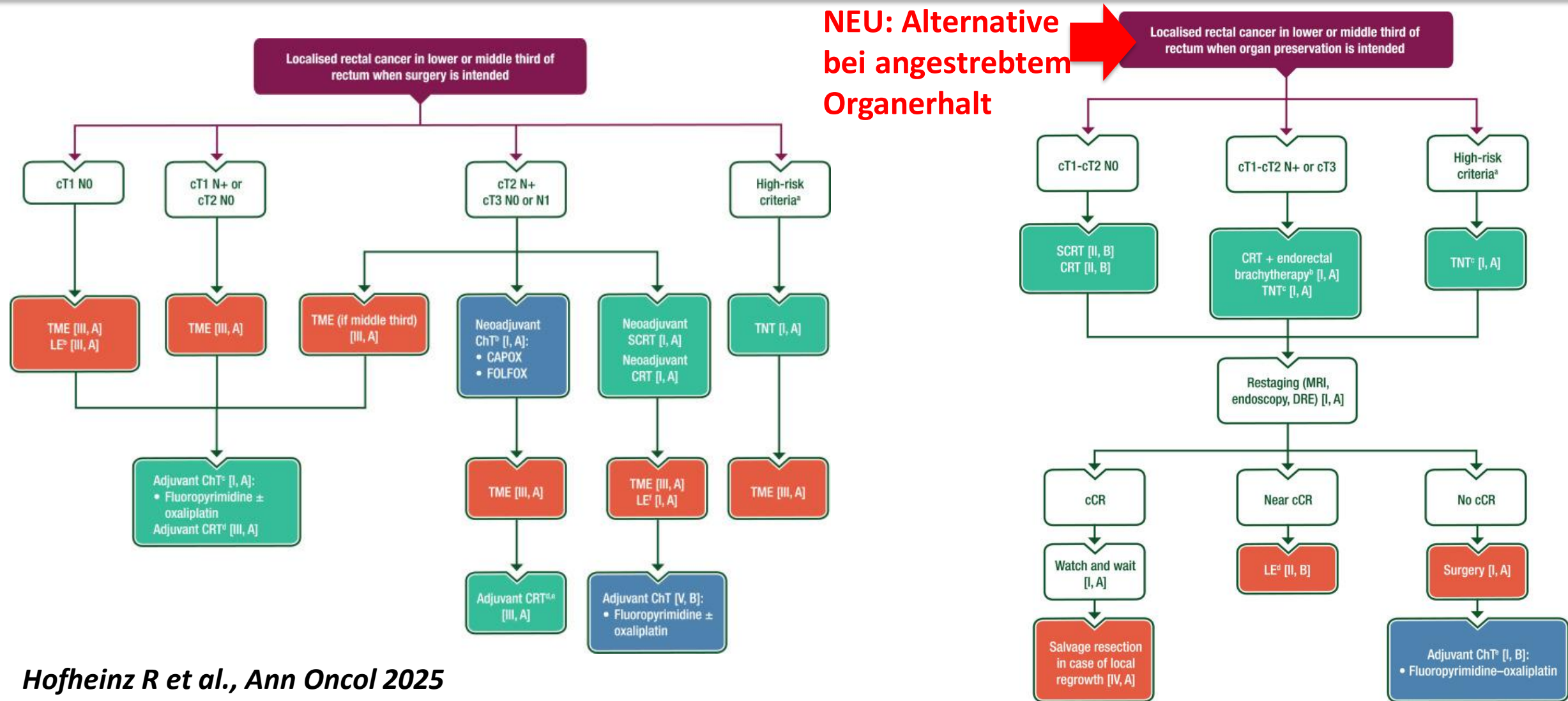
Claus Rödel

Department of Radiotherapy and Oncology
University of Frankfurt

Wichtige Neuerungen für die tägliche Praxis

- **Die neue ESMO-Guideline von 2025** sieht explizit einen separaten risikoadaptierten Therapiealgorithmus für lokalisierte MSS- (microsatellite-stable) Rektumkarzinome im unteren/mittleren Drittel vor: **angestrebter Organerhalt vs. primäre OP**
- Multimodale Therapiekonzepte mit Integration von RT $\pm$ lokaler Exzision (LE) haben in Studien durchgehend hohe Raten von Organerhalt mit überlegenem funktionellem Ergebnis bei frühen Stadien gezeigt: **STAR-TREC, TESAR und TAU-TEM-Studien mit Organerhalt bei 60-80% der Patienten** (Studiendaten auf Folien 4 bis 10).
- **Shared decision making (SDM)** wird wegen der komplexen Therapie-Algorithmen beim Rektumkarzinom zunehmend relevant.

