

Wellcome to TACO!



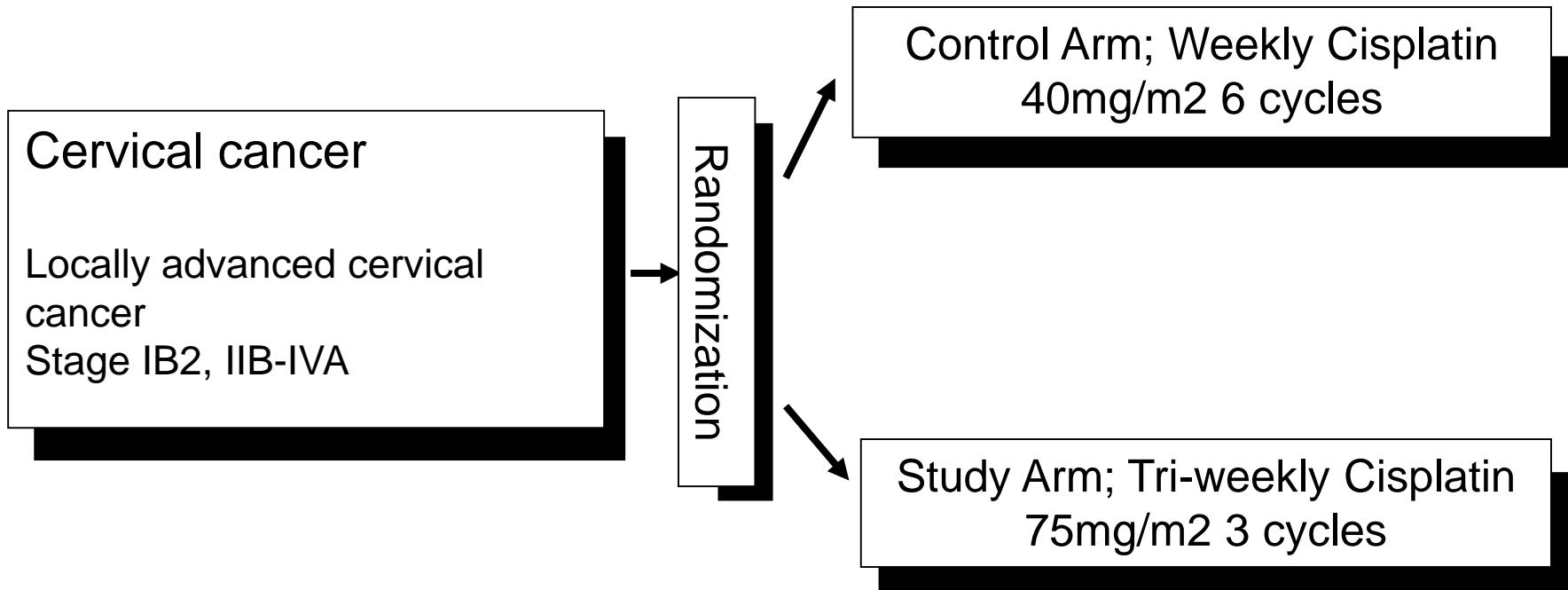
TACO



GCIG/KGOG1027/TGCS2012: Randomized Phase III Clinical Trial Comparing Weekly vs Tri-weekly Cisplatin Based Concurrent Chemoradiation in Locally Advanced Cervical Cancer

TACO

(Tri-weekly Administration of Cisplatin in Locally Advanced Cervical Cancer)



Chemoradiation

- 5 RCTs; 30-50% improvement of survival

Regimen	Cisplatin	No. of
cycle		
GOG 85	FP	50 mg/m ² /3wk 2
GOG120	W-P	40 mg/m ² /wk 6
	FP	50 mg/m ² /4wk 2
GOG 123	W-P	40 mg/m ² /wk 6
SWOG 8797	FP	70 mg/m ² /3wk 4
RTOG 90-01	FP	75 mg/m ² /3wk 3

Victory of Weekly Cisplatin 40mg/m²

- Weekly cisplatin 40 mg/m²
 - Favored because convenient, equally efficacious, less toxic
- GOG 120
 - Arm 1; W-cis #6 vs FP #3
 - Comparable** outcome

