

SBRT for Pancreatic cancers

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SBRT biliary tract

- Pancreatic Ca
- Liver Ca
- Cholangio

Background

- R0 resection is the only curative option for resectable or borderline resectable pancreatic cancers
- Even after R0 resection the 5 year survival is dismal 15-25%

NAT - Rationale

- Patients not been physiologically compromised by a major surgical procedure.
- Avoidance of major surgery in aggressive tumor biology
- Early treatment of micrometastatic disease which is likely to increase the underlying micrometastatic burden postop.
- Intact tumor mass is well perfused and the cytotoxic effects of chemotherapy and/or radiation are not compromised by the creation of a more hypoxic, inflammatory, and fibrotic surgical bed.
- Downstaging of tumor thereby improving the likelihood of an ultimate R0 resection.

Definitions

- **Resectable:**
 - no extension to celiac, CHA, SMA
 - patent SMV-PV confluence
 - stage I, II (T1-3, Nx, M0)
- **Borderline:**
 - arterial abutment (< 180deg)
 - venous abutment or encasement (with option for reconstruction)
 - stage III (minimal T4)
- **Locally Advanced:**
 - celiac, SMA encasement (> 180deg)
 - stage III (T4, Nx, M0)



R1 resections
Poorer outcomes

Varadhachary GR, et al. Ann Surg Oncol. 2006;13(8):1035-46

Katz MHG, et al. J Am Coll Surg. 2008;206(5):833-46

Resectable cancers - Causes of poor outcome

- Rate of R0 resection **70% margin positive** (Sohn 2000, Howard 2006)
- The failure to consistently achieve microscopic surgical clearance contributes to the high rates of disease relapse:

TMH (M Bal). Pancreatic ca
(**77% +ve** in NAT naïve vs. **40% post NAT**)
67% for the entire group. Posterior margin
(43%) SMA (29%) DBD (14%) and PN (14%)

Pancreatic Cancer Surgery

The New R-status Counts

Annals of surgery 2016

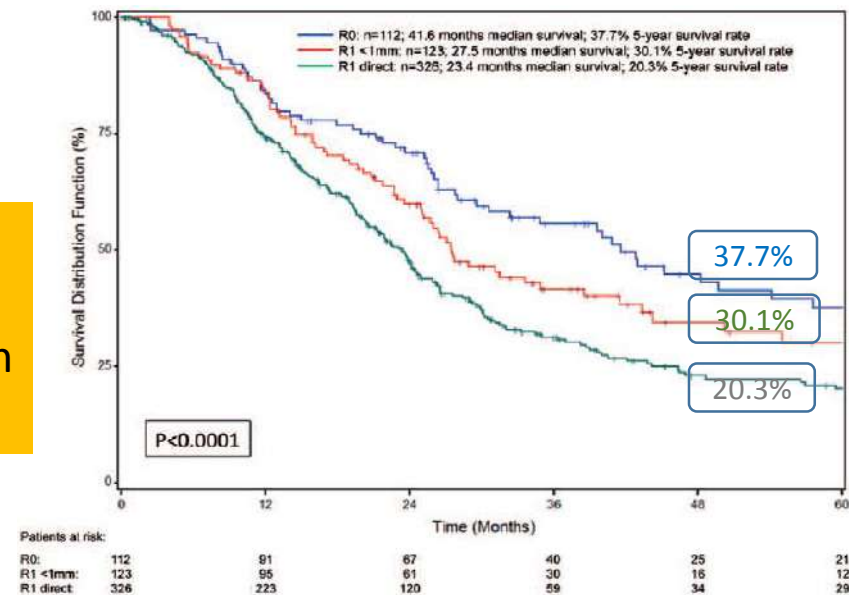
n=561

R0- 112(20%)

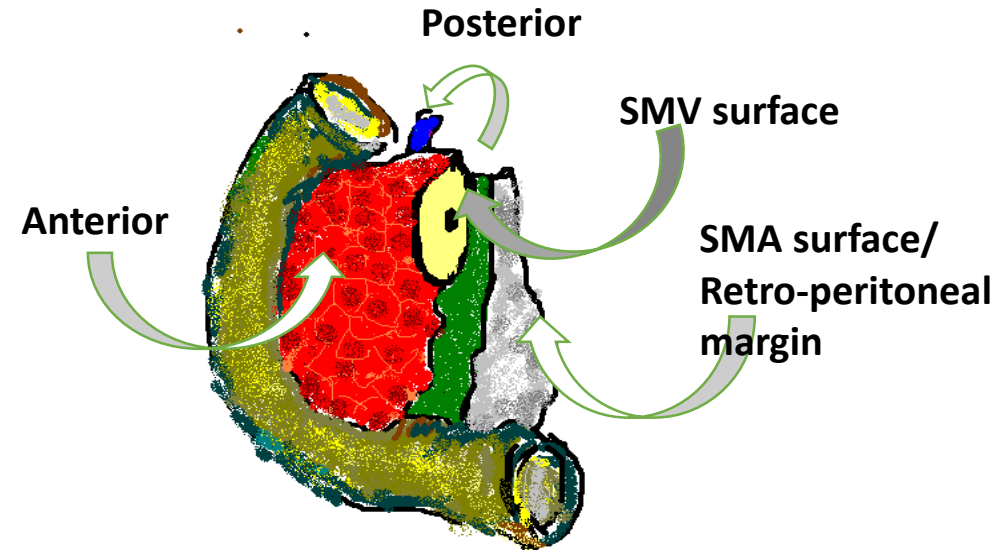
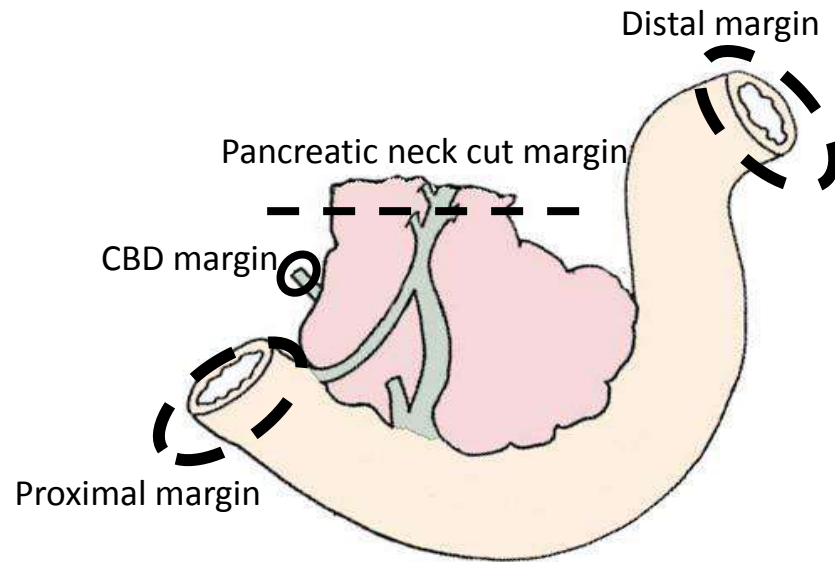
R1(<1mm)- 123 (21.9%)

R1 (direct)- 326 (58%)

In R0N0M0 5-year survival was 62.2%,



R0 resection – changing concepts



Transection Margins

Reported R1 resection rate – 25%
in older studies



Circumferential resection

Margins (includes all margins)

Reported R1 resection rate – 75%
In newer studies

Evidence -NAT

- 3 Metaanalysis (2 BRPC, 1 RC +BRPC)
- 1 ph 3 RCT

Metaanalysis – (NACRT borderline resectable tumors)

- Festa et al (2013)
- Radiological downstaging of the lesion is uncommon
- If no distant or local progression all patients should be explored surgically
- A clear benefit of this regimen could be to spare surgery to patients with progressive disease during the frame-time chemo-radiotherapy is being delivered

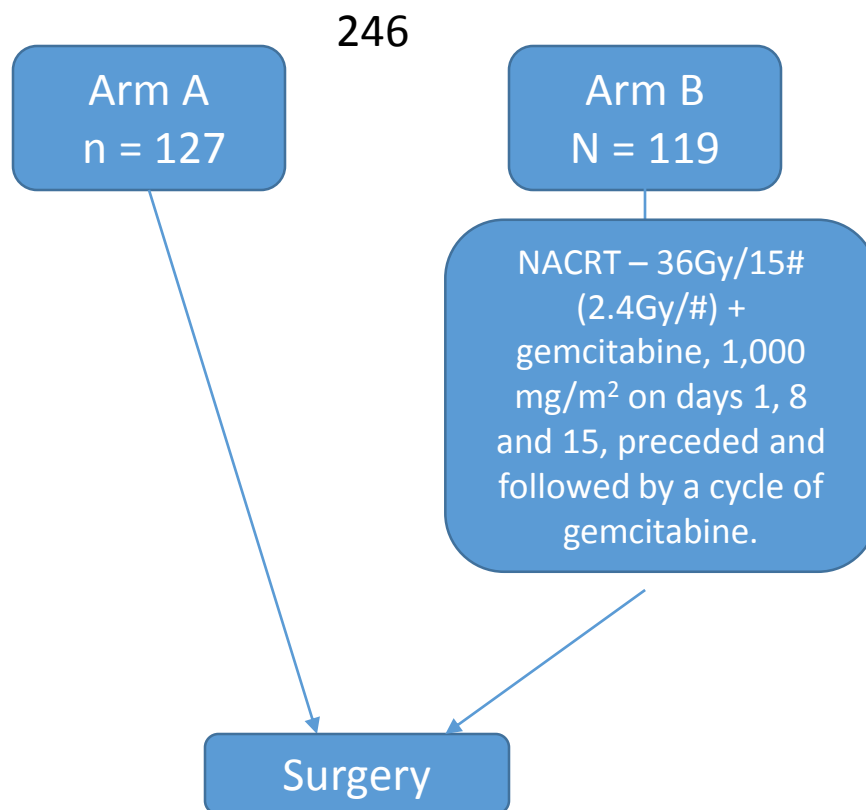
Neoadjuvant therapy for patients with borderline resectable pancreatic cancer: A systematic review and meta-analysis..

- Cochrane database 1966-2015, 18 studies (N=959)
- CR= 2.8% PR= 28.7% SD= 45.9%, tumor progression under therapy = 16.9%
- Resection = 65.3% –76.5%), R0 = 57.4%
- mean of median survival = 17.9 months all patients, 25.9 months resected, and 11.9 months for unresected patients.
- Conclusion- The resection and R0 resection rates and survival in the group of borderline resectable tumor patients after neoadjuvant therapy are **similar** to the resectable tumor patients

Dutch meta-analysis 2018 contd....

