Sharing Successful Clinical Trial Experiences

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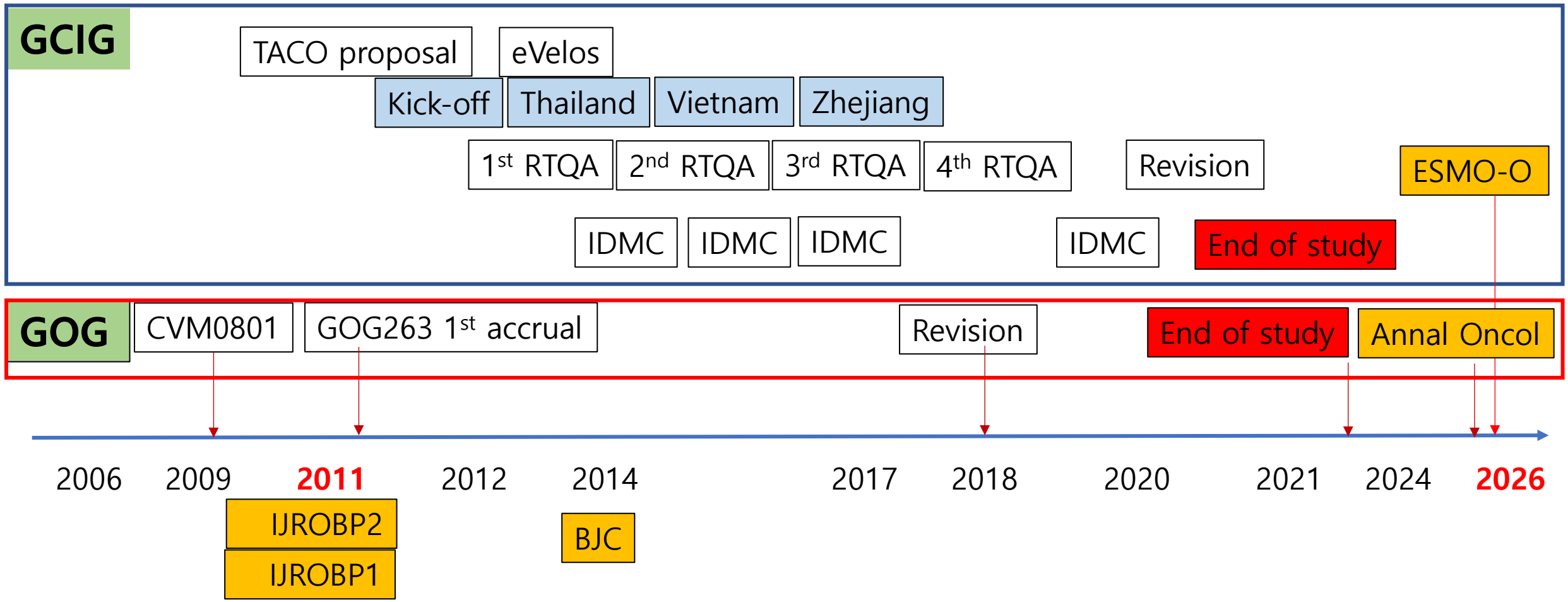
- NRG/GOG-263/KGOG1008
- TACO(GCIG/KGOG1027/THAI2012)

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Korea Cancer Center Hospital

DECLARATION OF INTERESTS

Nothing to declare

Time Line


GCIG
TACO proposal
eVelos
Kick-off
Thailand
Vietnam
Zhejiang
1st RTQA
2nd RTQA
3rd RTQA
4th RTQA
Revision
ESMO-O
IDMC
IDMC
IDMC
IDMC
End of study
GOG
CVM0801
GOG263 1st accrual
Revision
End of study
Annal Oncol
2006
2009
2011
2012
2014
2017
2018
2020
2021
2024
2026
IJROBP2
IJROBP1
BJC

TACO and GOG 263 Trial

Lancet:	88.5		
NEJM:	84.5		
Annal Oncol:	**80.4**	**GOG263/KGOG1008**	2025
ESMO Open:	**10.6**	**TACO/KGOG1027**	2026
BJC:	8.8	KGOG1021 (IMF group)	2014
IJROBP:	6.4	KCCH1001(Triweekly)	2011
		KCCH1002(IMF)	2011
GO:	**4.5**	**GOG263/KGOG1008**	2025

국중박 유물놀이 대상



Motivation?

1% Inspiration
: < 1 second

99% Perspiration

Chemo-radiation era

Central dogma;

1. RT+Cis >> RT alone
2. Weekly Cis

Two unanswered questions by Otrovert.

Q1: Why not CRT in intermediated risk group?

Any evidence?

Q2: Why not Tri-weekly Cisplatin?

Any evidence?

Unanswered?

Q1; Is there RCT in intermediate risk group? No

- GOG 92: RT only vs NFT
- **KCCH 1002; CRT > RT**
- KGOG 1008-> **GOG 263**

Q2; Is weekly cisplatin CRT a standard? No

- GOG 120: Weekly vs triweekly (FP)
- **KCCH 1001; tri-weekly> weekly**
- KGOG 1027-> GCIG-> **TACO**

TACO: Why not Tri-weekly?

GOG 120: Weekly vs FP tri-weekly (Rose et al., 2007)

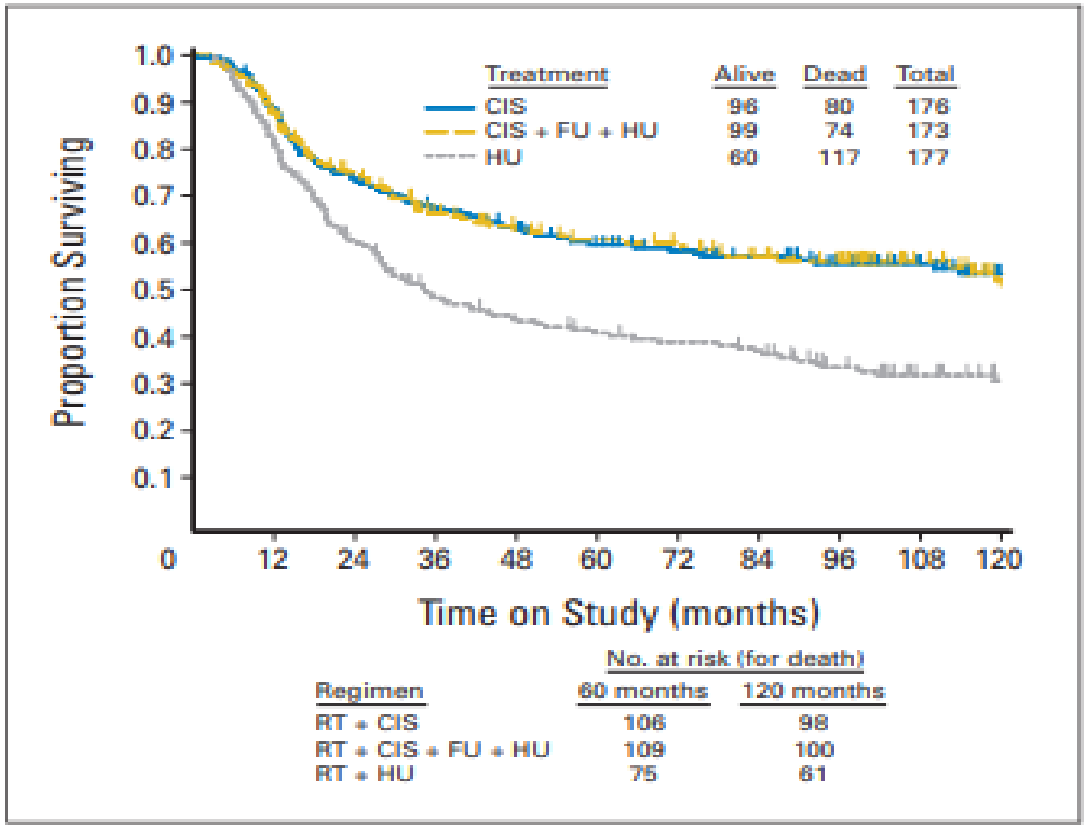


Fig 2. Overall survival by treatment and number of patients at risk (for death) at 60 and 120 months. CIS, cisplatin; FU, fluorouracil; HU, hydroxyurea; RT, radiation therapy.

Survival: Weekly=Tri-weekly

Toxicity: Weekly<< Tri-weekly

So, winner is Weekly!

TACO: Why not Tri-weekly?

Dose dependency of Cisplatin

- 50 mg/m^2 every 21 days (regimen 1)
- 100 mg/m^2 every 21 days (regimen 2)
- 20 mg/m^2 for five days repeated every 21 days (regimen 3)

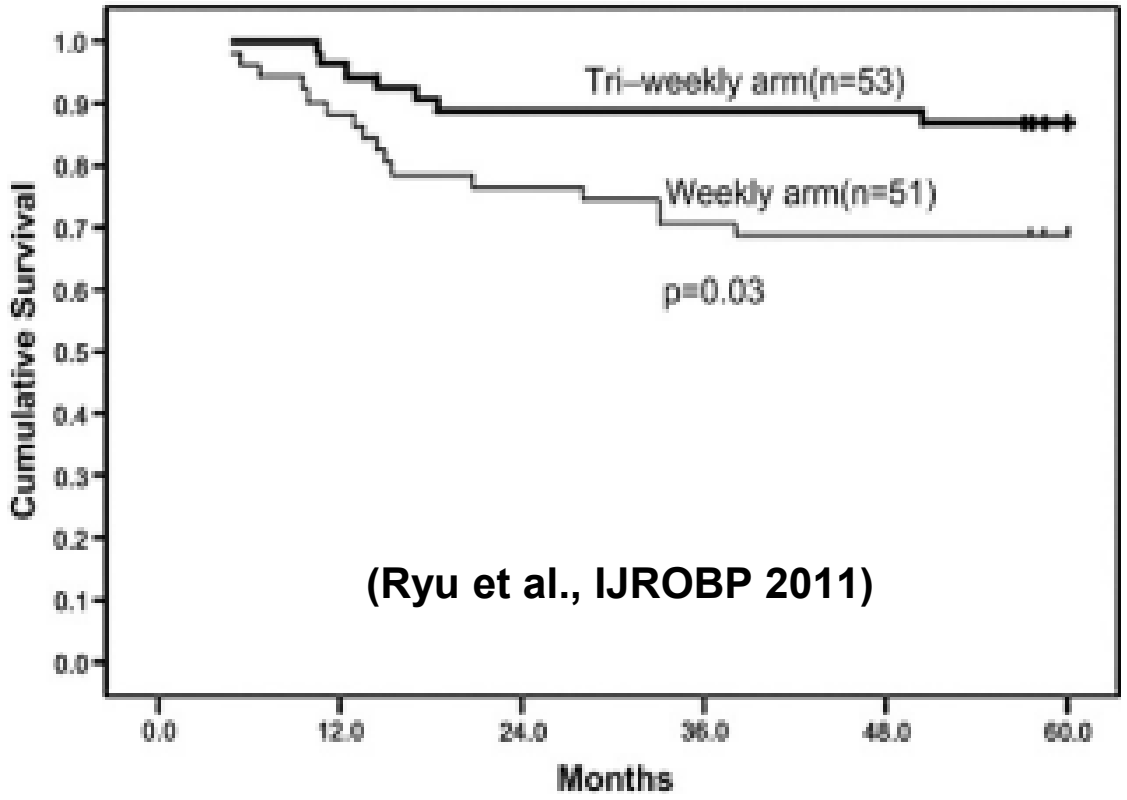
(Bonomi et al., 1985)