Neue ESMO guideline 2025: unteres und mittleres Rektumdrittel



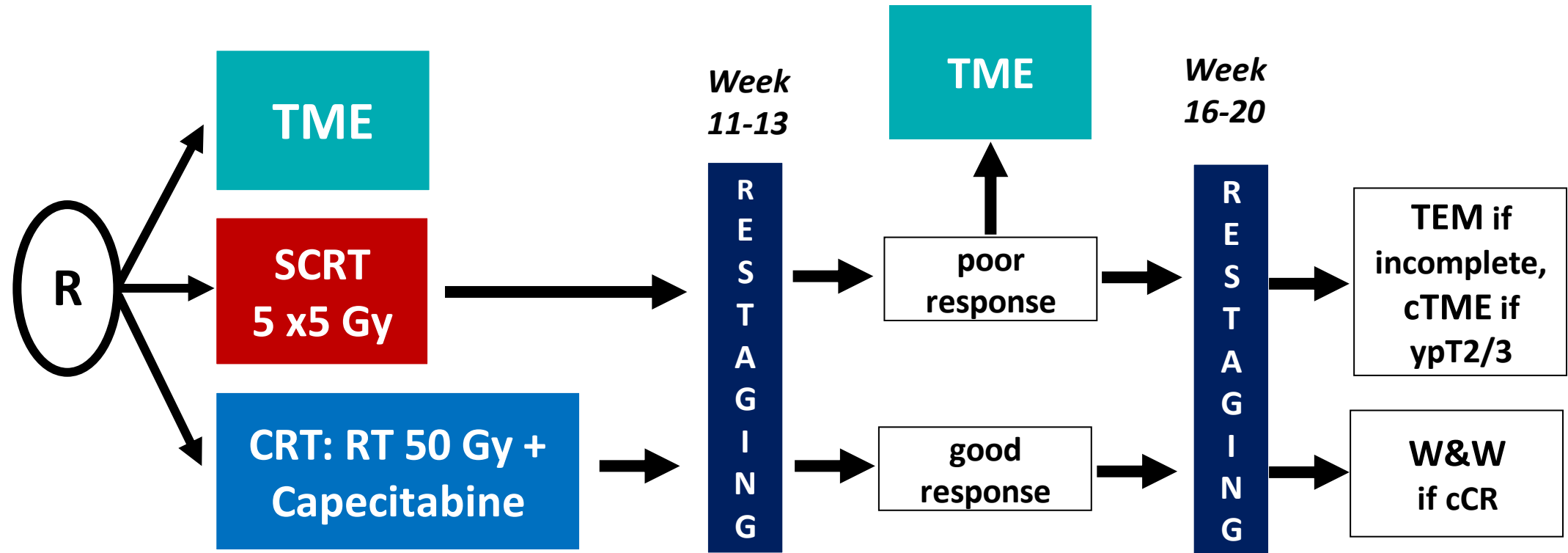
Hofheinz R et al., Ann Oncol 2025

Abkürzungen: SCRT = short course RT, CRT = sim. Radiochemotherapie, TNT = totale neoadjuvante Therapie.

Röm. Ziffern und Buchstaben in Klammern geben Evidenzlevel und Empfehlungsgrad an.

STAR-TREC phase II/III trial

Inclusion: cT1-3b N0M0, < 4 cm



Primary endpoint: **recruitment (n=120, phase II), organ preservation (n=383, phase III)**

TME: total mesorectal excision
TEM: transanal endoscopic microsurgery
cCR: clinical complete remission