	Upfront Sx	NAT	p
MOS in months N= 1746	14.8 (11.6–25.3) months	18.8 (range 9.4–50.2) months Post NAT	
819 RC BRPC 927	17.5 (12–25.3) months 12.8 (11.6–16.3) months	18.2 (10–50.2) months 19.2 (11–32) months	
R0 resection post NAT	-	26.1months	
Overall resection rate	81.3%	66%	0.001
R0 Resection rate	66.9% RC-71.4% BRPC- 63.9%	86.8% RC-85% (Gain of 14%) BRPC-88.6% (Gain of 22%)	0.001
pLN rate	63.8%	43.8%	0.001

Preoperative chemoradiotherapy versus immediate surgery for resectable and borderline resectable pancreatic cancer (PREOPANC-1) : A randomized, controlled, multicenter phase III trial. Dutch Group (Versteine JCO 2022)

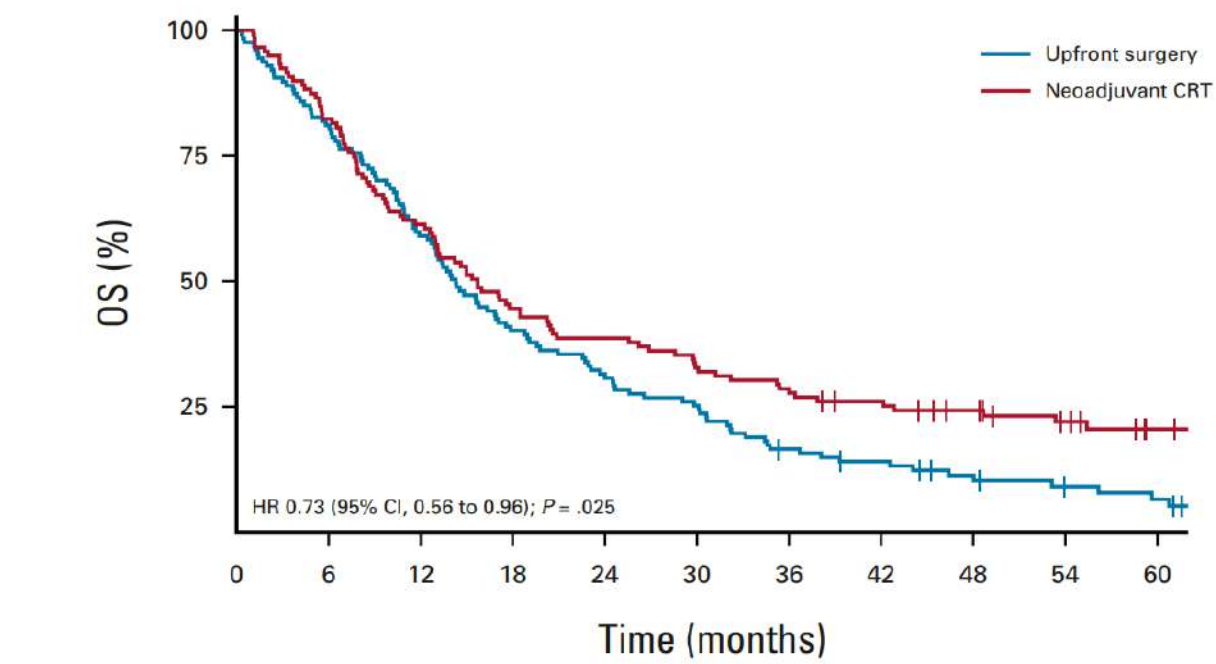


	Arm A	Arm B	HR	P
5yr OS	6.5	16.5	0.71	0.025
R0 rate	31%	65%		0.001
DFS	7.9	11.2	0.67	0.010
DMFI	10.2	17.1	0.63	0.012
LRFI	11.8	NR	0.47	0.001
Resection rate	72%	62%		0.15
mOAS for operated patients	16.8	29.9		0.001

No significant difference was observed in grade ≥ 3 adverse events between both groups ($p = 0.17$).

Preopanc – Long term outcomes

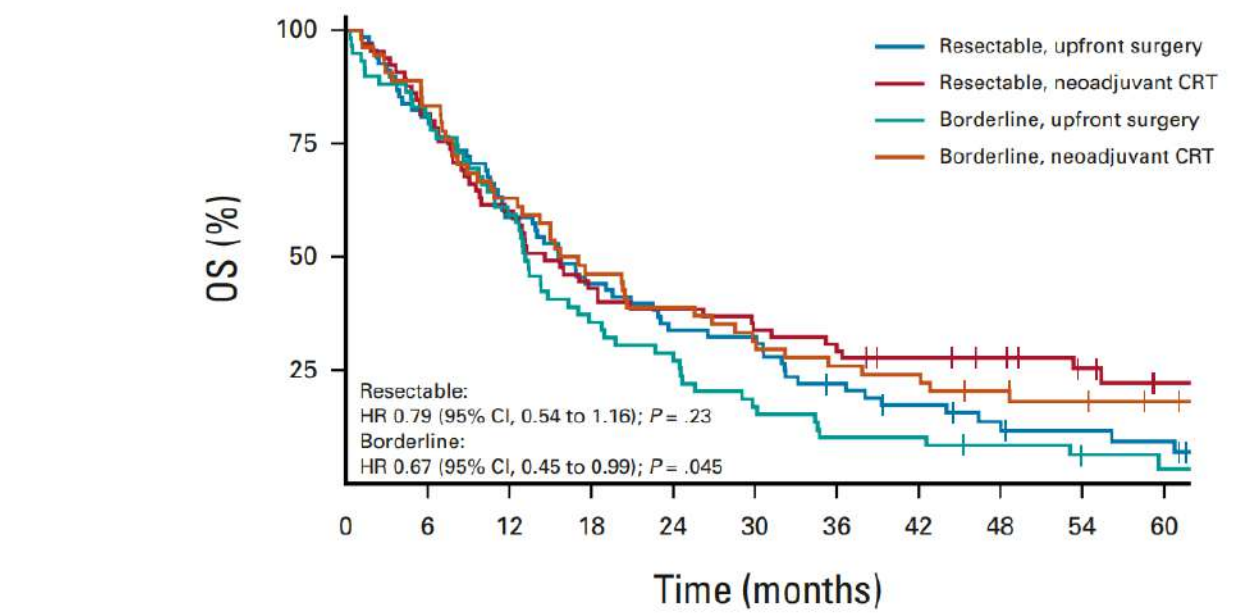
A



No. at risk:

Upfront surgery	127 (0)	103 (0)	75 (0)	51 (0)	40 (0)	32 (0)	20 (1)	16 (2)	11 (4)	7 (6)	5 (6)
Neoadjuvant CRT	119 (0)	98 (0)	73 (0)	53 (0)	46 (0)	39 (0)	34 (0)	29 (2)	24 (5)	17 (10)	11 (15)

B



No. at risk:

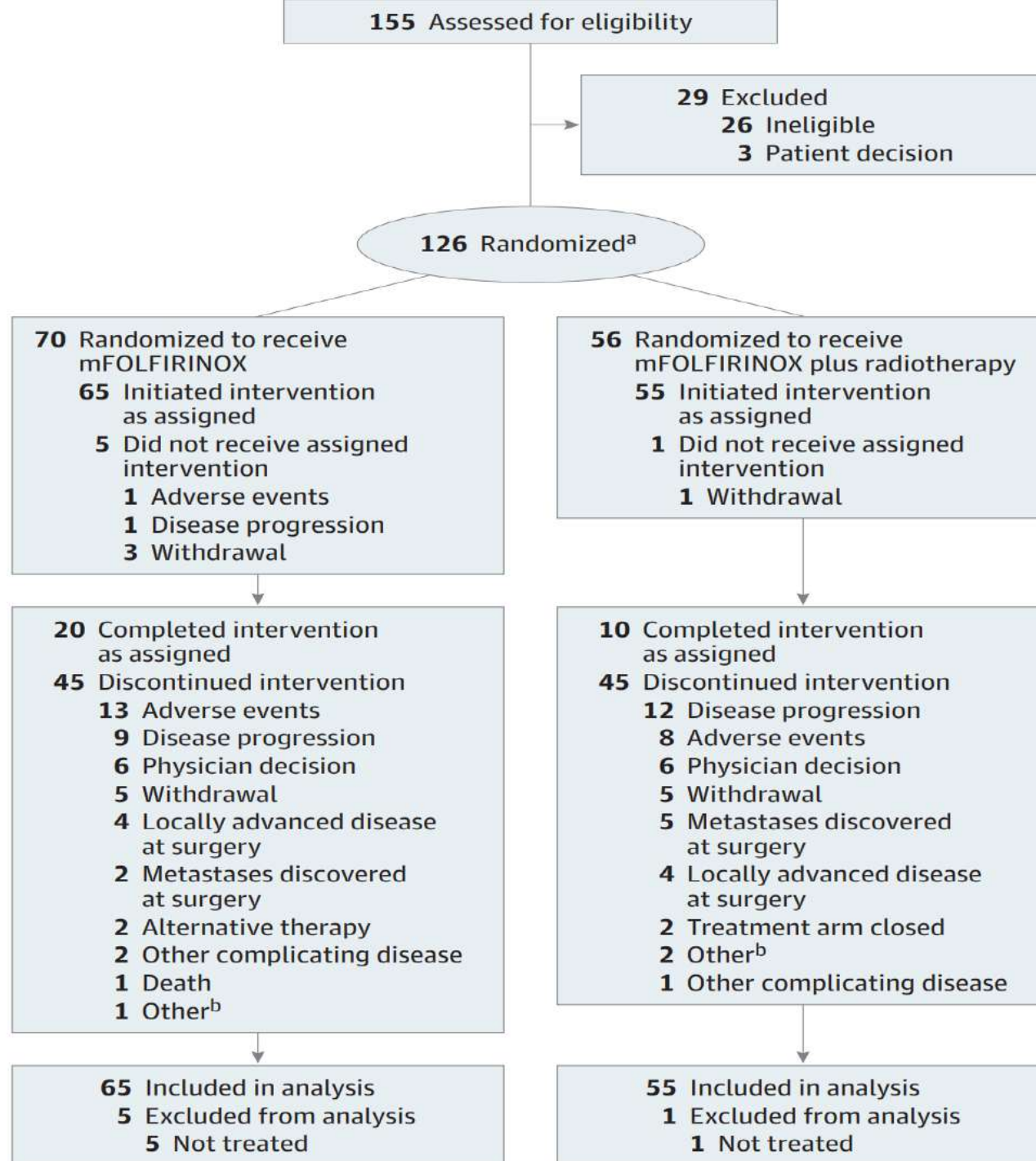
Resectable, upfront surgery	68 (0)	55 (0)	40 (0)	30 (0)	23 (0)	22 (0)	14 (1)	10 (2)	7 (3)	5 (4)	4 (4)
Resectable, neoadjuvant CRT	65 (0)	53 (0)	39 (0)	28 (0)	25 (0)	22 (0)	20 (0)	16 (2)	14 (4)	9 (8)	5 (11)
Borderline, upfront surgery	59 (0)	48 (0)	35 (0)	21 (0)	17 (0)	10 (0)	6 (0)	6 (0)	4 (1)	2 (2)	1 (2)
Borderline, neoadjuvant CRT	54 (0)	45 (0)	34 (0)	25 (0)	21 (0)	17 (0)	14 (0)	13 (0)	10 (1)	8 (2)	6 (4)