Table 2. Response by Treatment

	Cisplatin			
Response	50 mg/m^2/ Every 3 wk (%)	100 mg/m^2/ Every 3 wk (%)	20 mg/m^2/ d × 5 (%)	Total
Complete response	15 (10.0)	21 (12.7)	11 (8.6)	47
Partial response	16 (10.7)	31 (18.7)	21 (16.4)	68
Stable disease	60 (40.0)	63 (38.0)	41 (32.0)	164
Increasing disease	59 (39.3)	51 (30.6)	55 (43.0)	165
Total	150 (100.0)	166 (100.0)	128 (100.0)	444

NOTE. Of the 497 evaluable patients, 30 have nonmeasurable disease and 23 are inevaluable for response.

TACO: Why not Tri-weekly?



(Ryu et al., IJROBP 2011)

Fig. Kaplan-Meier estimates of survival difference between weekly and triweekly cisplatin-based chemoradiation in patients with locally advanced cervical cancer.

Better survival, less toxicity in Tri-weekly

TACO trial

GOG 263: Why not CRT in IMF?

Cx ca IMF grouping

GOG 49 (Delgado et al., 1990)

1. DOI

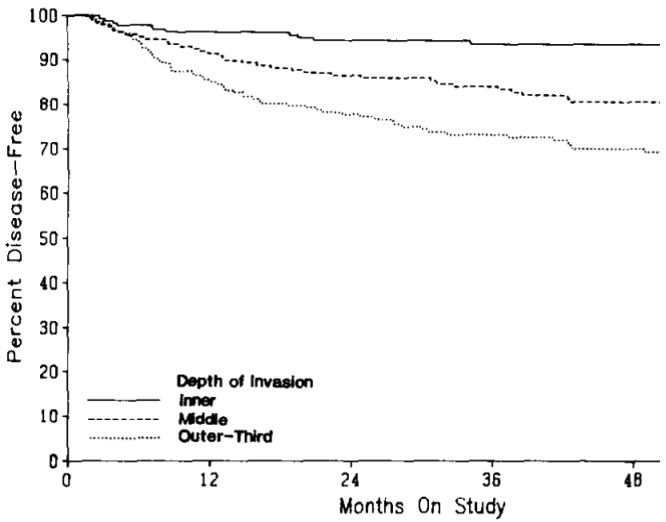


FIG. 4. Disease-free interval by depth of tumor pene

2. CLS involvement

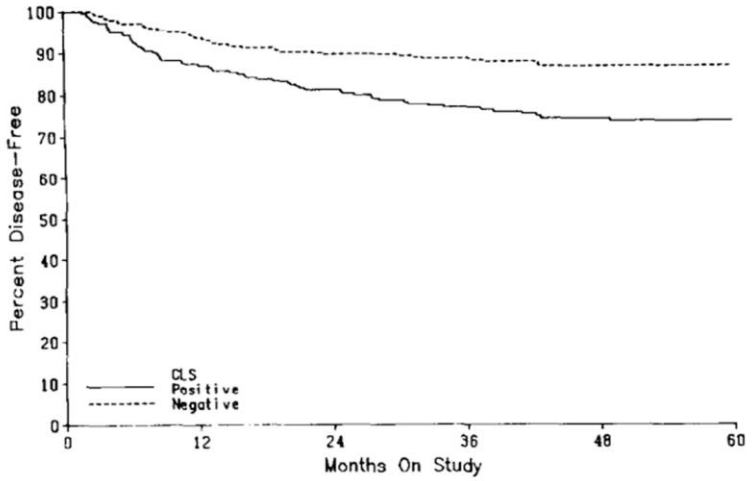


FIG. 6. Disease-free interval by capillary/lymphatic space.

CLS	NED	Recurred	Total
Positive	211	65	276
Negative	320	46	366

3. Tumor size

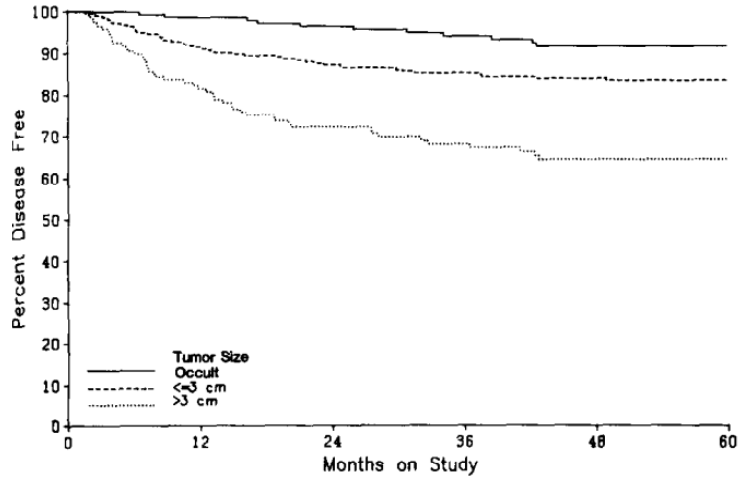
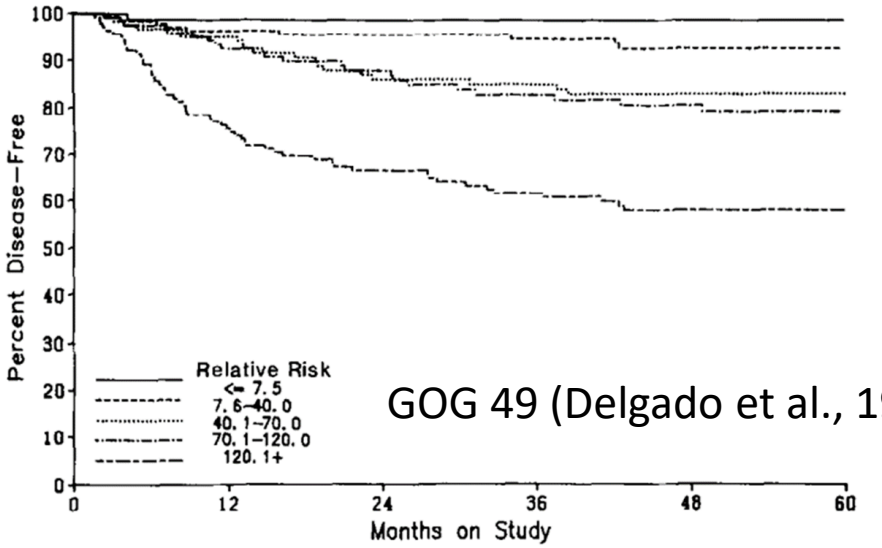


FIG. 5. Disease-free interval by clinical tumor size.

Tumor size	NED	Recurred	Total
Occult	157	11	168
≤3 cm	276	49	325
≥3 cm	101	51	152

GOG 263: Why not CRT in IMF?

CX ca IMF group



GOG 49 (Delgado et al., 1990)

FIG. 7. Disease-free interval by relative risk group.

Relative risk	NED	Recurred	Total
≤7.5	90	1	91
7.6– 40.0	133	9	142
40.1– 70.0	107	21	128
70.1–120.0	108	22	130
120.1+	83	58	141

Sedlis' criteria
3 factor-model(CLS, SI, size)

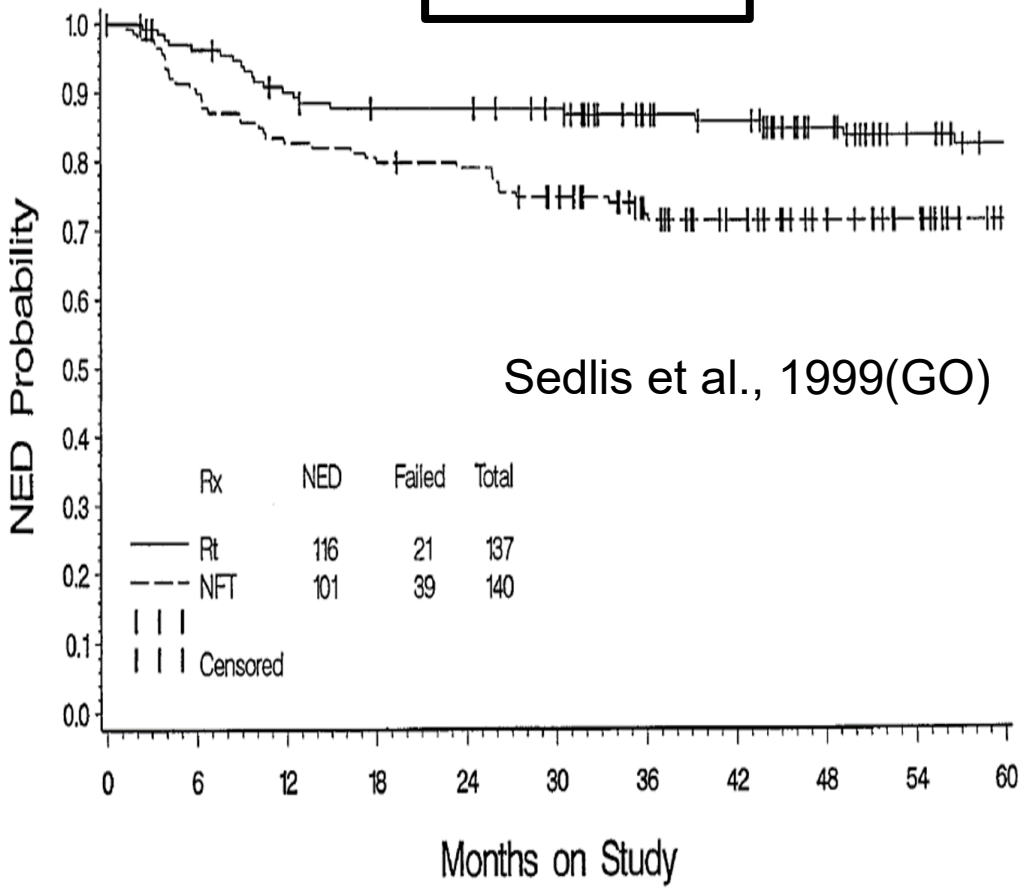
TABLE 1
Eligibility Criteria

CLS[a]	Stromal invasion	Tumor size
Positive	Deep 1/3	Any
Positive	Middle 1/3	≥2 cm
Positive	Superficial 1/3	≥5 cm
Negative	Deep or middle 1/3	≥4 cm