CRT: chemoradiotherapy
SCRT: short course radiotherapy

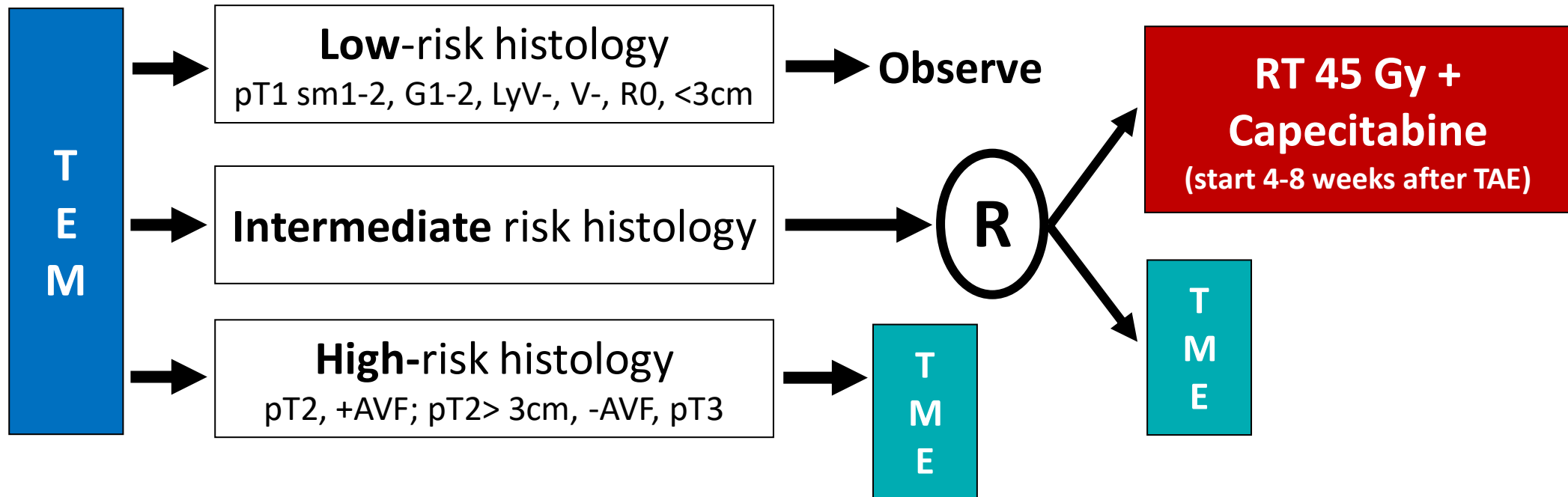
STAR-TREC phase II/III trial

Inclusion: cT1-3b N0M0, < 4 cm

1-year F/U	SCRT (N=168)	CRT (N=168)	1° TME (N=78)	Stats
TME-free survival	60.6%	78.5%	-	HR 1,9
G3 toxicity (no G4/5 events)	7.7%	6.2%	8%	-
TEM	29%	21%	-	-
Salvage for regrowth	7.8%	6%	-	-
<i>*QoL/bowel outcomes superior after organ preservation vs. 1° TME</i>				

TESAR phase III trial

Inclusion: $pT1 > 3-5\text{cm}$; $pT1 \leq 3\text{cm}$ & +AVF; $pT2 \leq 3\text{cm}$ & -AVF; R0; all $< 10\text{cm}$ from AV