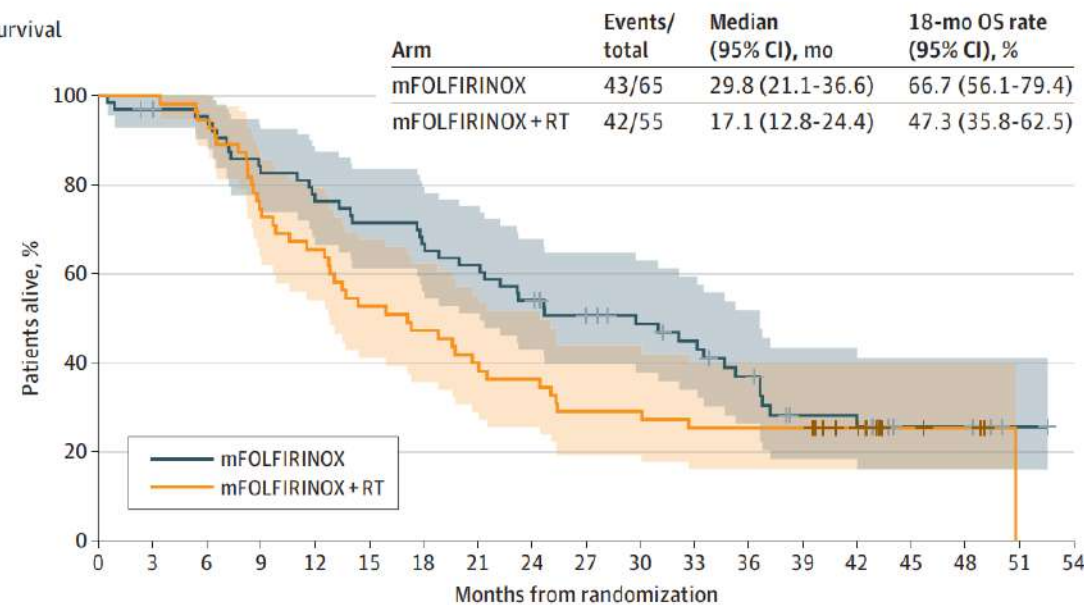
Neoadjuvant CRT and chemotherapy for Resectable and Borderline Resectable Pancreatic Cancer: The New Standard

JAMA Oncology | Original Investigation

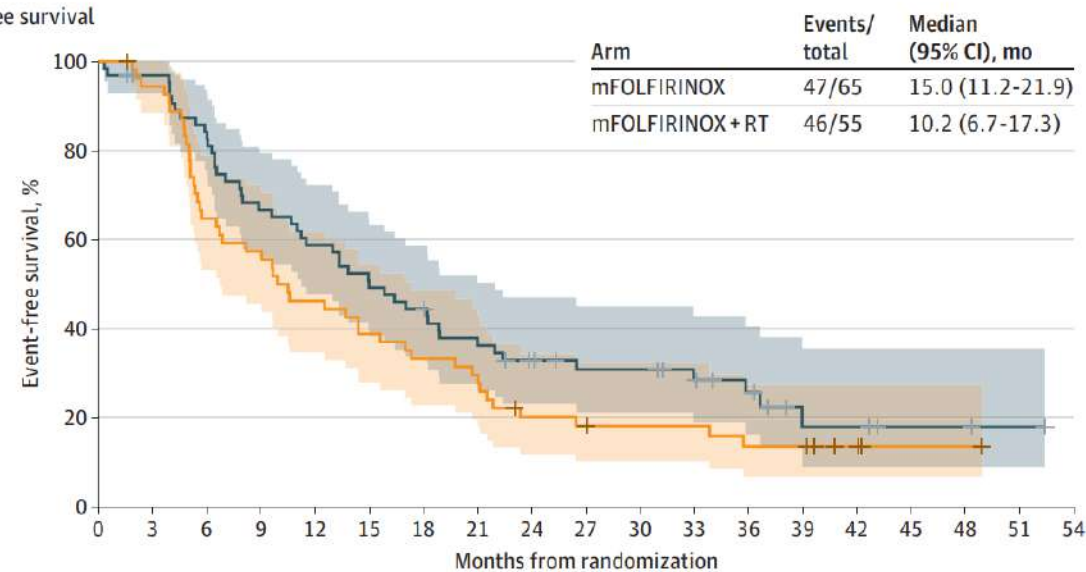
Efficacy of Preoperative mFOLFIRINOX vs mFOLFIRINOX Plus Hypofractionated Radiotherapy for Borderline Resectable Adenocarcinoma of the Pancreas

The A021501 Phase 2 Randomized Clinical Trial



A Overall survival

No. at risk		65	62	60	52	48	45	42	39	34	29	26	23	18	11	10	4	4	1	0
mFOLFIRINOX		65	55	52	41	36	29	26	22	20	16	16	14	14	14	9	4	3	0	
mFOLFIRINOX + RT		55	55	52	41	36	29	26	22	20	16	16	14	14	14	9	4	3	0	

B Event-free survival

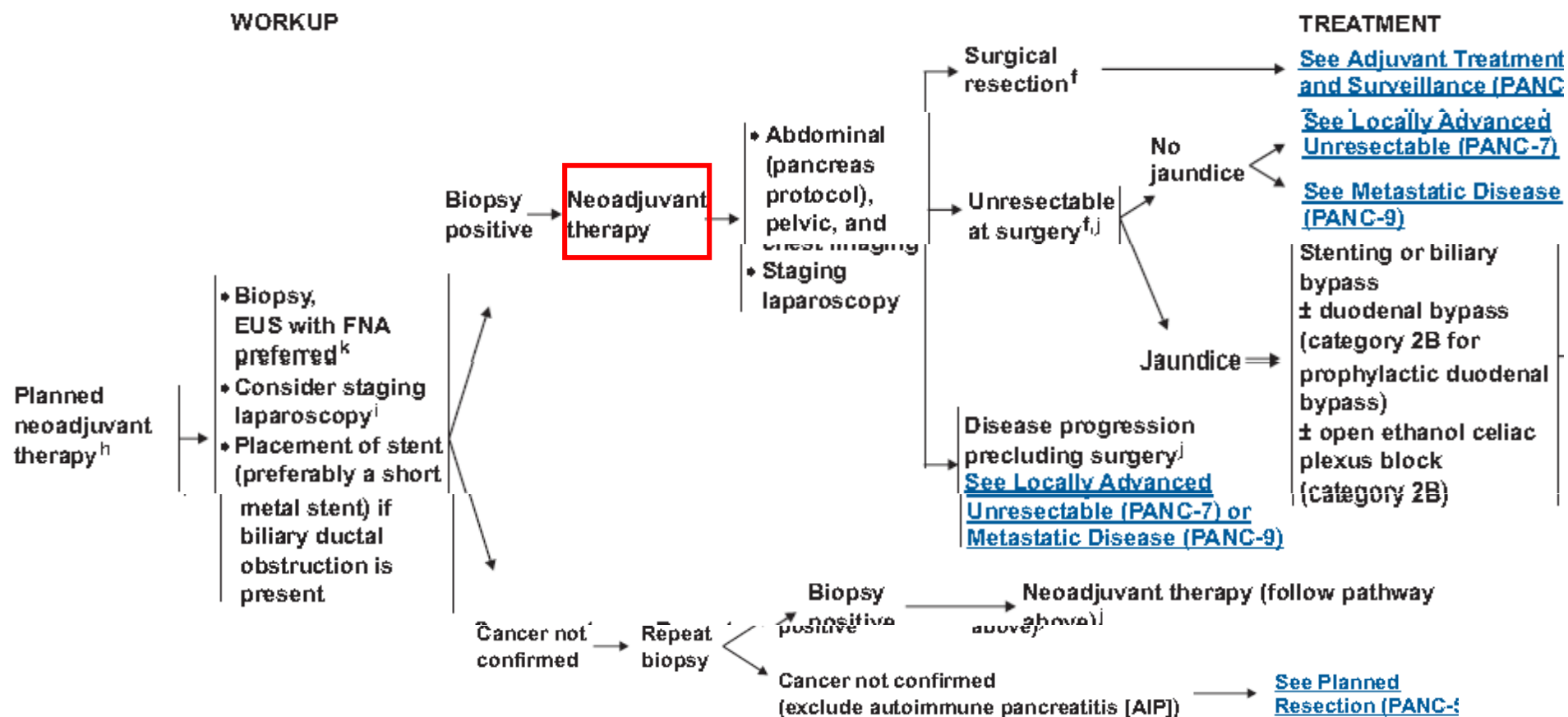
No. at risk		65	61	53	42	37	31	28	22	18	15	15	12	9	4	4	2	2	1	0
mFOLFIRINOX		65	51	35	31	25	21	18	16	10	9	8	8	6	6	3	1	1	0	
mFOLFIRINOX + RT		55	51	35	31	25	21	18	16	10	9	8	8	6	6	3	1	1	0	

Alliance

- Interim 17/30 NACT arm
- 10/30 RT arm
- 30/126 patients completed assigned interventions
- Lower doses of RT
- 39 patients in 27 centres
- 28% RT deviations in QA arm – poor contouring ASTRO 2022

NCCN guidelines

BORDERLINE RESECTABLE^{d,e} NO METASTASES, PLANNED NEOADJUVANT THERAPY



Sequencing of NAT

BRPC

NACT 4-6# followed by CRT or SBRT

LAPC

NACT 6-8# followed by CRT or SBRT + Contd CT

What chemotherapy....