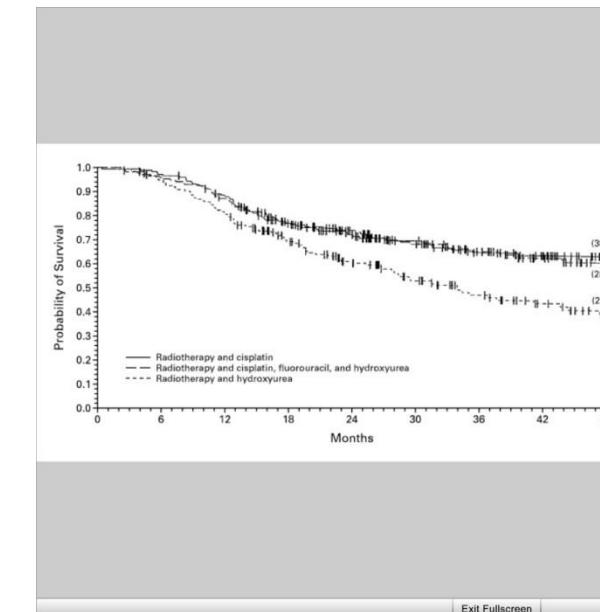


Figure 2. Kaplan-Meier Estimates of Overall Survival.

The overall survival rate was significantly higher among patients in the group given radiotherapy combined with cisplatin therapy (117 of 176, P=0.004) and among patients in the group given radiotherapy combined with treatment with cisplatin, fluorouracil, and hydroxyurea (116 of 173, P=0.002) than among patients in the group given radiotherapy combined with hydroxyurea therapy (88 of 177). Tick marks indicate patients who died. Numbers in parentheses are the numbers of patients at risk at four years.

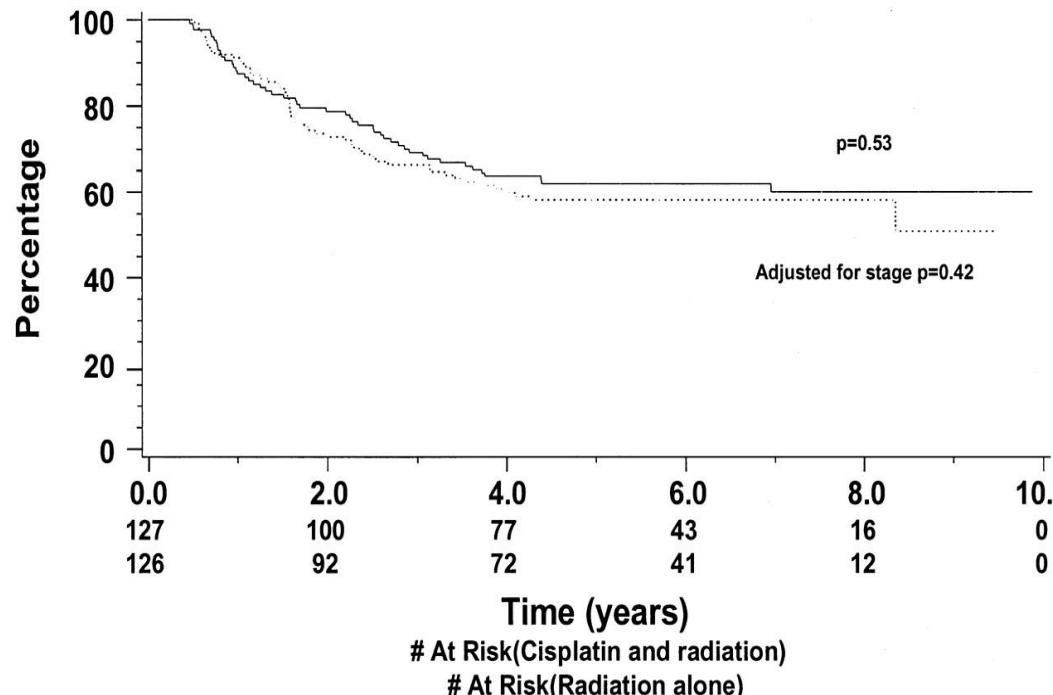
NCIC trial

- Sixth RTC: NCI Canada, 2002**

259 patients, Stage IB to IVA, > 5cm, or pelvic lymph node (+)