Primary endpoint: 3-year locoregional recurrence

**AVF: adverse features (G3, L1, V1, pT1 SM3)*

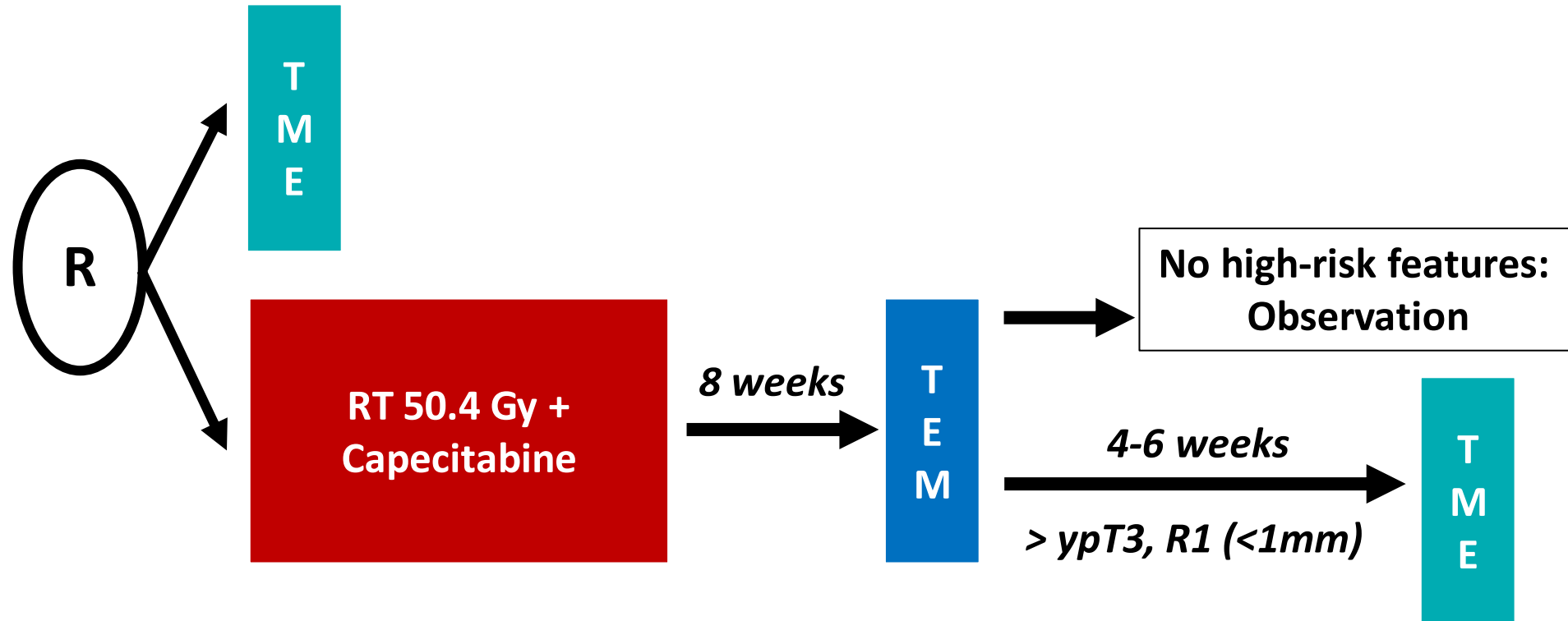
TESAR phase III trial

Inclusion: pT1> 3-5cm; pT1≤ 3cm & +AVF; pT2≤ 3cm & -AVF; R0; all <10cm from AV

<i>ITT (median F/U: 50M)</i>	adj CRT (N=101)	TME (N=96)	P-value
3-year LRR (<i>p-value for non-inferiority</i>)	5%	1.1%	0.16
3-year unsalvagable LRR	1.3%	0%	n.s.
3-year DFS	92%	96%	n.s.
3-year stoma	2.6%	45%	< 0.001
G3 tox / postop morbidity	9.5%	43.8%	-
*QoL superior after adj CRT (<i>urinary & stool frequency, constipation, buttock pain, body image, embarrassment and sexual function</i>)			

TAU-TEM phase III trial

Inclusion: cT2-3bN0M0, < 4 cm, < 10 cm from AV



Primary endpoint: Non-inferiority for local recurrence

(limit 10%, one-sided $p < 0.05$, power 80%; assuming 5% in TME control group)

TAU-TEM phase III trial

Inclusion: cT2-3bN0M0, < 4 cm, < 10 cm from AV

<i>mITT (early data & 5-year F/U)</i>	TME (N=81)	CRT + TEM (N=81)	P-value
Organ preservation	n.a.	78%	-
Converted to TME	n.a.	12%	-
Operative morbidity (overall)	51%	21%	<0.001
5-year LRR*	6.2%	7.4%	0.76
5-year DFS	79%	79%	n.s

TAU-TEM phase III trial

Inclusion: cT2-3bN0M0, < 4 cm, < 10 cm from AV

<i>PROs: median (IQR)</i>	TME (N=81)	CRT + TEM (N=81)	P-value
Global QoL	66.7	83.3	0.02
Permanent stoma	28.4%	7.4%	<0.001
Flatus incontinence	4 (7)	0 (4)	<0.001
Bowel frequency	2 (2)	0 (2)	0.02
Clustering / Urgency	9 (11)	0 (0)	<0.001
Major LARS	36.4%	7.7%	0.001
No LARS	47.7%	80.8%	0.001

QoL/functionality superior after CRT+TEM for organ preservation

Nur zur Info (nicht neu): ESMO guideline 2025 für das obere Rektumdrittel