- Modified FOLFIRINOX 3-4# (GI- ASCO 2013)
- NAB - PACLI
- Concurrent Gemcitabine – traditionally given
- Concurrent Capecitabine – Promising (SCALOP trial)

Neoadjuvant Rx – New standard of care

Evidence

- 3 Metaanalysis (2 BRPC, 1 RC +BRPC)
- 1 ph 3 RCT

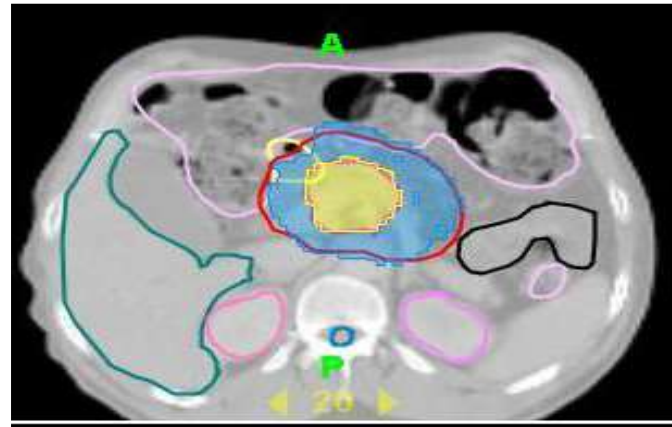
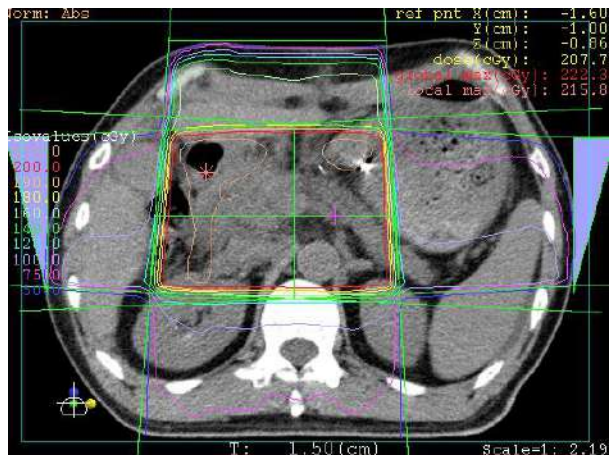
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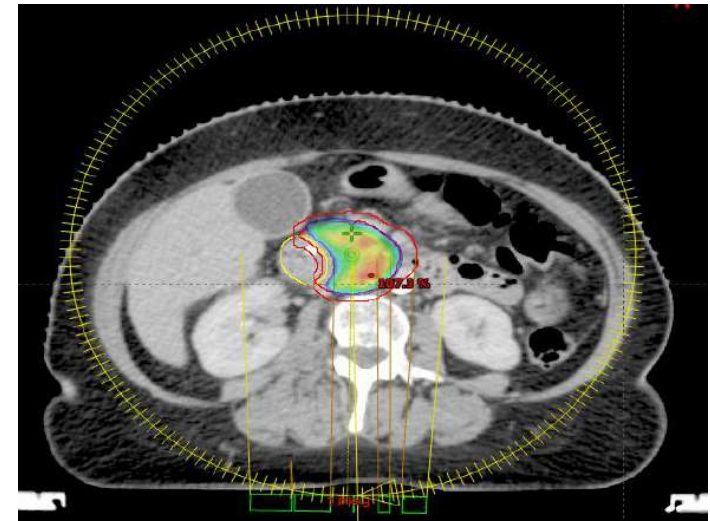
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From 3DCRT to SBRT



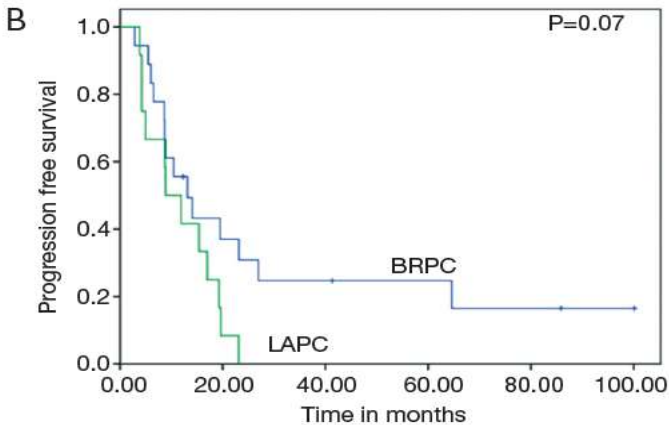
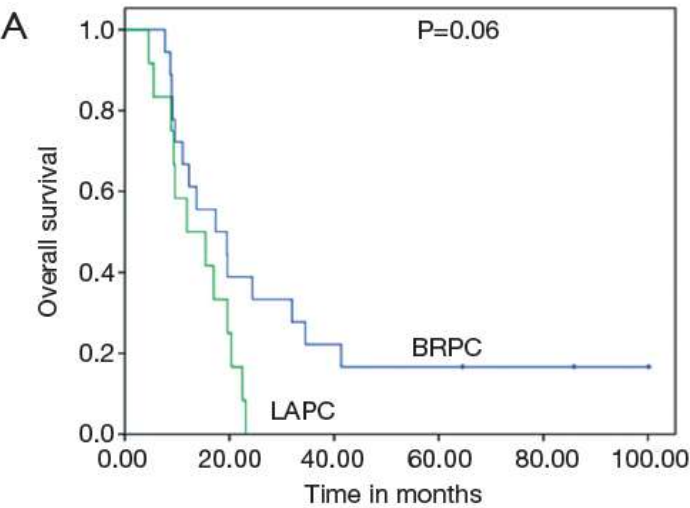
55-60gY/25#/5weeks



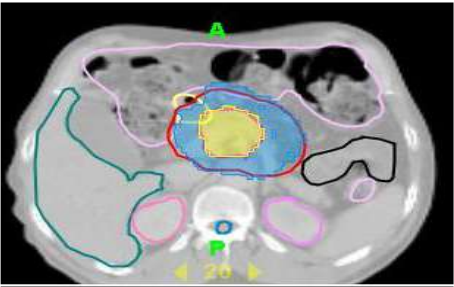
Dose escalated concurrent chemo-radiation in borderline resectable and locally advanced pancreatic cancers with tomotherapy based intensity modulated radiotherapy: a phase II study

J Gastrointest Oncol 2019;10(3):474-482

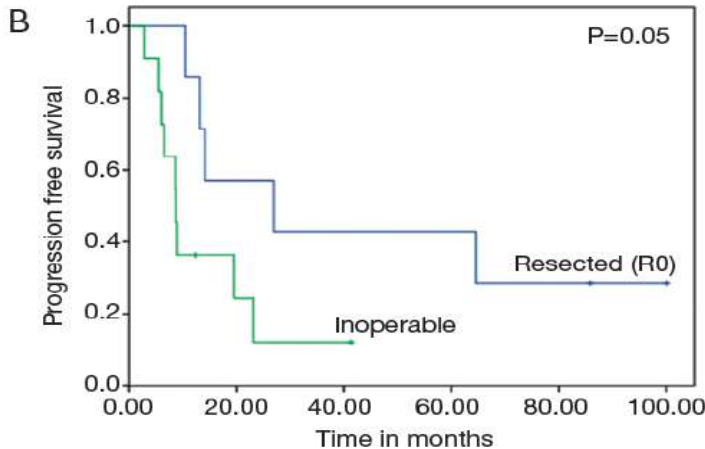
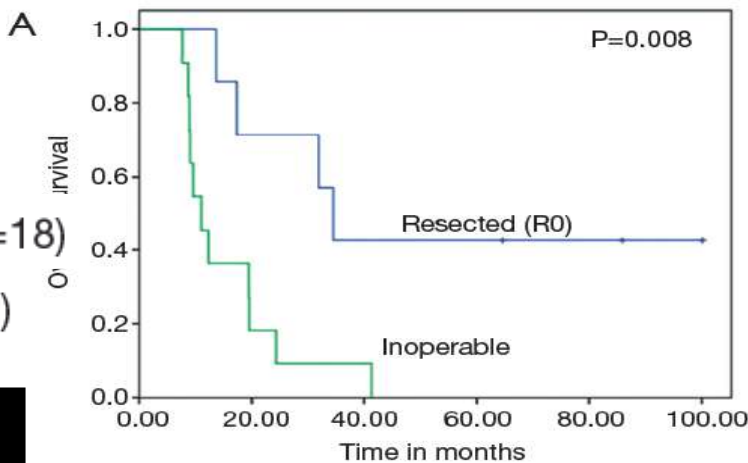
Shirley Lewis¹, Supriya Chopra Sastri², Supreet Arya³, Shaesta Mehta⁴, Prachi Patil⁴, Shyamkishore Shrivastava⁵, Reena Phurailatpam², Shailesh V. Shrikhande⁶, Reena Engineer²



Overall (n=30)
Borderline resectable (n=18)
Locally advanced (n=12)



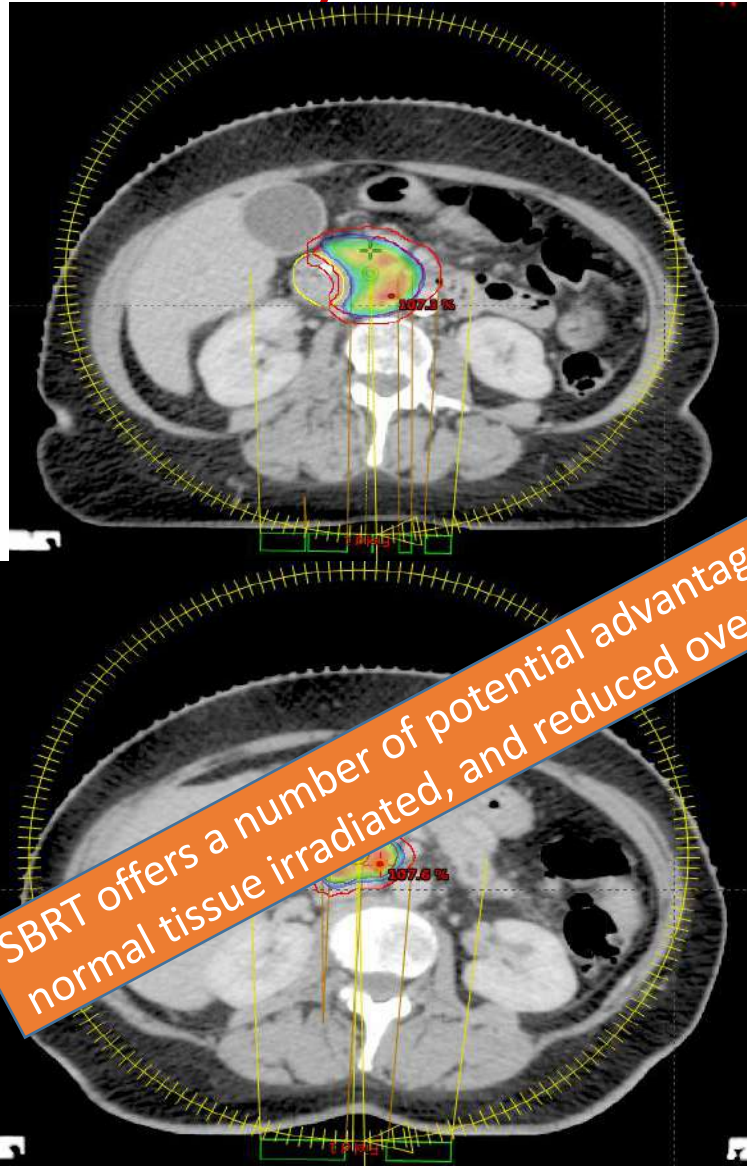
55-60gY/25#/5weeks



SBRT - Pancreas

- Why
- When
- How

SBRT - Why



	SBRT	
Treatment time	1 -2 weeks	3-6 weeks
Effective RT dose	50 Gy Gy (50 Gy/5#)	65 Gy (55Gy/25#)
Overall survival	Same	
Radiological downstaging	Seen	Not seen
R0 resection (BRPC)	90%	60%

- No direct / Randomized evidence to say SBRT is superior to fractionated IMRT
- SBRT > 5Gy with motion Mx



Evolution of SBRT

Table 1 A summary of clinical studies of stereotactic body radiation therapy in pancreatic cancer