[a] Capillary lymphatic space tumor involvement.

GOG 263: Why not CRT in IMF?

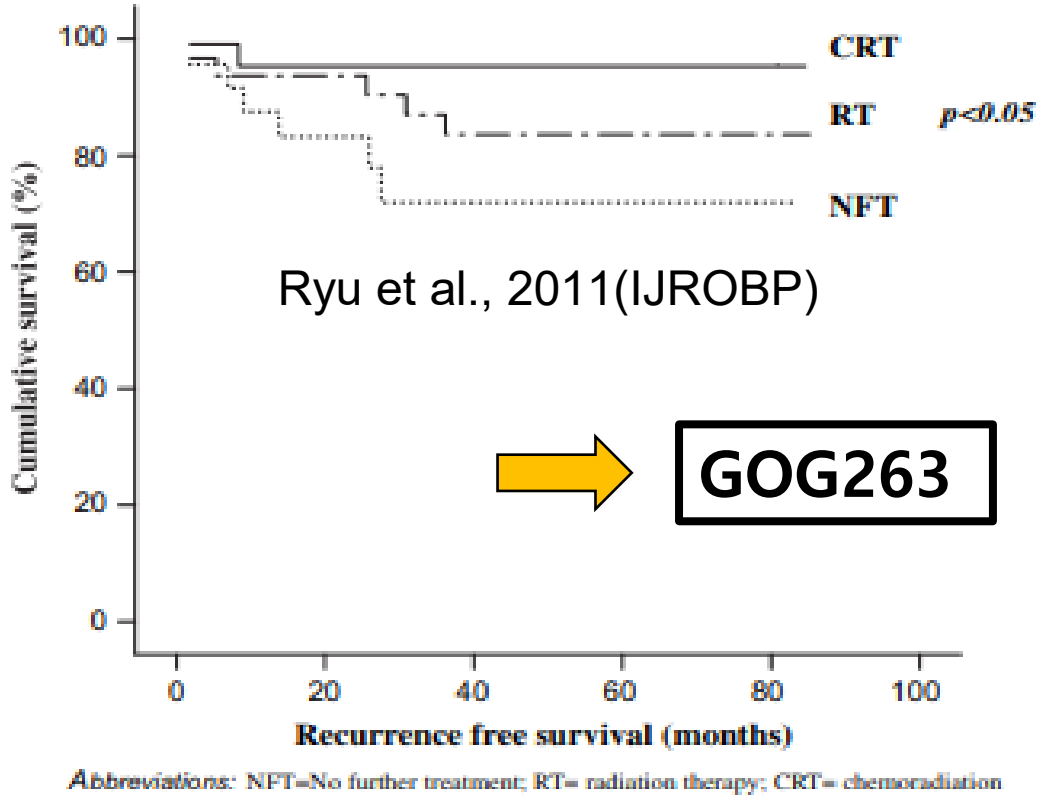
RT> NFT



Sedlis et al., 1999(GO)

FIG. 1. Recurrence-free interval by treatment.

CRT> RT > NFT



Ryu et al., 2011(IJROBP)

GOG263

Abbreviations: NFT=No further treatment; RT= radiation therapy; CRT= chemoradiation

Fig. 1. Recurrence-free survival of patients with two or more intermediate risk factors.

Q1: KGOG1008/GOG 263

Cervical cancer

Stage I-IIA
Radical hysterectomy+BPLND
≥2 of intermediate risk factors

Randomization

Control Arm; Radiation therapy

*IMRT allowed

CRT Arm; Weekly CDDP 40mg/m² concurrent to radiation

*IMRT allowed



Q2: KGOG1027/TACO

Cervical cancer

Locally advanced cervical cancer
Stage IB2, IIB-IVA

Randomization

Control Arm; Weekly Cisplatin 40mg/m2 6 cycles

Study Arm; Tri-weekly Cisplatin 75mg/m2 3 cycles

How to make a RCT possible?

GOG263

"Holding Tightly Fast-Running Mommy's Back" Strategy



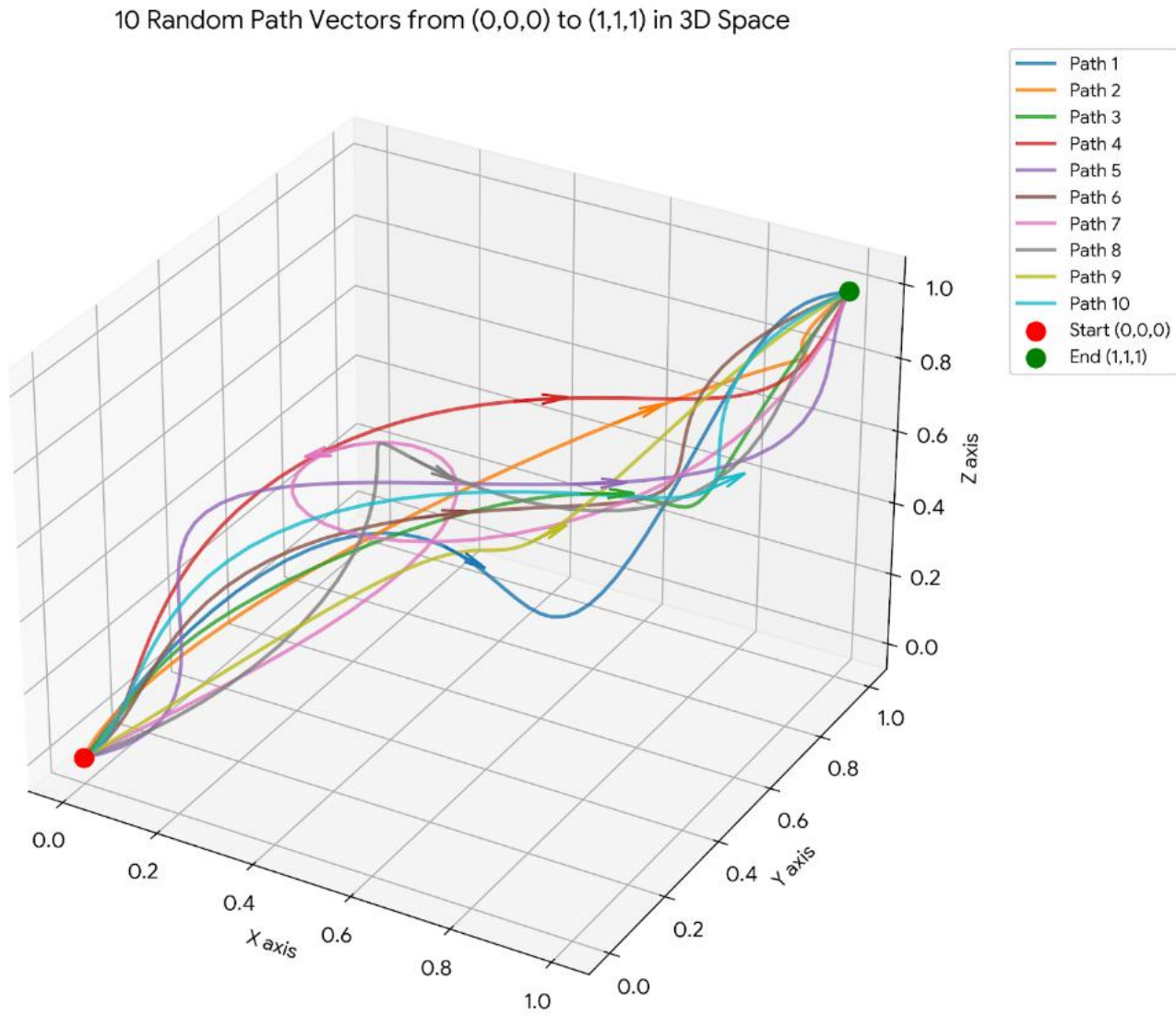
TACO

"堂狗風月"