W-Cisplatin 40 mg/m² vs RT only

- NO significant difference in PFS and 5YSR



Pearcey R et al. JCO 2002;20:966-972



CRT

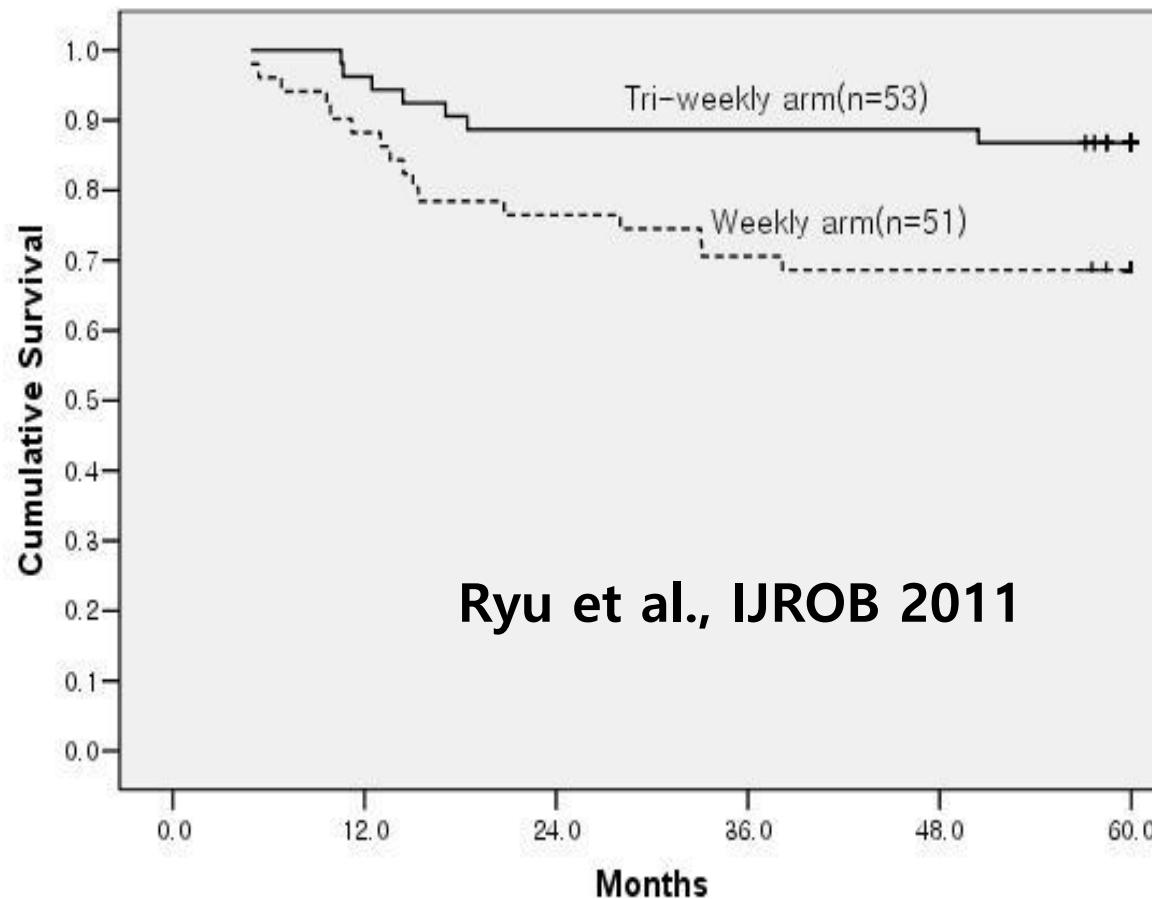
Is Weekly-cisplatin an optimal dose ?