Study (year)	Patients (n)	SBRT dose & fraction	1-year LC	Median OS (m)	Toxicity	Chemotherapy
Koong <i>et al.</i> (15) 2004	15 LA	15-25 Gy ×1	100%	11	33% Grades 1 & 2 0% ≥ Grade 3	None
Koong <i>et al.</i> (16) 2005	16 LA	25 Gy ×1 (boost)	94%	8.3	69% Grades 1 & 2 12.5% ≥ Grade 3	5-FU with EBRT prior to SBRT
Schellenberg <i>et al.</i> (21) 2008	16 LA	25 Gy ×1	100%	11.4	19% Acute 47% Late	1 cycle induction GEM + post-SBRT GEM
Hoyer <i>et al.</i> (17) 2005						
Mahadevan <i>et al.</i> (18) 2010						Post-SBRT GEM
Mahadevan <i>et al.</i> (22) 2011						cycle induction GEM
Polistina <i>et al.</i> (20) 2010						week induction GEM
Moningi <i>et al.</i> (23) 2015	74 LA 14 BR	5-6.6 Gy ×5	61% LPFS	18.4	3.4 % ≥ Acute Grade 3 5.7% ≥ Late Grade 2	Pre-SBRT Chemo in 77 cases
Gerka <i>et al.</i> (24) 2013	10 LA	5 Gy ×5	40%	12.2	0% Grade 3	1 cycle pre-SBRT GEM +5 cycle post-SBRT GEM
Herman <i>et al.</i> (25) 2015	49 LA	6.6 Gy ×5	83% LPFS	13.9	2% ≥ Acute Grade 2 11% ≥ Late Grade 2	GEM followed by SBRT

- Lack of fractionation
- Inadequate motion management techniques
- Absence of image guidance using fiducial markers
- Lack of specific dose constraints for OARs

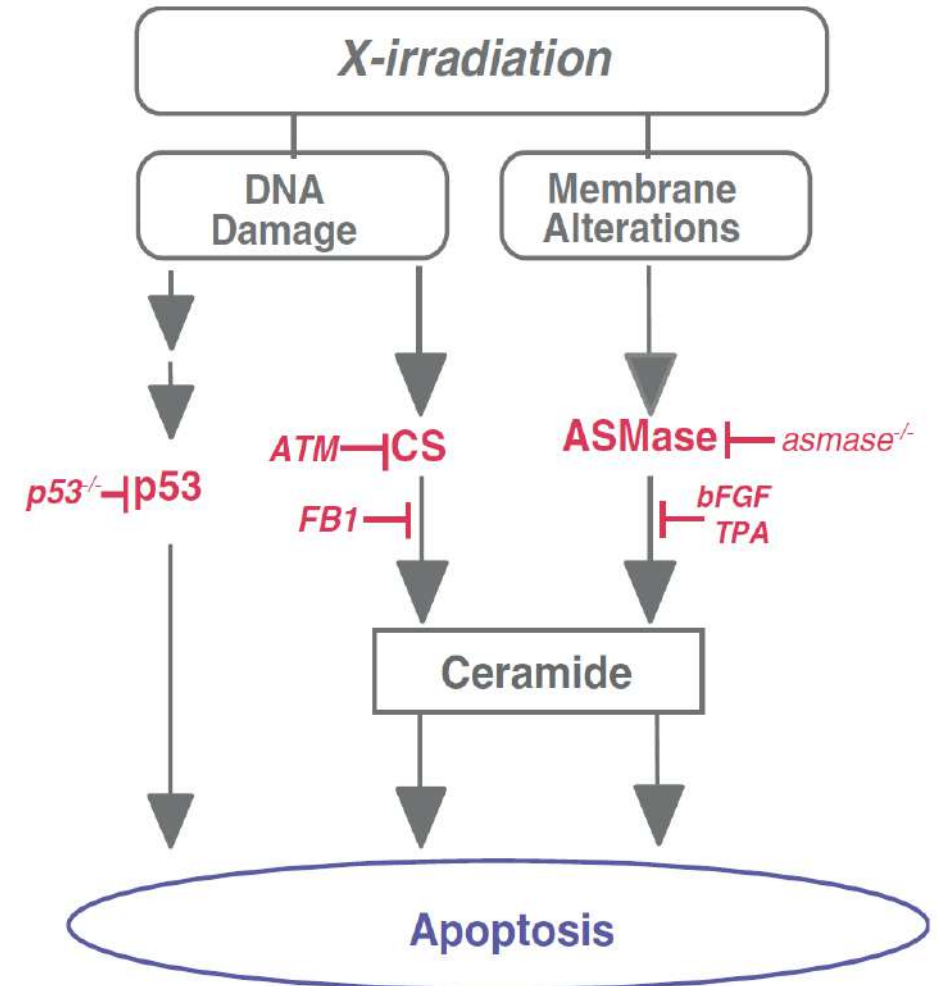
Stanford vs. Danish groups

- Median volume treated - 136cc, whereas the by the Stanford group was 41cc
- PTV was encompassed by the 67% isodose surface.

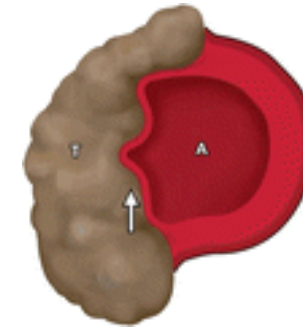
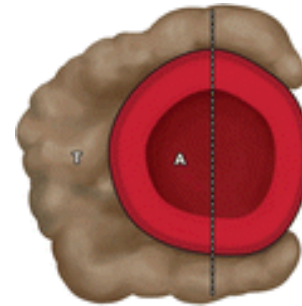
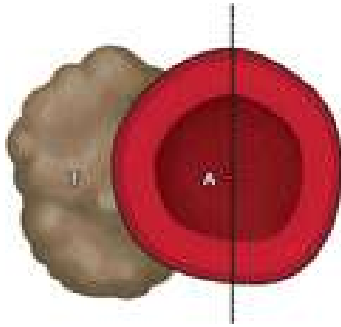
Kolesnick R, Fuks Z 2003 Oncogene

Pathway of Radiation induced apoptosis

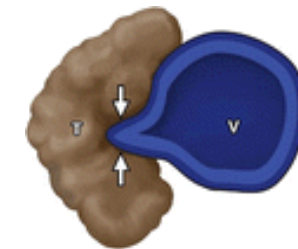
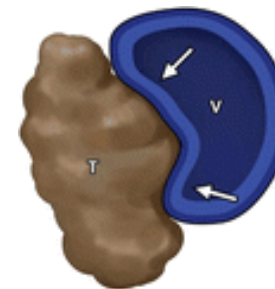
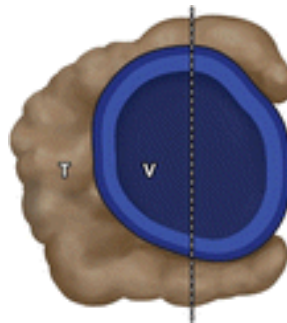
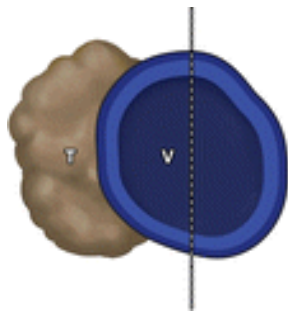
- High-dose (>8 Gy) /#
- Rapidly activates the cell membrane acid sphingomyelinase (ASMase) that hydrolyses sphingomyelin to generate the proapoptotic second messenger ceramide
- Thus initiating transmembrane signaling of apoptosis



Definitions BRPC- MDACC/NCCN/AHPBA/SSO/SSAT/ Alliance



Stage	Arterial	Venous
Resectable	Clear fat planes around CA, SMA, and HA	No SMV/portal vein distortion
Borderline resectable	Gastroduodenal artery encasement up to the hepatic artery with either short segment encasement or direct abutment of the hepatic artery without extension to the CA. Tumor abutment of the SMA not to exceed greater than 180° of the circumference of the vessel wall	Venous involvement of the SMV or portal vein with distortion or narrowing of the vein or occlusion of the vein with suitable vessel proximal and distal, allowing for safe resection and replacement
Unresectable**	Aortic invasion or encasement. Based on tumor location: Pancreatic head—More than 180° SMA encasement, any CA abutment, IVC Pancreatic body/tail—SMA or CA encasement greater than 180°	Unreconstructible SMV/portal vein occlusion



Questions?

- Role in BRPC
- Role in LAPC
- Is it safe
- Is it well tolerated
- Is it effective
- Comparison with IMRT

Challenges of SBRT in Pancreas

- The head of Pancreas, where majority of the tumor is in close proximity to the Duodenum
- RT dose of >50Gy (1,8-2Gy daily) results in ulcerations stenosis, bleeding and perforation
- The Pancreas moves with respiration and peristalsis