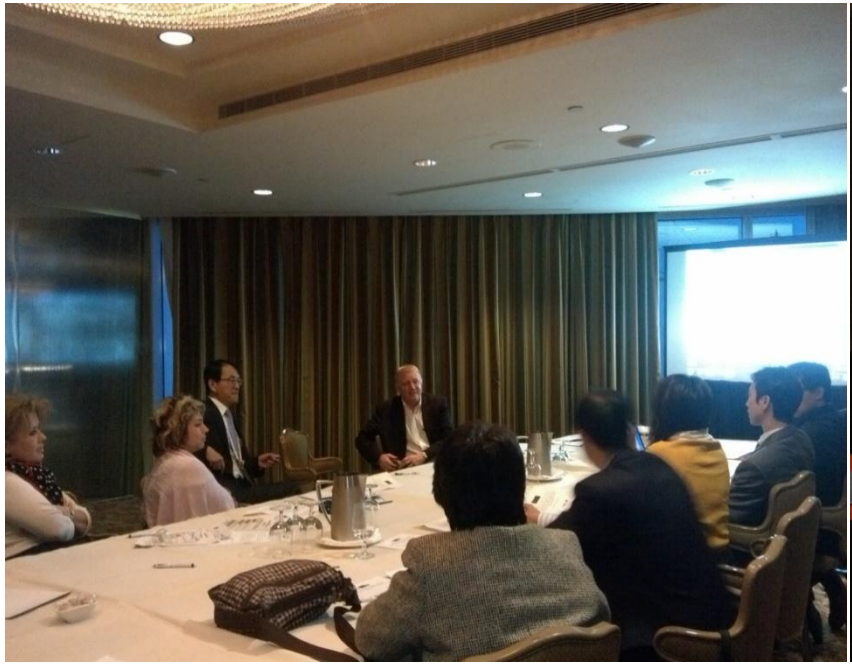
99% Perspiration

1. **Funding**
2. **Collaborator**
3. Contract: reimbursement
4. TMC: international
5. Statistics
6. Protocol: translation
7. QOL: translation/validation
8. IRB: intra, international
9. E-Velos system
10. SOP
11. IROC-Huston collaboration
12. RT validation
13. Kick-off meeting
14. Site visiting, education
15. Funding
16. GCIG/CCRN report
17. RT-QA
18. IDMC
19. RT review
20. Gyn review
21. Interim analysis
22. Data monitoring
23. Query sending
24. End of enrolment
25. End of study
26. Data analysis
27. Publication



Radiation Treatment Quality Assessment
IROC-Houston, MD Anderson

RT-QA(2012. 11 Vancouver)



RT-QA (2013.4 Bankok)



RT-QA(2014.10 Seoul)



QC monitoring

Ramathibodi Hospital, Thailand (2013.4)



Ho Chi Minh City Hospital, Vietnam (2014.6)



IDMC

IDMC 2013. 11 London





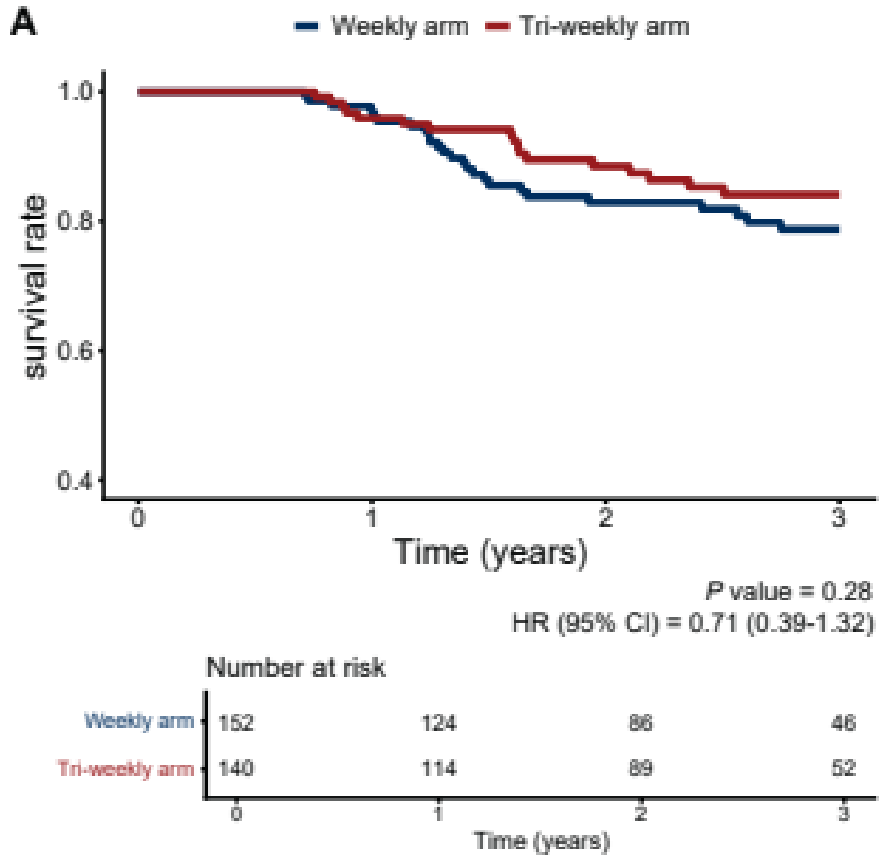
IDMC 2014.10 Melborne



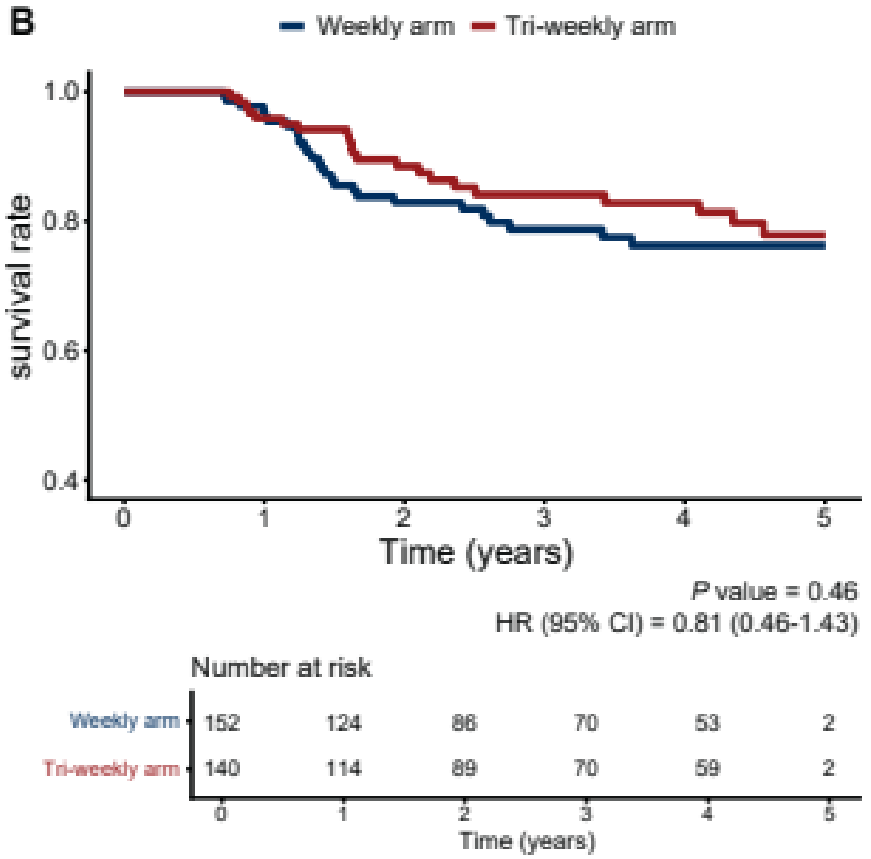
Results: TACO

Results: Why not Tri-weekly?

TACO-survival



3Y-RFS



3Y-OS

Results; Why not Tri-weekly?

TACO-recurrences

Table 2. Pattern of recurrence in patients with locally advanced cervical cancer treated with weekly or tri-weekly cisplatin-based chemoradiotherapy

	Weekly (n = 152)	Tri-weekly (n = 140)	P value
Recurrence, n (%)			0.647
No	124 (81.6)	118 (84.3)	—
Yes	28 (18.4)	22 (15.7)	—
Recurrence site, n (%)			0.634
Central or regional	12 (35.3)	7 (23.3)	—
Distant	19 (55.9)	19 (63.3)	—
Mixed	3 (8.8)	4 (13.3)	—
Persistent disease, n (%)			0.890
No	135 (88.8)	126 (90.0)	—
Yes	17 (11.2)	14 (10.0)	—

Results; Why not Tri-weekly?

TACO- Toxicity

...cally advanced cervical cancer treated with weekly or tri-weekly cisplatin-based chemoradiotherapy

	Grades 1-2			Grades[a] 3-4		
	Weekly (n = 674)	Tri-weekly (n = 575)	P value	Weekly (n = 211)	Tri-weekly (n = 181)	P value
Hematological, n (%)	270 (40.1)	277 (48.2)	<0.001	104 (49.3)	55 (30.4)	<0.001
Anemia	124 (18.4)	120 (20.9)	—	15 (7.1)	10 (5.5)	—
Neutropenia	104 (15.4)	134 (23.3)	—	75 (35.5)	38 (21.0)	—
Thrombocytopenia	42 (6.2)	23 (4.0)	—	12 (5.7)	4 (2.2)	—
Others	0	0	—	2 (0.9)	3 (1.7)	—
Gastrointestinal, n (%)	200 (29.7)	153 (26.6)	0.285	14 (6.6)	29 (16.0)	0.005
Endocrinological, n (%)	71 (10.5)	36 (6.3)	0.011	55 (26.1)	48 (26.5)	>0.99
Hepatic, n (%)	1 (0.1)	21 (3.7)	<0.001	13 (6.2)	12 (6.6)	>0.99
Urological, n (%)	24 (3.6)	9 (1.6)	0.046	6 (2.8)	9 (5.0)	0.406
Inflammatory, n (%)	18 (2.7)	5 (0.9)	0.033	3 (1.4)	7 (3.9)	0.226
Pulmonological, n (%)	4 (0.6)	3 (0.5)	>0.99	9 (4.3)	6 (3.3)	0.822
Cardiovascular, n (%)	1 (0.1)	0	>0.99	2 (0.9)	6 (3.3)	0.196
Kidney, n (%)	12 (1.8)	29 (5.0)	0.002	4 (1.9)	1 (0.6)	0.465
Dermatological, n (%)	5 (0.7)	9 (1.6)	0.263	1 (0.5)	0	>0.99
Orthopedic, n (%)	0	0	NA	0	1 (0.6)	0.939
Allergic, n (%)	2 (0.3)	2 (0.3)	>0.99	0	0	NA
Ophthalmological, n (%)	2 (0.3)	3 (0.5)	0.853	0	0	NA
Dental, n (%)	1 (0.1)	1 (0.2)	>0.99	0	0	NA
Neurological	46 (6.8)	17 (3.0)	0.003	0	0	NA
Esophagitis	0	1 (0.2)	0.934	0	0	NA
Myalgia	0	1 (0.2)	0.934	0	0	NA
Others	17 (2.5)	8 (1.4)	0.228	0	7 (3.9)	0.048

CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable.