Table 3. Toxicity (Ryu et al., IJROBP 2011)

	Weekly(%) (n=51)		Tri-weekly(%) (n=53)		P-value
	Grade 1-2	Grade 3-4	Grade1-2	Grade3-4	
Neutropenia	20(38.5)	21(40.4)	23(43.4)	12(22.6)	P< 0.05
Thrombocytopenia	13(25.0)	5(9.6)	3(5.7)	3(5.7)	
Nausea	43(82.7)	3(5.8)	46(86.8)	2(3.8)	
Vomiting	13(25.0)	0	11(20.8)	0	
Nephrotoxicity	8(15.4)	0	15(28.3)	1(1.8)	
Neurosensory	5(9.6)	0	2(3.8)	0	
Alopecia	13(25.0)	0	17(32.1))	0	

Preliminary Data; Long term outcome

5YSR ; 88% vs 66% ; HR 0.375 , 95% CI(0.154-0.914) p=0.03

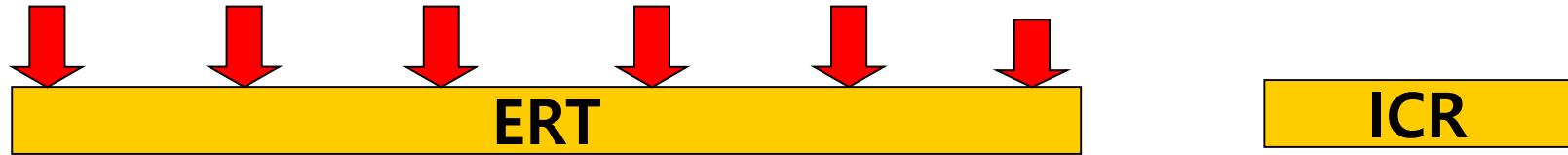


What we want to prove is...

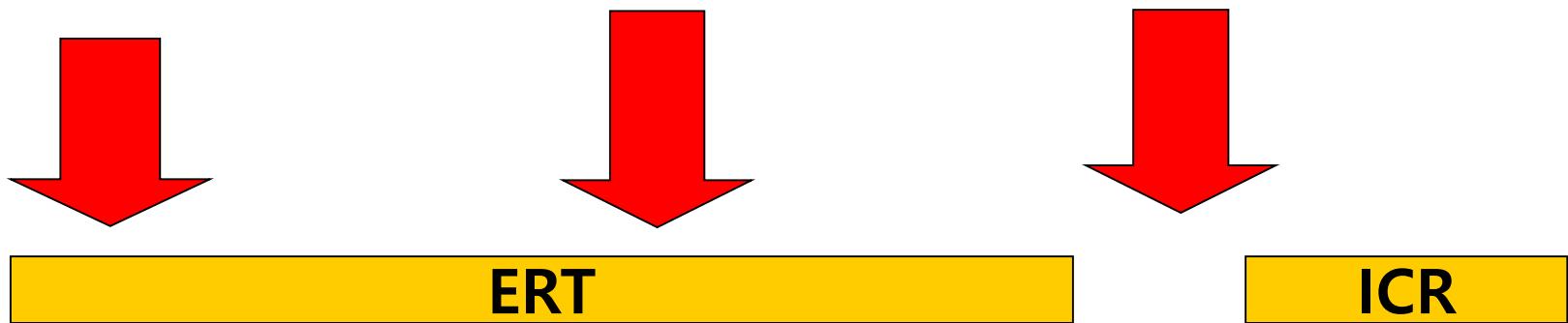
- Hypothesis
 - Peak concentration > Not exposure time