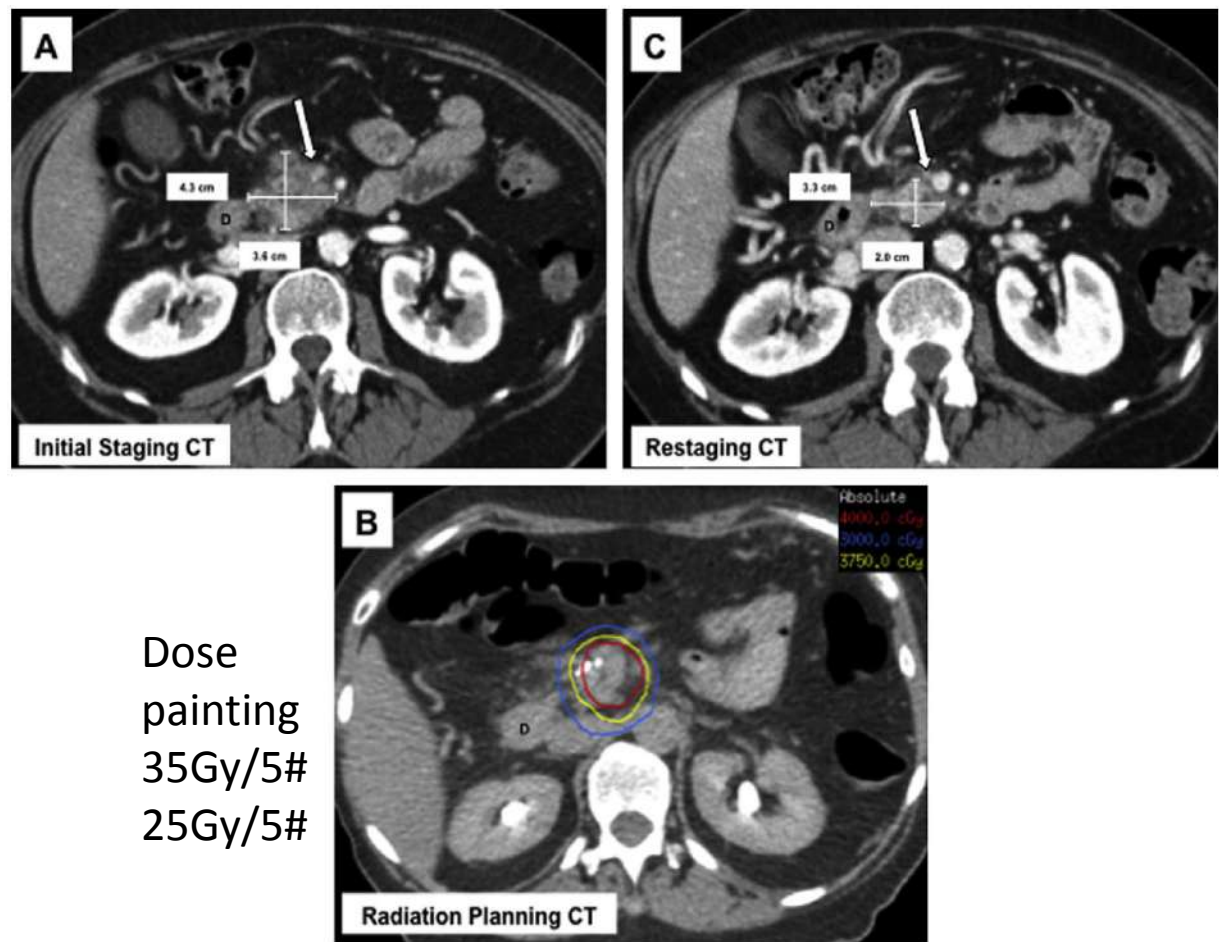
SBRT for BRPC

Indicated to improve resectability in the Neoadjuvant setting

NACT + SBRT Chuong 2012

- 30 patients completed NAT and were offered surgical exploration.
- 17 (56.7 %) reported no acute adverse effects during SBRT. No grade 3 or higher toxicity was observed from SBRT.
- **29 (96.7 %)** underwent exploration.
- **Twenty-one (70%) patients underwent R0 resection none requiring vessel resection**
- One (3.3 %) patient was resected with microscopic positive margins.

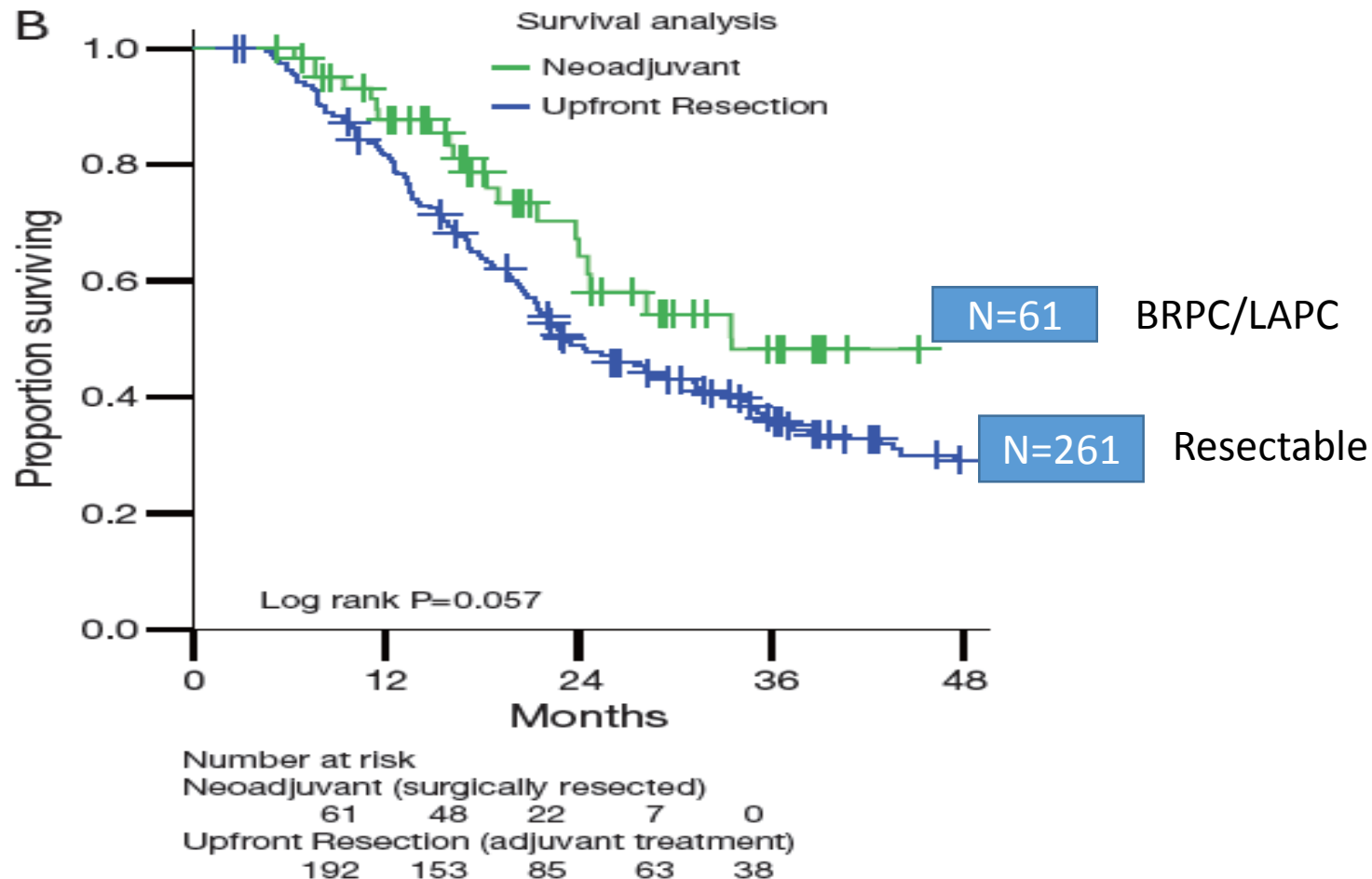
SBRT for LAPC and BRPC Is Effective and Well Tolerated Chuong 2013



	BRPC	LAPC
Median 1Yr OS	72.2%	68.1%
Median PFS	16.4 mths	15 months
1 Yr PFS	9.7 mths	9.8 mths
BRPC with R0 resection MOS	Operated	Not operated
Median 1Yr OS	19.3 mths vs 84.2%	12.3 mthsp.03 58.3%
Median PFS		
1 Yr PFS	56.5%	25% p.0001
1 yr local control non Sx pts		81%
No acute grade 3 toxicity, and late grade 3 toxicity was minimal (5.3%).		

Upfront resected Vs. BRPC + LAPC with NAT (SBRT) 2016

Mellon et al. Pancreatectomy ± neoadjuvant SBRT and chemotherapy

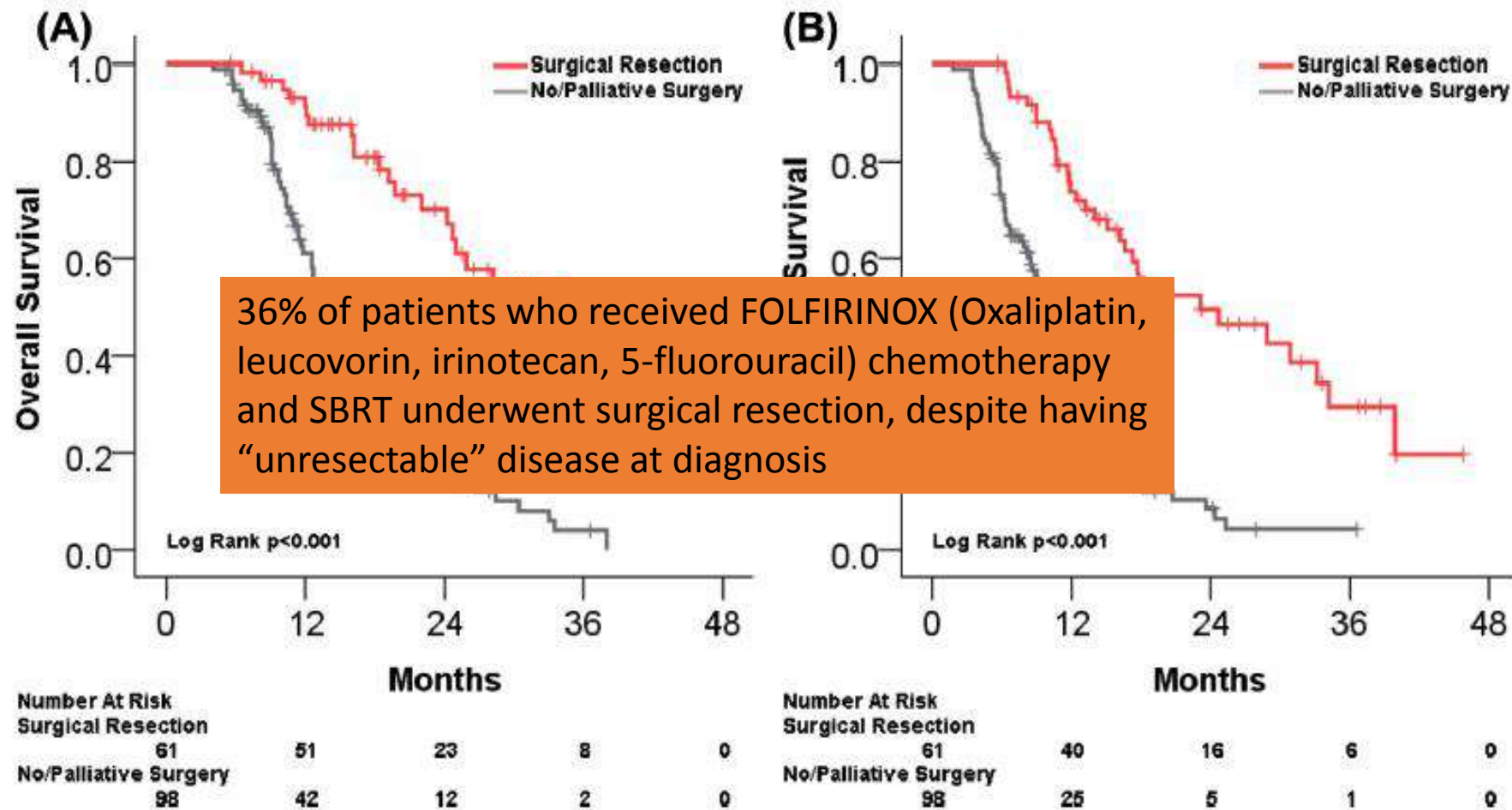


Surgical positive margin rate was lower after neoadjuvant therapy (3.3% vs. 16.2%, $P=0.006$).
Median OS - 33.5 months in NAT

vs.

23.1 months in upfront resection patients who received adjuvant treatment ($P=0.057$).