[a]Grade based on CTCAE version 3.0.

Results: Why not Tri-weekly?

TACO-QOL

Table 4. Comparison of quality of life in patients with locally advanced cervical cancer treated with weekly or tri-weekly cisplatin-based chemoradiotherapy

	Weekly	Tri-weekly	*P* value
Global health status/QOL	61.9 ± 23.4	66.5 ± 21.5	0.001
QL: global health status	80.4 ± 19.2	82.4 ± 17.3	0.078
Functional scales (higher values signify better functioning)	77.9 ± 25.8	80.8 ± 24.0	0.062
PF: physical functioning	80.1 ± 19.8	83.4 ± 18.6	0.007
RF: role functioning	85.5 ± 17.3	88.3 ± 15.3	0.006
EF: emotional functioning	80.8 ± 24.7	83.3 ± 22.4	0.101
CF: cognitive functioning	31.4 ± 23.8	27.2 ± 22.3	0.003
SF: social functioning	14.9 ± 21.6	14.4 ± 22.2	0.721
Symptom scales (higher values indicate greater symptom severity)	19.1 ± 22.7	16.8 ± 21.2	0.097
FA: fatigue	14.9 ± 22.1	11.8 ± 20.0	0.097
NV: nausea and vomiting	24.4 ± 27.3	22.8 ± 25.1	0.347
PA: pain	29.5 ± 29.9	28.1 ± 28.3	0.466
Single-item symptom scores (higher values indicate greater symptom severity)	18.8 ± 26.1	17.2 ± 23.8	0.296
DY: dyspnea	18.1 ± 25.1	15.0 ± 22.8	0.038
SL: insomnia	19.3 ± 27.5	17.2 ± 25.5	0.219
AP: appetite loss	61.9 ± 23.4	66.5 ± 21.5	0.001
CO: constipation	80.4 ± 19.2	82.4 ± 17.3	0.062
DI: diarrhea	77.9 ± 25.8	80.8 ± 24.0	0.007

Values are indicated as means ± standard deviations.
QOL, quality of life.

Results: GOG263

Results: Why not CRT in IMF?

GOG 263-compliance

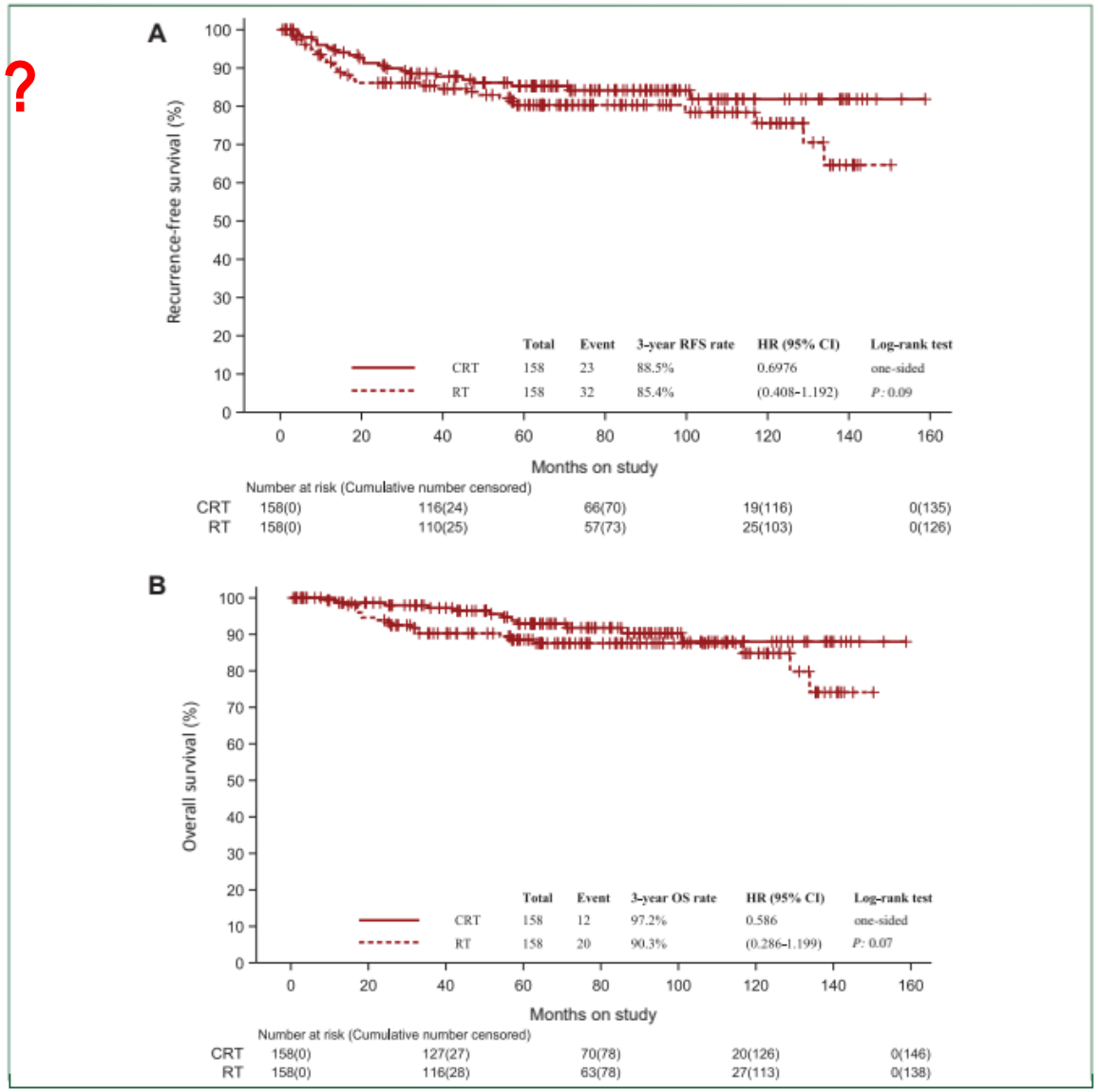
Table 2. Study treatment outcomes

	RT arm (n = 158)	CRT arm (n = 158)	Total (n = 316)	P value[a]
Reason off protocol therapy				**<0.001**
Completion of planned protocol therapy	157 (99.4%)	134 (84.8%)	291 (92.1%)	
Patient withdrawal/refusal	0 (0%)	14 (8.9%)	14 (4.4%)	
Toxicity	0 (0%)	2 (1.3%)	2 (0.6%)	
Other	1 (0.6%)	8 (5.1%)	9 (2.8%)	
Cycles of cisplatin				NA
0		5 (3.2%)		
1		3 (1.9%)		
2		1 (0.6%)		
3		6 (3.8%)		
4		4 (2.5%)		
5		26 (16.5%)		
6		113 (71.5%)		
Number of fractions				**0.001**
28 times	154 (97.5%)	138 (87.3%)	292 (92.4%)	
Less than 28 times	4 (2.5%)	20 (12.7%)	24 (7.6%)	
Total radiation dose				**0.001**
<50.4 Gy	4 (2.5%)	20 (12.7%)	24 (7.6%)	
≥50.4 Gy	154 (97.5%)	138 (87.3%)	292 (92.4%)	
RT duration (days)				**0.03**
Median	39	38.5	39	
Min–Max	31-53	0-64	0-64	
Radiation therapy compliance				0.41
Acceptable	109 (69.0%)	103 (65.2%)	212 (67.1%)	
Minor violation	37 (23.4%)	38 (24.1%)	75 (23.7%)	
Major violation	2 (1.3%)	7 (4.4%)	9 (2.8%)	
Not reviewed	10 (6.3%)	10 (6.3%)	20 (6.3%)	
Survival status				0.18
Dead - disease-related	16 (10.1%)	9 (5.7%)	25 (7.9%)	
Dead - neither treatment or disease	4 (2.5%)	1 (0.6%)	5 (1.6%)	
Dead - undetermined	0 (0.0%)	2 (1.3%)	2 (0.6%)	
Alive - without recurrence	126 (79.7%)	135 (85.4%)	261 (82.6%)	
Alive - with recurrence	12 (7.6%)	11 (7.0%)	23 (7.3%)	
Lost to follow-up				0.58
Temporary	5 (3.2%)	8 (5.1%)	13 (4.1%)	
Temporary delay	5 (3.2%)	9 (5.7%)	14 (4.4%)	
Permanent	39 (24.7%)	36 (22.8%)	75 (23.7%)	
No	109 (69.0%)	105 (66.5%)	214 (67.7%)	

CRT, concurrent chemo-radiation treatment; NA, not applicable; NS, not significant; RT; radiation treatment only.
Bold text indicates statistically significant differences.
[a]Observations with missing values were included for discrete-type variables and excluded for continuous variables. Wilcoxon rank-sum test: RT duration. Exact chi-square tests: reason off protocol therapy, radiation therapy compliance, survival status, lost to follow-up. Fisher's exact tests: number of fractions (dichotomized), total radiation dose (dichotomized).

Results: Why not CRT in IMF?

GOG 263-survival



P=0.09

P=0.07

Figure 2. Patient survival outcomes in GOG-263. (A) Recurrence-free survival (RFS) by Kaplan–Meier method per randomized therapy (3-year RFS: 88.5% in the CRT arm and 85.4% in the RT arm respectively, $P = 0.09$). (B) Overall Survival (OS) by Kaplan–Meier method per randomized therapy (3-year OS: 97.2% in the CRT arm and 90.3% in the RT arm respectively, $P = 0.07$). (C) Forest plot for recurrence-free survival treatment effect by subgroup analyses. Confidence intervals should not be used to reject or not reject the null hypothesis of a treatment effect.
CI, confidence interval; CLS, capillary lymphatic space involvement; CRT, concurrent chemo-radiation treatment; GOG, Gynecologic Oncology Group; IMRT, intensity modulated radiation treatment; KGOG, Korean Gynecologic Oncology Group; OS, overall survival; RFS, recurrence free survival; RT, radiation treatment only; Strata, stratification used at randomization; XRT, external beam radiation treatment.

Why NOT CRT in IMF?

Results: Why NOT CRT in IMF?