- Synergy of chemoradiation
- Eliminate the micrometastasis

Weekly cisplatin



Tri-weekly cisplatin

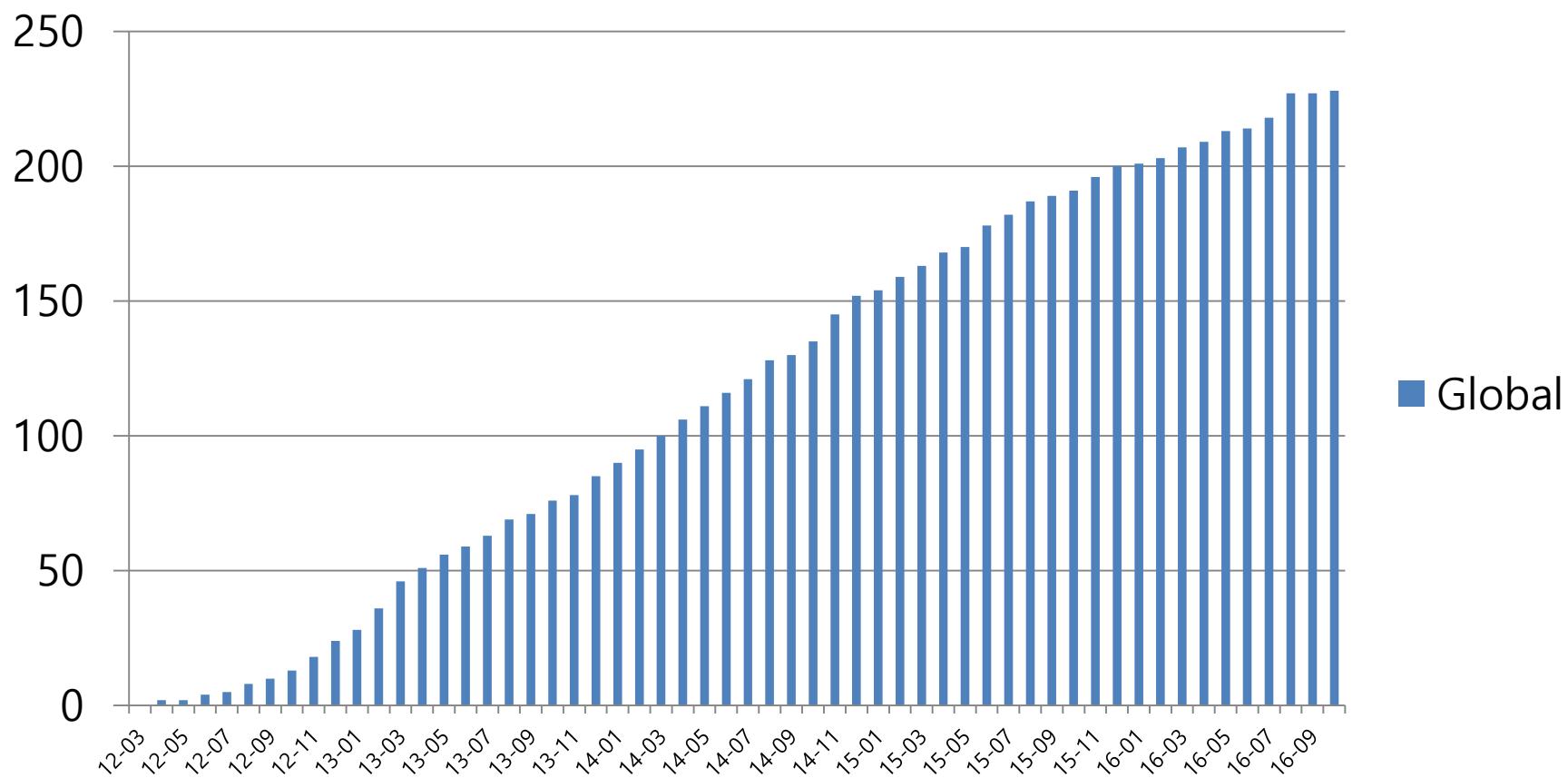


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- Statistics
 - 10% increase of 5YSR
 - 80% power, Two-sided test type I error=5%
 - Expected HR=1.50
 - 265/arm , 10% loss,
 - Total; **590**