Median overall survival approaching 3 years, far superior to contemporary outcomes



SBRT in LAPC

30-40% of all panc ca

SBRT for LAPC . Syst rev....2016 Petrelli IJROBP

Total of 19 studies (2005-2015)	N=1009
The pooled 1- year OS ranged from.	51.6%
The median OS	5.7 - 47 months (median 17)
Severe side effects	<10%
LRC rate at 1 year	72.3%
LRC appeared to correlate with the total SBRT dose and the number of #	

RT for LAPC

- Concurrent CTRT Vs. Chemo alone – Mixed results no definite evidence
- NACT followed by CTRT – Advantageous for non metastatic, 30% develop mets
- CTRT to 55 Gy with concurrent continuous infusion 5-FU improved survival compared to continued chemotherapy (median survival of 15.0 vs. 11.7 months, $P=0.0009$ (Huguet et al)

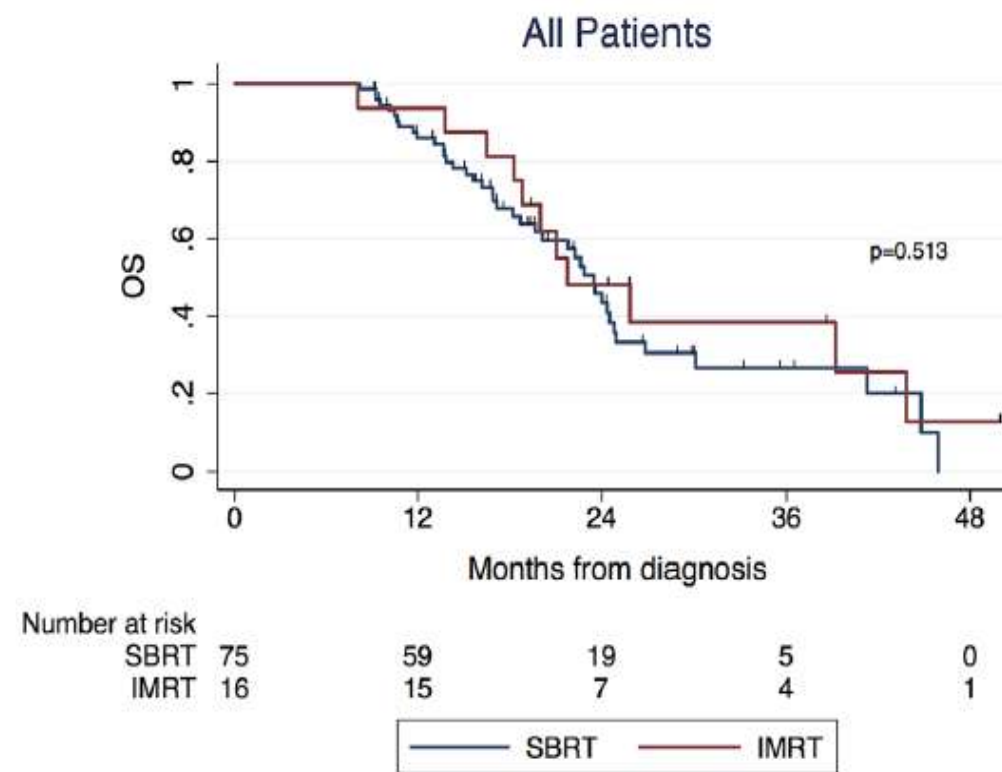
LAP07

- 15.2 mths CTRT vs. 16.5 mnths with chemotherapy, $P=0.83$).
- CTRT had - improved local control (68% vs. 54%)
 - prolonged time to second line treatment (6.1 months compared to 3.7 months, $P=0.02$). likely improves quality of life.

IMRT Vs SBRT

Chapman et al 2018

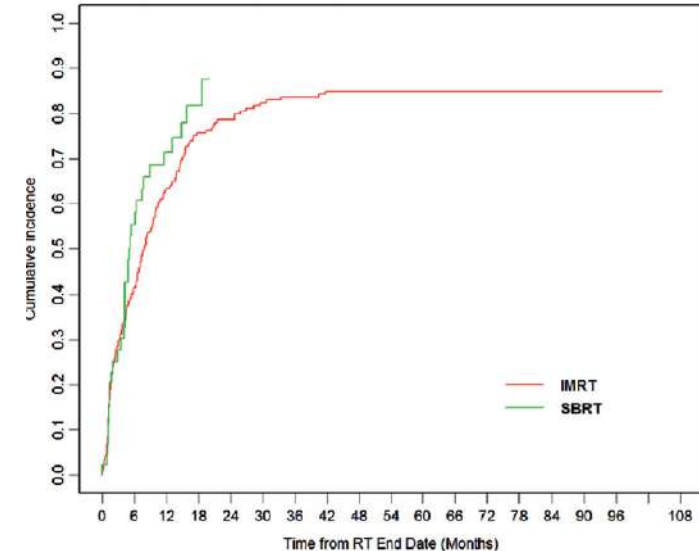
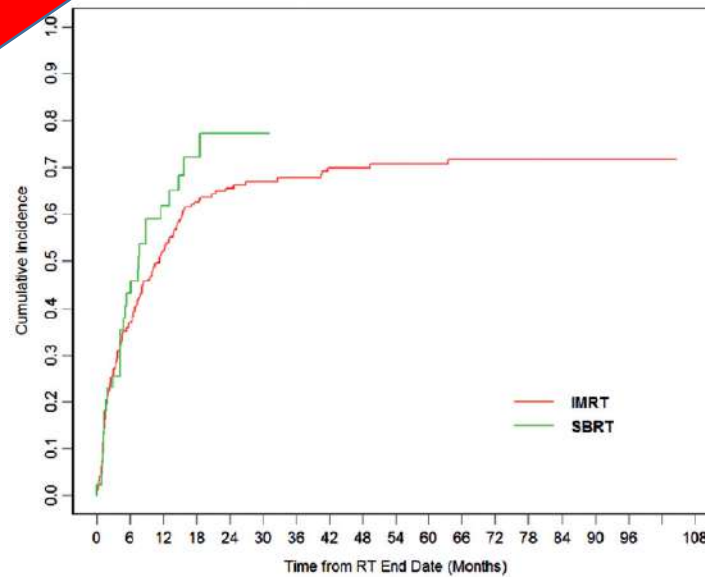
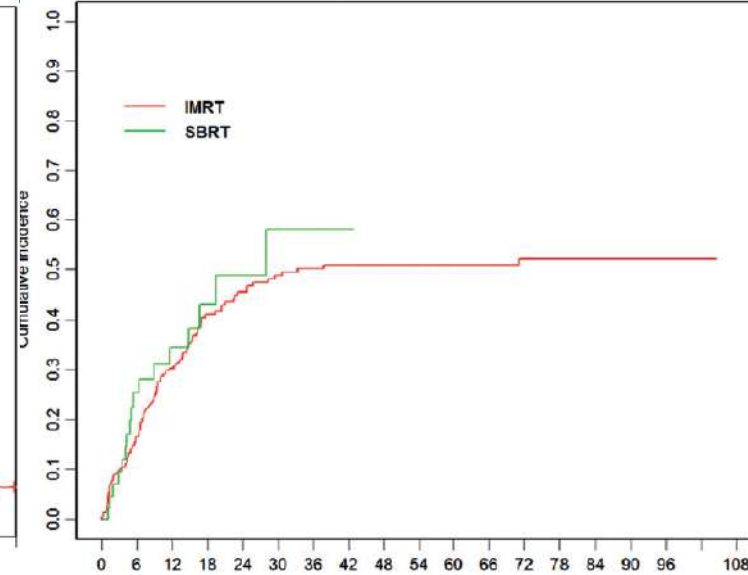
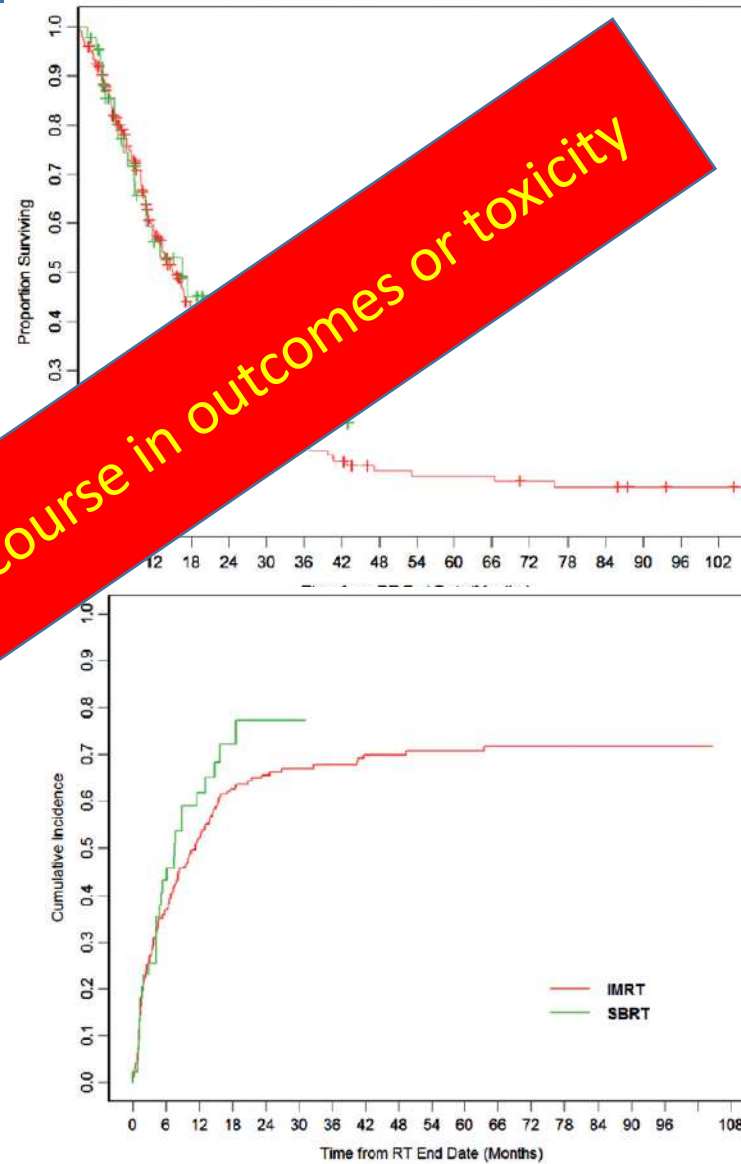
- Retrospective study
- 91 pts SBRT = 75 IMRT = 16
- 70% BRPC 30% LAPC
- RT dose 30Gy/5# or 50Gy/25#
- SBRT and IMRT appear to have similar rates of resection, perioperative outcomes, and survival outcomes



IMRT Vs SBRT for unresectable LAPC Park 2017

- Retrospective study
- SBRT n=44, IMRT n=226 treated from 2008 to 2016
- SBRT (five fractions, 30–33 Gy) or IMRT (25–28 #, 45–50 Gy) with concurrent chemotherapy