GOG 263-subgroup variable

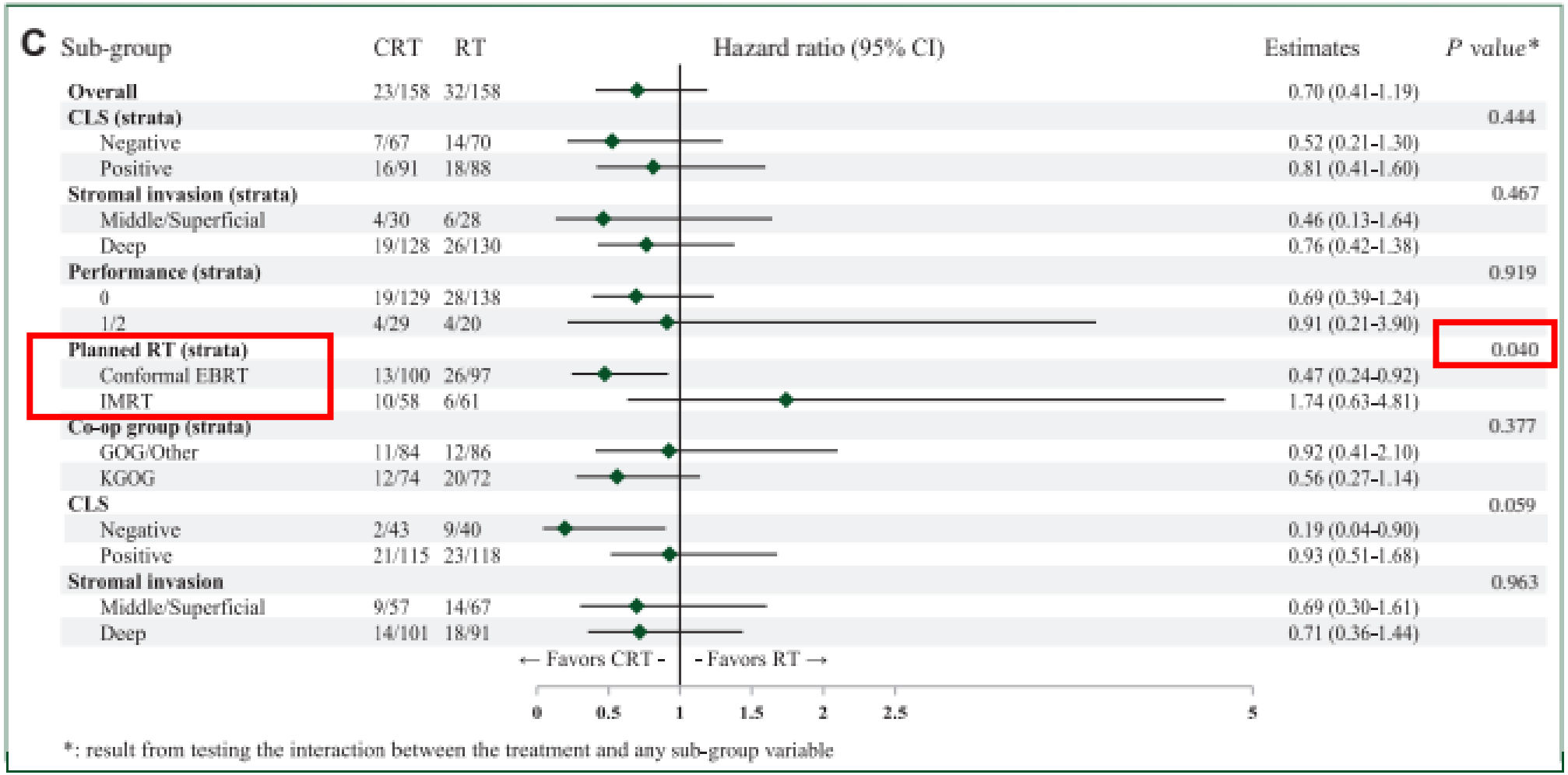


Figure 2. Continued.

Results: Why NOT CRT in IMF?

GOG 263-QOL

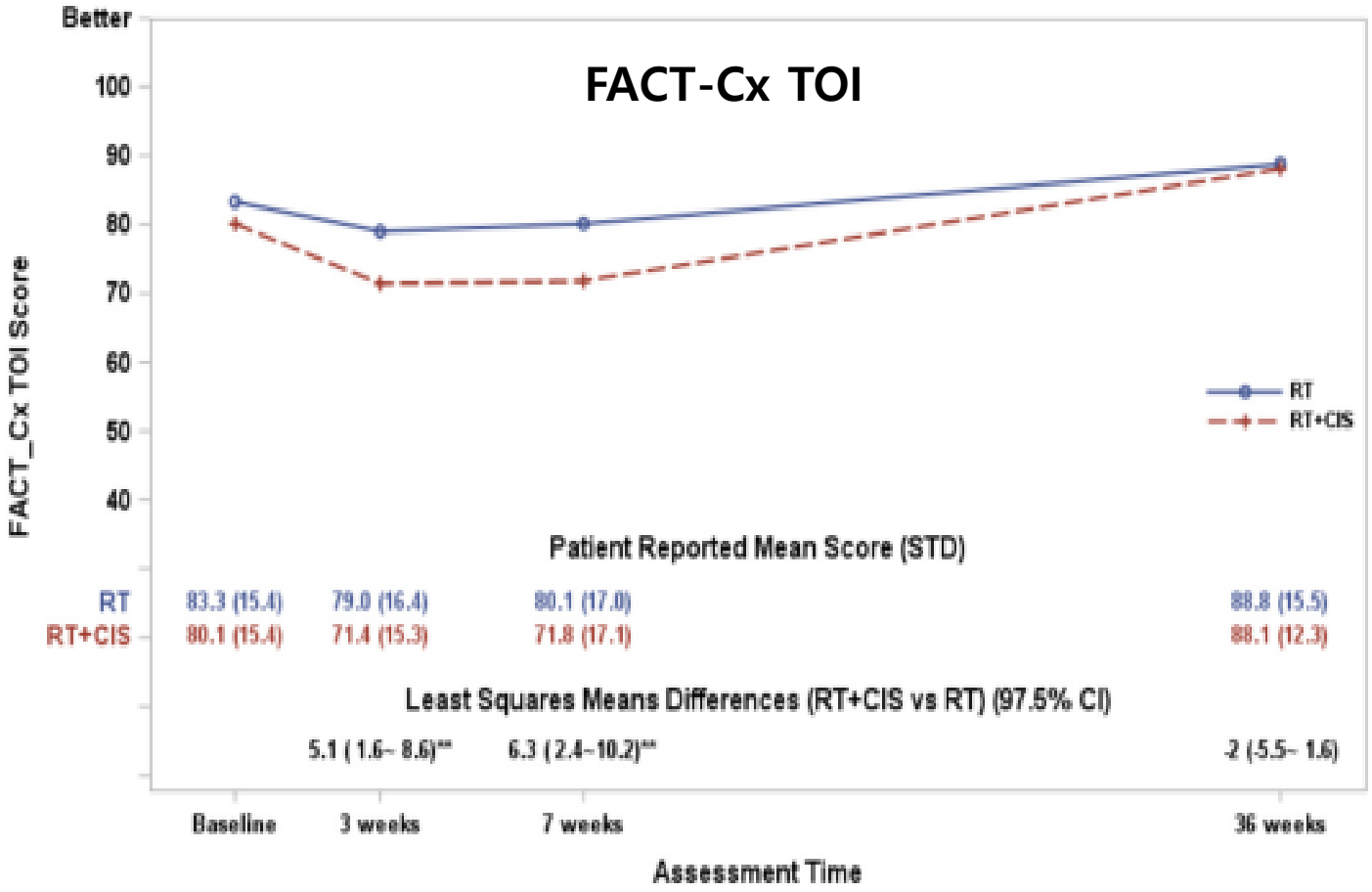


Fig. 2. The plot lines represent the FACT-Cx TOI scores. The estimated least-squares means (LSM) differences were obtained from a fitted mixed model adjusting for pre-treatment score (baseline score), patient's age and performance status at the enrollment, and the country the treatment was administered. A larger score indicates favorable or better QOL. Note "**" indicates Hochberg adjusted p-value <0.01.

Results: Why NOT CRT in IMF?

GOG 263-short term QOL

NTX4

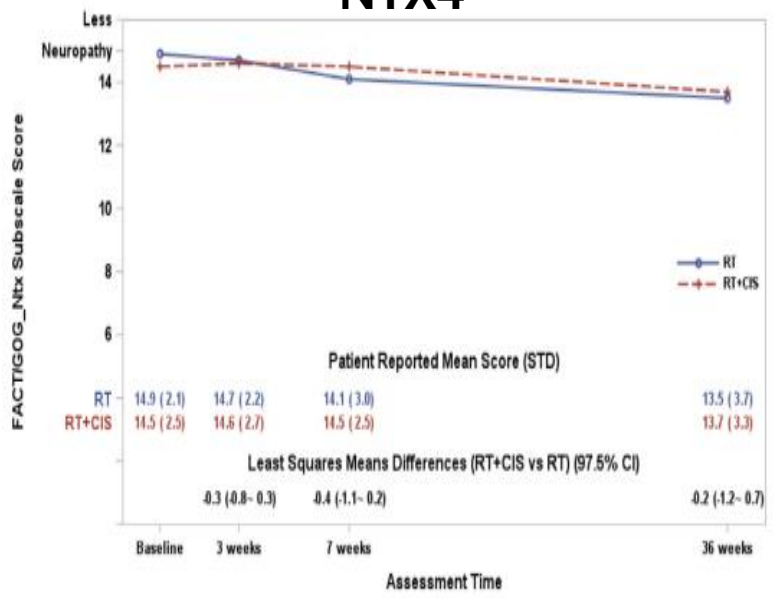


Fig. 3. The plot lines represent the FACT/GOG-Ntx-4 scores. The estimated least-squares means (LSM) differences were obtained from a fitted mixed model adjusting for pre score (baseline score), patient's age and performance status at the enrollment, and the country the treatment was administered. A larger score indicates less neurotoxic sym