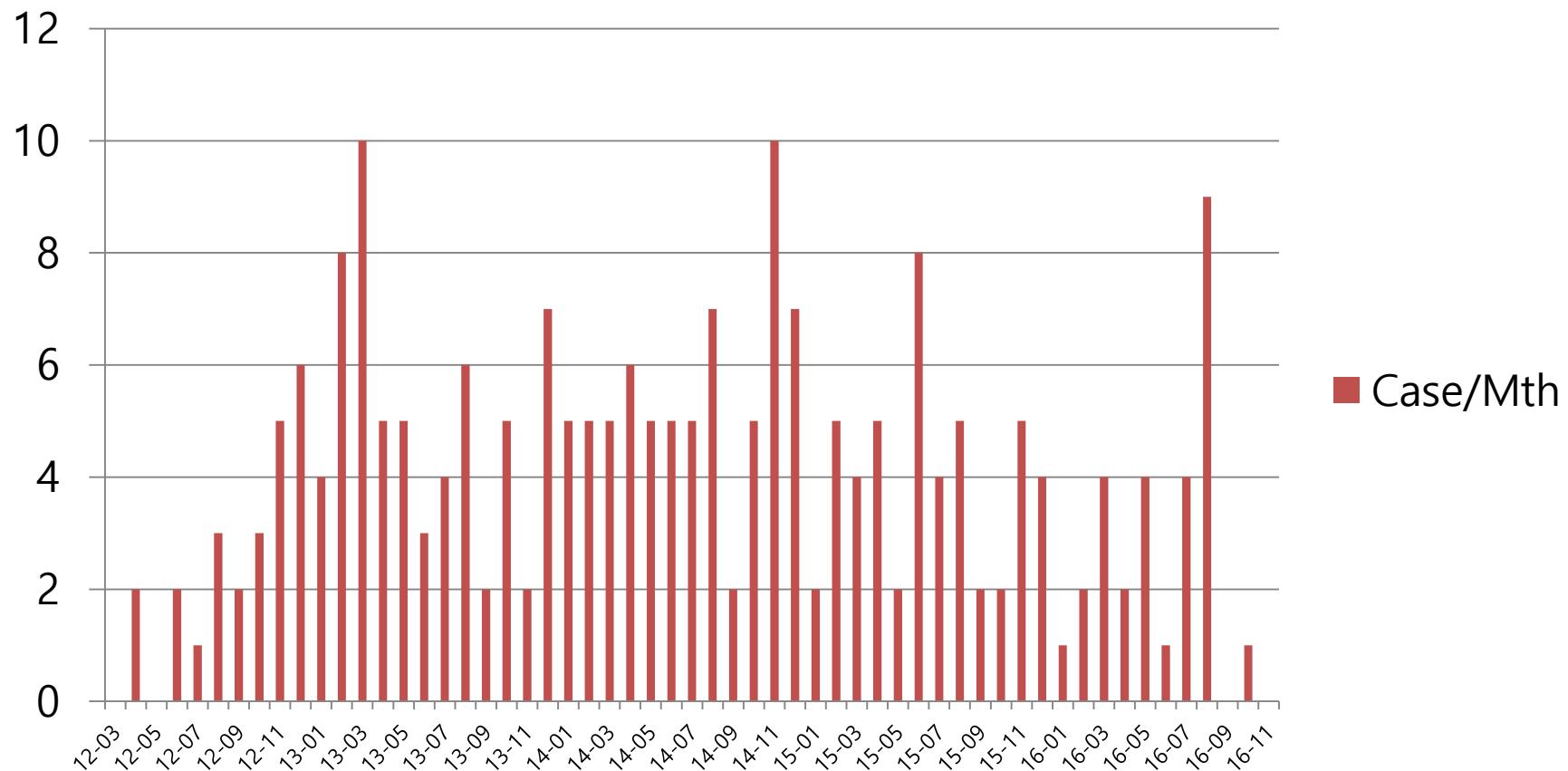
Accrual of TACO

Global



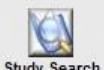
TACO Accrual

Case/Mth



TACO Monitoring

- QC monitoring/Audit
- Data Management/e-Velos
- RT QA



Study Search



Patient Search



Study Patients



Report Central

- Main
- Personalize Account
- Manage Protocols
- Manage Patients
- Report Central
- Manage Query/CRF
- Ad-Hoc Queries
- Help
- [Logout](#)

[Summary](#) | [Versions](#) | [Study Setup](#) | [Study Status](#) | [Reports](#) | [Study Team](#) | [Forms](#)
COPY AN EXISTING STUDY**Study Entered By ***Velos Admin [SELECT USER](#)**Principal Investigator**Velos Admin [SELECT USER](#) Principal Investigator was a major author/initiator of this study?

IF OTHER

 Investigator Held IND/IDE? IND/IDE # **Study Contact**[SELECT USER](#)**Study Definition****Study Number ***

C12003

[MORE STUDY DETAILS](#)**Title ***

Randomized phase III clinical trial of weekly versus tri-weekly cisplatin based chemoradiation in locally advanced cervical cancer

Objective

-Primary endpoint
To determine if the tri-weekly cisplatin chemotherapy during radiation improves overall survival compared to standard weekly

SummaryDo you want information in this section to be available to the public? Yes No [?](#)**Study Details****Agent/Device****Division**Gynecology [▼](#)**Therapeutic Area ***Other [▼](#)**Disease Site**[SELECT DISEASE SITE\(S\)](#)**Specific Sites**[SELECT SITE 1](#)[SELECT SITE 2](#)**Total Sample Size**

590

[LOCAL SAMPLE SIZE](#)**Study Duration**

8

[years](#) [▼](#)**Estimated Begin Date**Do you want information in this section to be available to the public? Yes No [?](#)

QC monitoring in Ramathibodi Hospital



RT-QA (GCIG-CCRN)

- Pretreatment AP/Lat portal film review
 - within 24 hours
- Post treatment RT review
 - William Small, Chomporn Sitatanee, HackJae Kim
 - Biennial meeting
 - Acceptable/Deviation acceptable/Unacceptable

RT-QA

(1st RT-Film review 2012. 11)



(2nd RT-Film review at Bangkok 2013.4)



TACO

- Participating group: KGOG (11), TGCS(1), VietNam(1), China(1), US(1)
- Funding; 250 USD/case from CCRN, KGOG

RT-QA

(1st RT-Film review 2012. 11)



(2nd RT-Film review at Bangkok 2013.4)