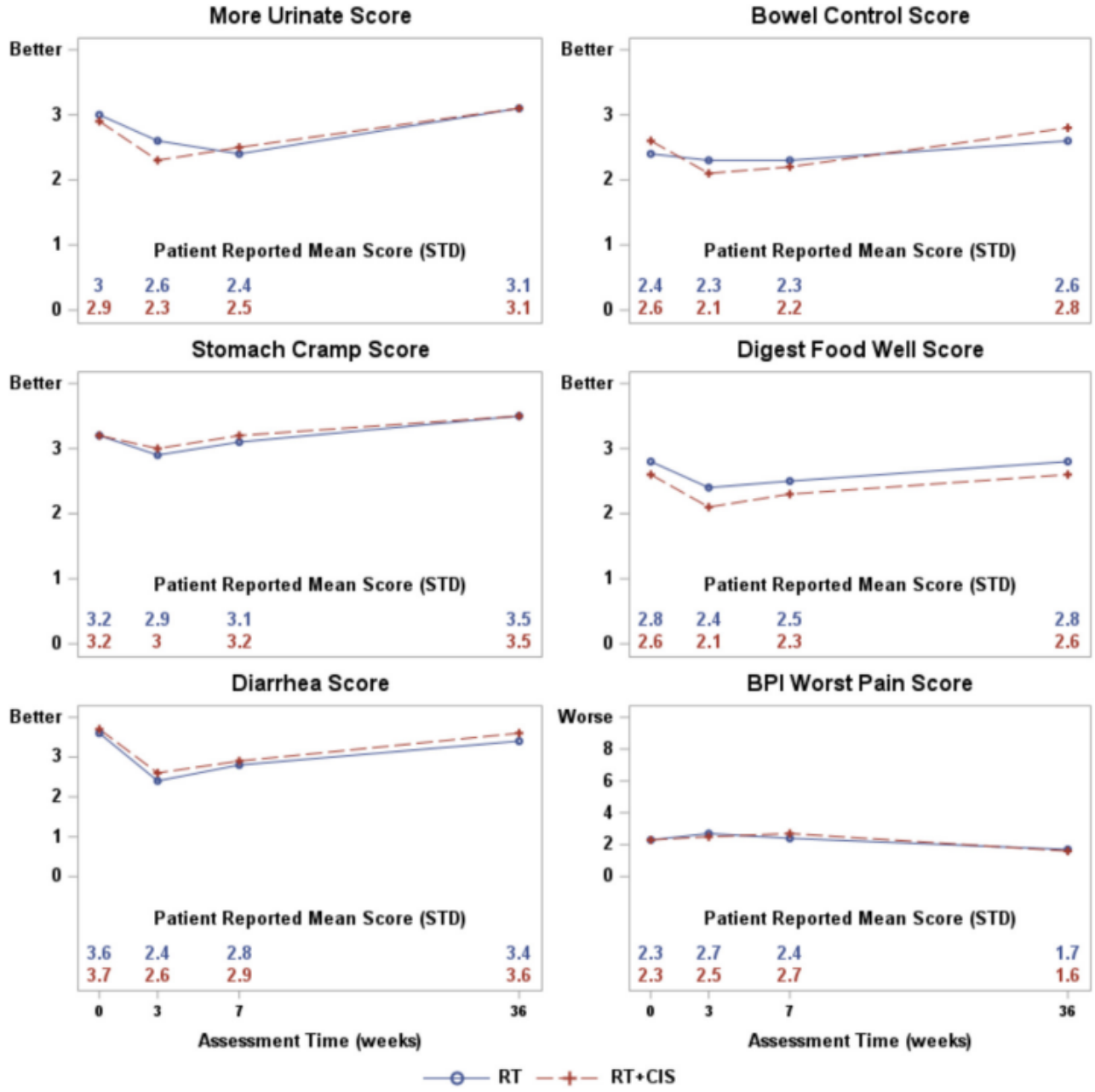


Fig. 4. The plot lines represent the patient-reported symptoms and pain scores. A larger score indicates better or favorable status except for the BPI worst pain score in which a larger score indicates worse pain.

Summary of GOG 263 and TACO

Difference of QOL and toxicity profile

	GOG 263	TACO
Arms	**RT vs CRT**	**Weekly vs tri-weekly**
Survival outcome	No difference	No difference
Toxicity	CRT > RT	Weekly > Tri-weekly
Short-term QOL	RT > CRT	Tri-weekly > Weekly

Discussion

Limitation

1. Not non-inferiority trial

2. Slow enrollment; revised the total number of study (600-> 300)

Strength

1. Complete observation > 5 years

2. Includes QOL component

Discussion: TACO
Why not Tri-weekly? : Similar survival, less toxicity

1. **Minimum total dose** > **Cisplatin 200mg/m²**
   - Weekly 40mg/m² x 6 cycles = 240m
   - Tri-weekly 75mg/m² x3 cycles = 220mg

2. Tri-weekly provides **longer recovery time**

   ; Reduced toxicity-> increase compliance and QOL

Discussion: GOG 263

Why NOT CRT in IMF? - Targets

Ryu's criteria
4 factor-model (CLS, SI, size, histology) (BJC 2014)

1. Classic: 3 factor model

Any two of; Tumor size >2 cm, LVSI, stromal invasion >1/3

2. GOG: 3 factor model (Sedlis)

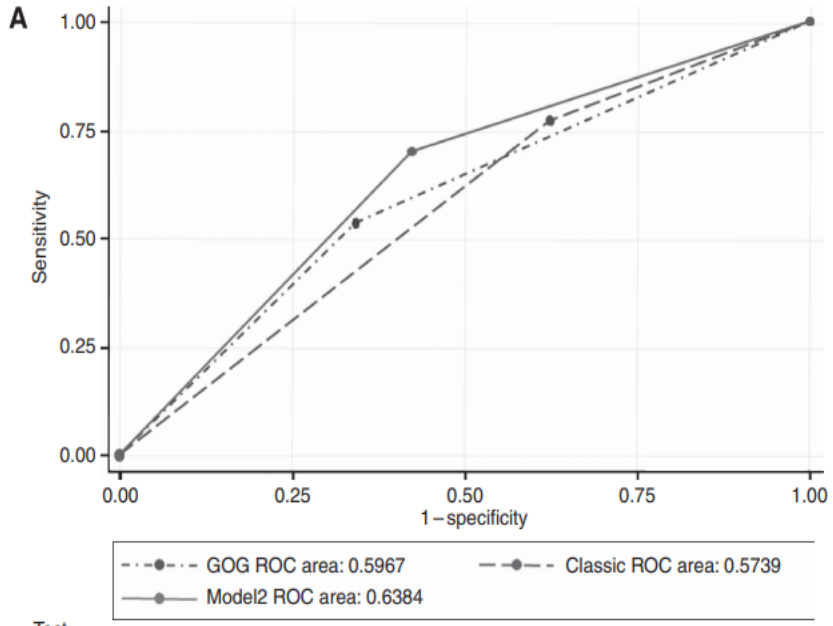
Combinations of; LVSI, DSI, tumor size

3. KGOG: 4-factor model (Ryu)

Any two of; Tumor > 3cm, outer 1/3, LVSI, adenoca

4. ESGO(CERVANTES):4-factor model (Cibula)

Combinations of Tumor size, LVS, tumor free distance, DSI



Test

Model	Obs	ROC area	s.e.	95% CI		Chi-square	*P*-value
GOG	1568	0.5967	0.0231	0.551	0.642		
Classic	1568	0.5739	0.0198	0.535	0.613	10.7	0.0048
Model2	1568	0.6384	0.0214	0.596	0.680		

Ho: area (GOG) = area (Classic) = area (Model 2)

Which target?

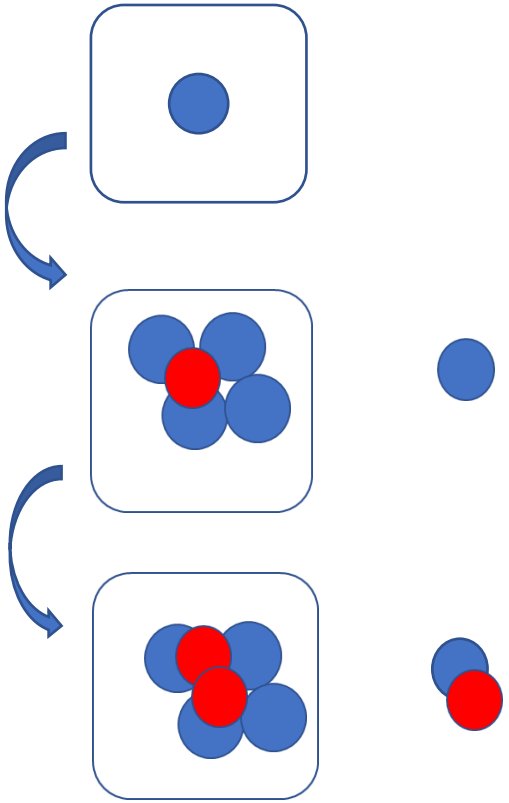
Each probability



Discussion: GOG 263 Why NOT CRT in IMF?