Gynecologic Cancer InterGroup Cervix Cancer Research Network

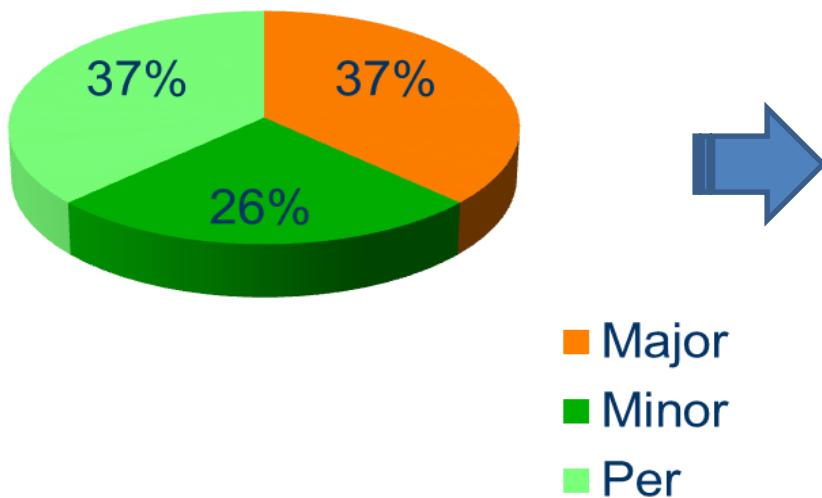


RT QA in TACO

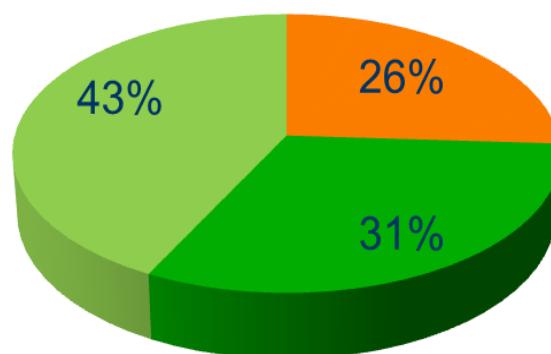


Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand

Deviation

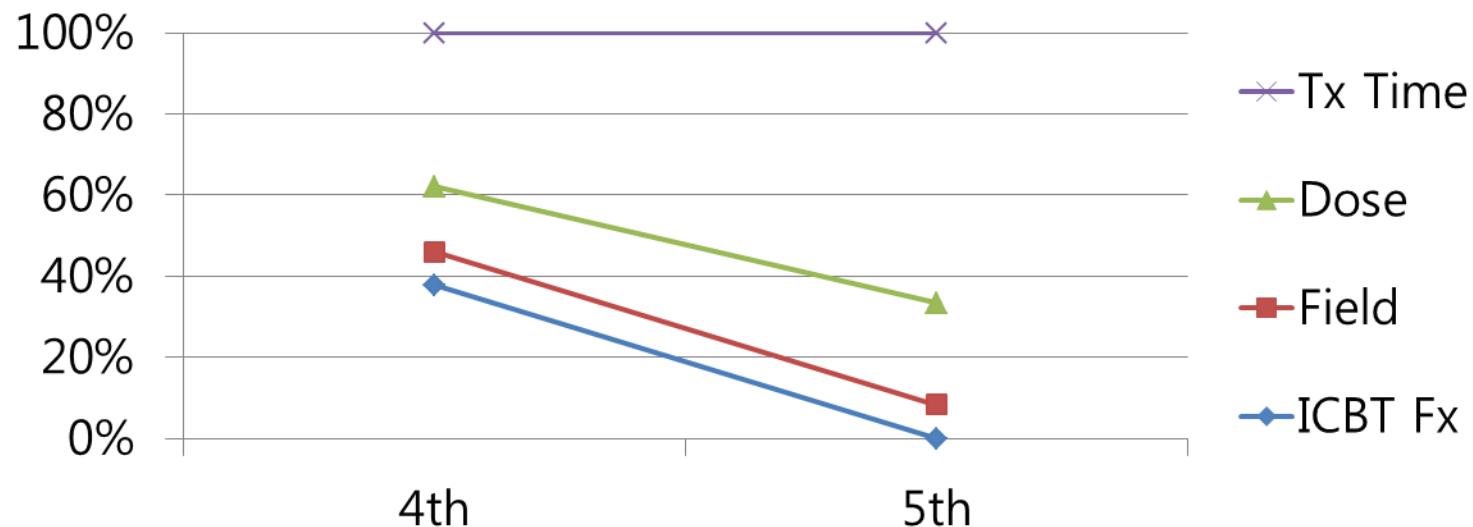


Deviation



Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand

RT QA in TACO



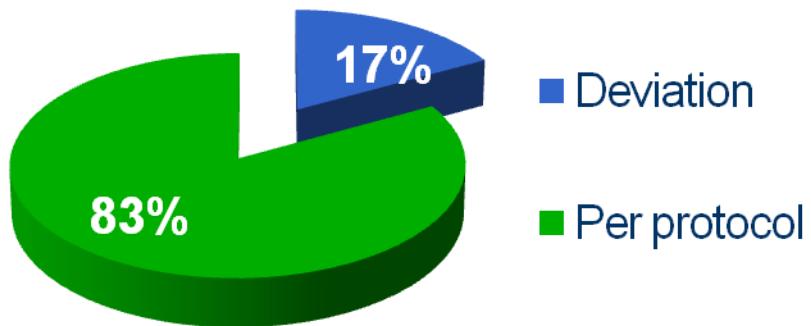
Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand

Gynecologic Cancer InterGroup Cervix Cancer Research Network

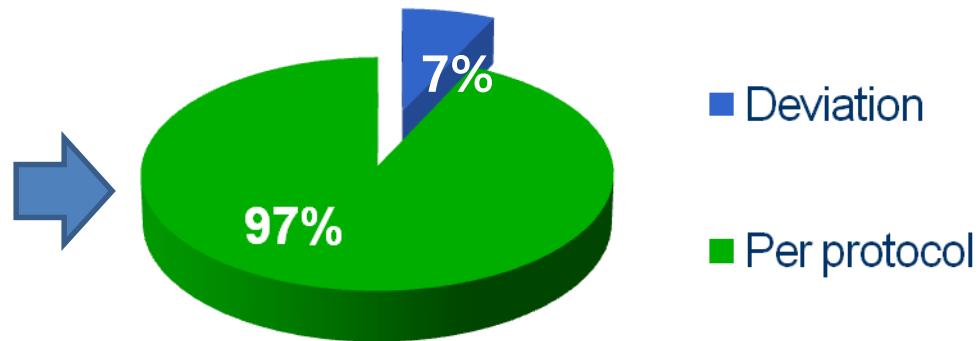


1 st QC Deviation	2 nd QC Deviation
17%	7%

1st QC Monitoring



2nd QC Monitoring



Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand

TACO GONNA CHANGE STANDARD!

A first GCIG and
CCRN guided
international
multicenter trial



Tri-weekly cisplatin
may be better than
current standard
weekly cisplatin-
CRT.

Thank you for your attention.