Probability of remnant cancer cell

1. Low -> NFT(Low risk)
2. Probably radio-sensitive cell -> RT alone (Intermediate risk)
3. Probably radio-resistant cell -> CRT(High risk)



Conclusion: TACO & GOG263

1) Any change of standard treatment? **NO**

2) Any change of clinical impact? **YES**

1. No obligation of CRT in IMF

; Physician's discretion based on recurrence risk(RR), QOL, salvage rate

a. If RR 15%: Salvage 60%-> Cure rate 94%

b. If RR 30%: Salvage 60%-> Cure rate 88%

2. No obligation of weekly cisplatin based CRT

;Tri-weekly CRT- better QOL and Toxicity profile

; Availability of salvage, medical infrastructure

Early cervical cancer treatment

Low risk: SHAPE
(Plante et al., 2024)

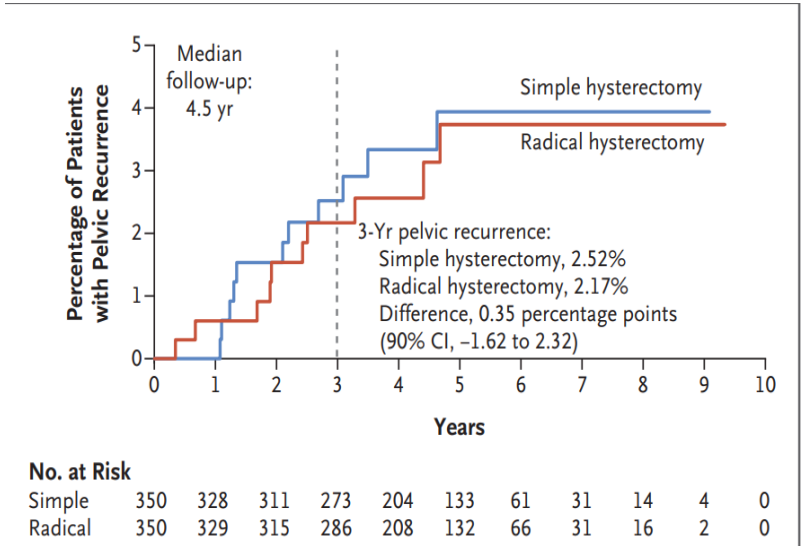
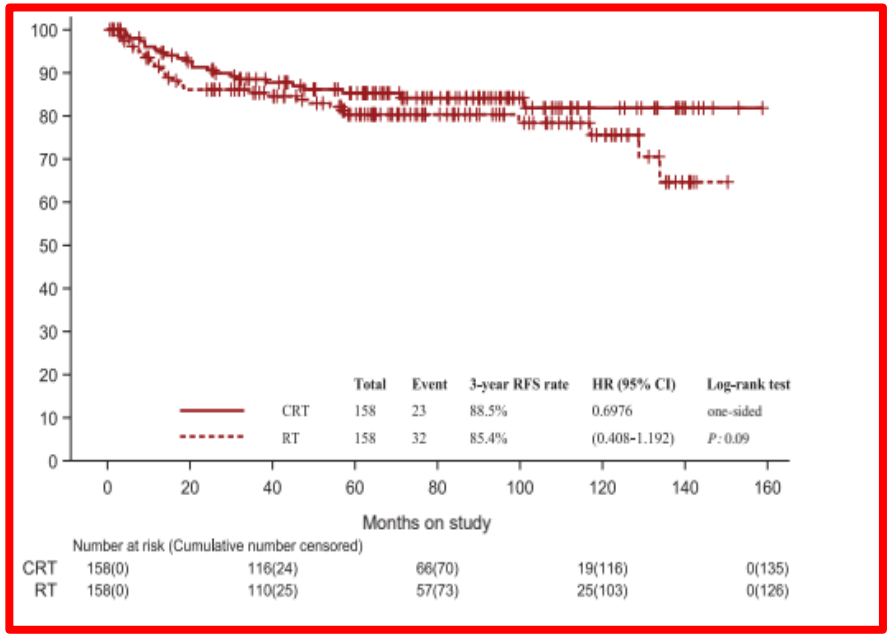


Figure 1. Kaplan–Meier Curves for Pelvic Recurrence.

Intermediate risk: GOG 263
(Ryu et al., 2025)



High risk: GOG109
(Peter et al., 2000)

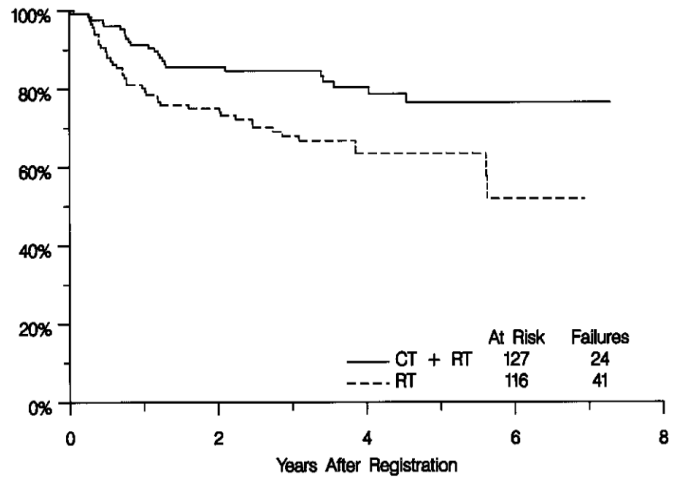


Fig 1. Progression-free survival for 127 patients randomized to receive CT + RT and for 116 patients randomized to receive RT alone.

Acknowledgements



SB Kang
Bradly Monk
Wui-Jin Koh
Madden Leah
Ali Shamshad
Gil Karen
Rodgers William
Heugel Anne
Kuras Angela
Deung Wei
Charles Leath

BH Nam
Henry Kitchner
William Small
David Gaffeny
Sarikapan Williailak
D. Thinh
Stephan Kry
GOG members
KGOG members
KROG





KGOG1008/GOG263

W. Deng, K. Albuquerque, W-J Koh, J. Mayadev, B-J Kim, D-Y Kim, C-H Cho, J-W Kim, J. H. No, A.Heugel, R. S. Mannel, K. Miller, D. Fabian, D. M. Chase, K. M. Gil, W. Small Jr., W. Rodgers, C. A. Leath III,* B. J. Monk,

Gangnam Severance Hospital (Korea), Shikoku Cancer Center (Japan), Ohio State University Comprehensive Cancer Center (USA), Women's Cancer Center of Nevada (USA), University of Cincinnati (USA), Nebraska Methodist Hospital (USA), Tohoku University School of Medicine (Japan), Saint Joseph's Hospital and Medical Center (USA), University of New Mexico (USA), University of Iowa Hospitals and Clinics (USA), University of Texas Southwestern Medical Center (USA), University of Kansas Medical Center (USA), Summa Akron City Hospital/Cooper Cancer Center (USA), Kagoshima City Hospital (Japan), Kyung Hee University Hospital at Gangdong (Korea), Yonsei University Health SystemSeverance Hospital (Korea), Parkview Regional Medical Center (USA), The New York Methodist Hospital (USA), Abington Memorial Hospital-Asplundh Cancer Pavilion (USA), Walter Reed National Military Medical Center (USA), Woman's Hospital (USA), State University of New York (USA), Downstate Medical Center (USA), Southwest Gynecologic Oncology Associates Inc (USA), Memorial Hermann Texas Medical Center (USA), Avera Cancer Institute (USA), Kure National Hospital (Japan), The Mark H Zangmeister Center (USA), Inha University (Korea), Northeast Georgia Medical Center (USA), Baystate Medical Center (USA), Western Pennsylvania Hospital (USA), Intermountain Medical Center (USA), CoxHealth South Hospital (USA), St. Johns Mercy Medical Center (USA), Greenville Health System Cancer Institute-Faris (USA), Interim LSU Public Hospital (USA), Good Samaritan Hospital-Cincinnati (USA), University of Mississippi Medical Center (USA), LDS Hospital (USA), Olive View-University of California Los Angeles Medical Center (USA), Seattle Cancer Care Alliance (USA), Abramson Cancer Center of The University of Pennsylvania (USA), Indiana University Hospital/Melvin and Bren Simon Cancer Center (USA), University of New Mexico (USA), Cleveland Clinic Foundation (USA), Saint Luke's University Hospital-Bethlehem Campus (USA), Memorial Sloan Kettering Cancer Center (USA), Memorial Sloan Kettering Cancer Center Rockville Centre (USA), Wheeling Hospital/ Schiffler Cancer Center (USA), Loyola University Medical Center (USA), Case Western Reserve University (USA), John Muir Medical Center-Concord Campus (USA), Iwate Medical University School of Medicine (Japan), Niigata University Medical & Dental Hospital (Japan), Medical College of Wisconsin (USA), Pikeville Medical Center (USA), Pomona Valley Hospital (USA), Catholic University of Korea-Seoul Saint Mary's Hospital (Korea), National Cancer CenterKorea (Korea), John B Amos Cancer Center (USA), Jackson Memorial Hospital (USA), University of Missouri - Ellis Fischel (USA), Avera Cancer Institute (USA), University Medical Center Brackenridge (USA), Dartmouth-Hitchcock Medical Center (USA), University of Rochester (USA), Mercy Cancer Center (USA), West Michigan Cancer Center (USA), Fairview-Southdale Hospital (USA), Mercy Hospital - Coon Rapids (USA), Greenville Health System Cancer Institute-Seneca (USA), Florida Hospital Cancer Institute CCOP (USA), Adena Regional Medical Center (USA), Presbyterian Rust Medical Center/Jorgensen Cancer Center (USA), Memorial University Medical Center (USA), Alaska Women's Cancer Care (USA), Saint Luke's Mountain States Tumor Institute-Twin Falls (USA), Swedish Medical CenterFirst Hill (USA), Riverside Methodist Hospital (USA).

KGOG1027/TACO

B. H. Nam, M. H. Kim, W. I. Jang, C. Sitathane, D. Linh, K. H. Lee, W. M. Lee, E. T. Kim, S. B. Kang, J. H. Kim, J. Y. Park, K. B. Lee, C. H. Cho, H. Lou, Y. H. Kim, Y. T. Kim, Y. H. Lee, X. Wu, J. W. Kim, S. I. Park, S. Jeon, D. H. Thinh, S. F. Kry, D. Gaffney, W. Small, S. Wilailak

Korea Institute of Radiological & Medical Science, Korea Gynecologic Oncology Group, Ramathibodi Hospital, Ho Chi Minh City Oncology Hospital, St. Mary's Hospital, Catholic University, Hanyang University, Kosin University Gospel Hospital, Hosan Women's Hospital, Gangnam Severance Hospital, Yonsei University, Asan Medical Center, Gachon University Gil Hospital, Keimyung University, Zheijiang Cancer Center, Ewha Womans University College of Medicine, Severance Hospital, Yonsei University College of Medicine, Kyungpook National University College of Medicine, Fudan University Cancer Institute,Seoul National University College of Medicine, Dongnam Institute of Radiological & Medical Science, Soonchunhyang University Cheonan Hospital IROC Houston QA Center, Huntsman Cancer Institute, University of Utah, Stritch School of Medicine, Loyola University Chicago, Ramathibodi Hospital,

Thank you for your attention!



2026년
대한부인종양학회
제31차 추계 심포지엄

2026.10. 23. (금) - 24. (토)

정부세종컨벤션센터 / 세종 코트야드 바이 메리어트

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