Not inferior to Long course in outcomes or toxicity



Radiation in the era of FOLFIRINOX and gemcitabine/nab-paclitaxel

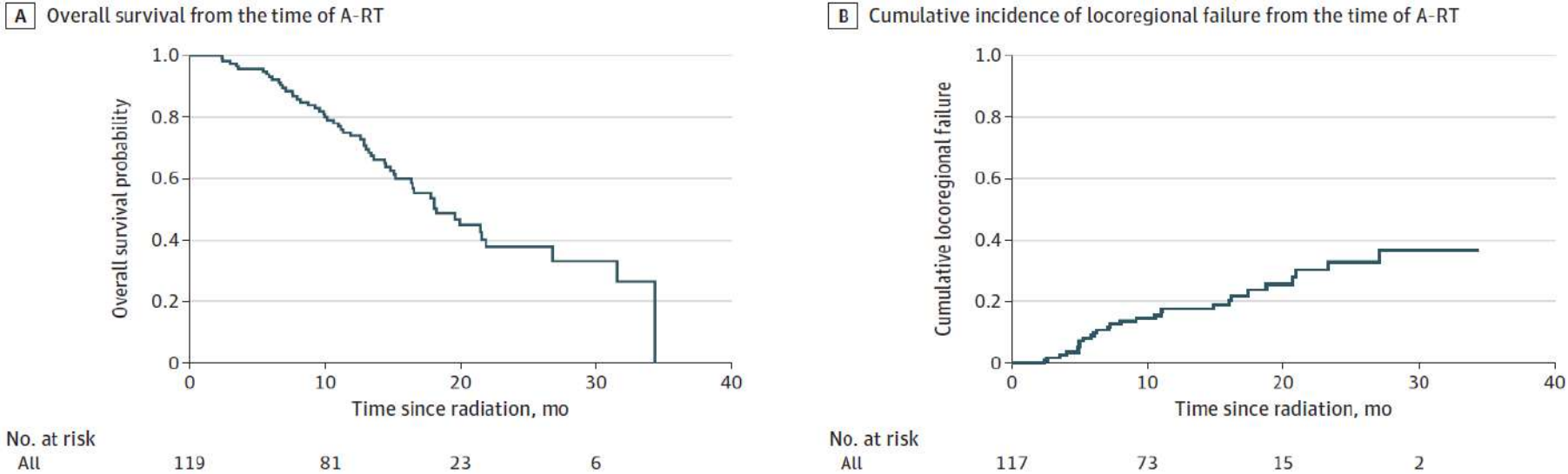
- The phase III PRODIGE4/ACCORD11 -FOLFIRINOX nearly doubled median overall survival compared to gemcitabine (11.1 vs. 6.8 months, $P<0.0001$)
- MPACT trial - superiority of gemcitabine and nab-paclitaxel compared to gemcitabine alone in the metastatic setting, with median overall survival of 8.5 vs. 6.7 months, respectively
- Recent Metaanalysis - Addition of RT improved mPFS and MOS to 15 and 24 months.

JAMA Oncology | **Brief Report**

Association of Ablative Radiation Therapy With Survival Among Patients With Inoperable Pancreatic Cancer

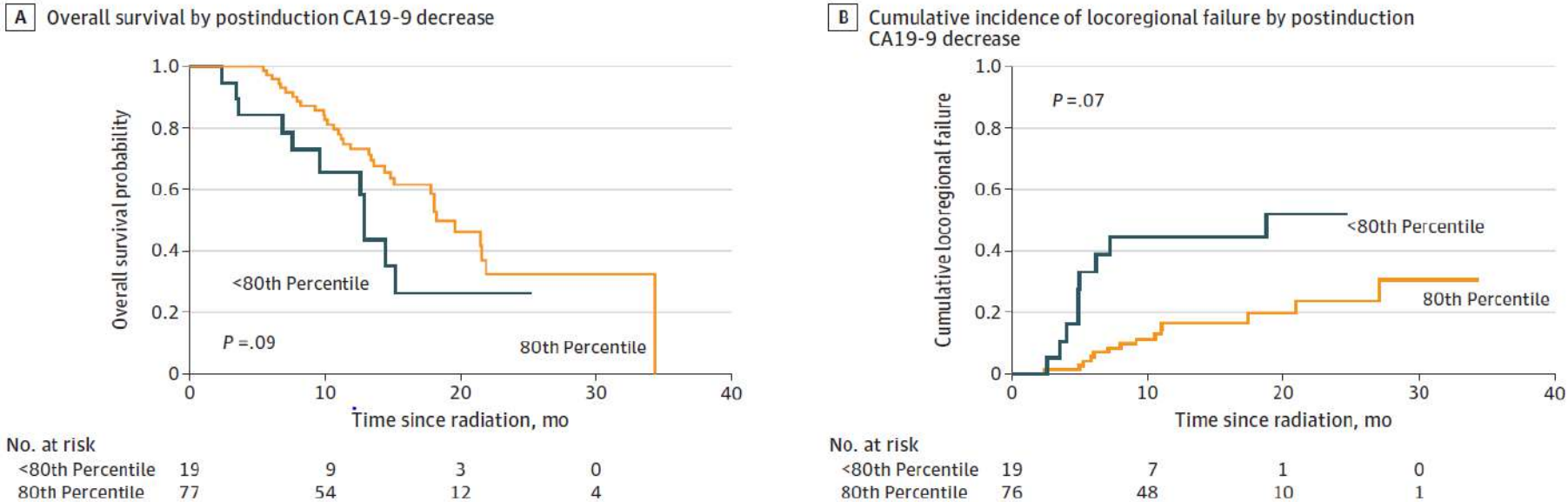
Marsha Reyngold, MD, PhD; Eileen M. O'Reilly, MD; Anna M. Varghese, MD; Megan Fiasconaro, MSc;
Melissa Ziegler, MD; Paul B. Denninger, MD; Abraham W. Wu, MD; Gabe Hult, MD; John J. Gross, MD

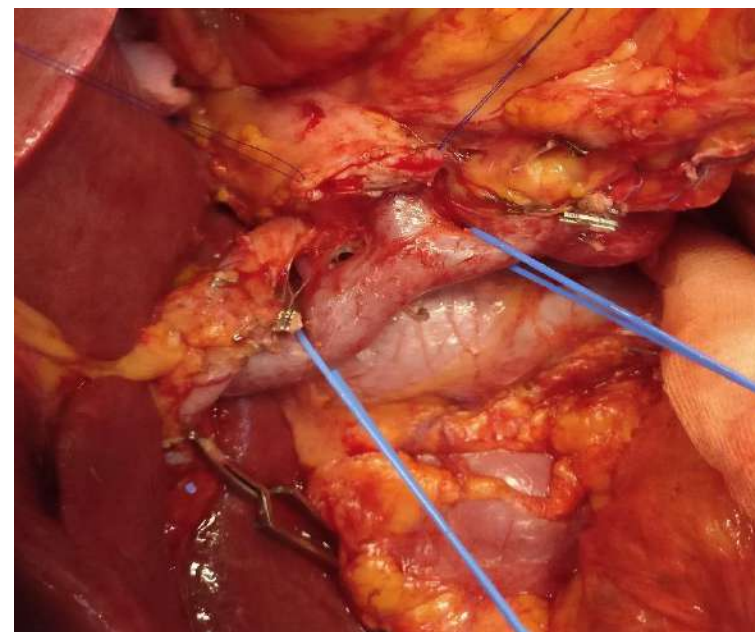
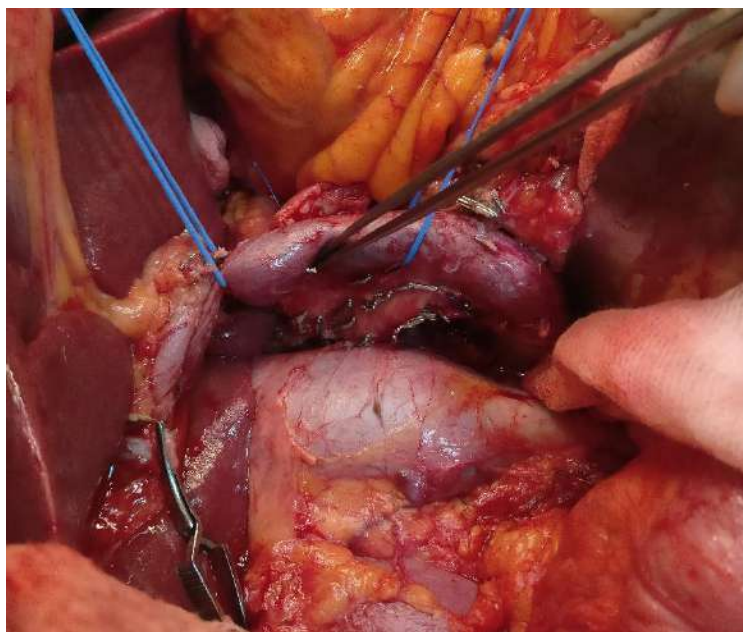
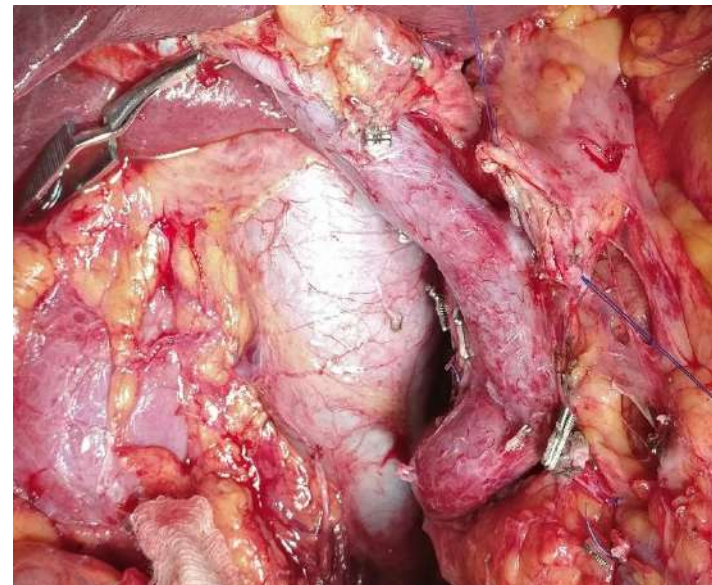
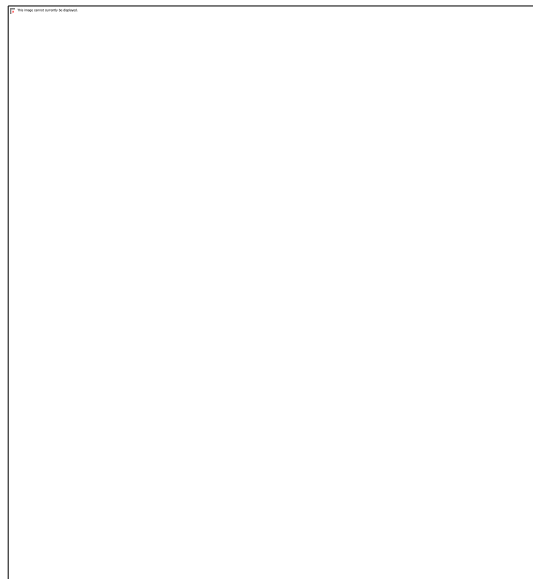
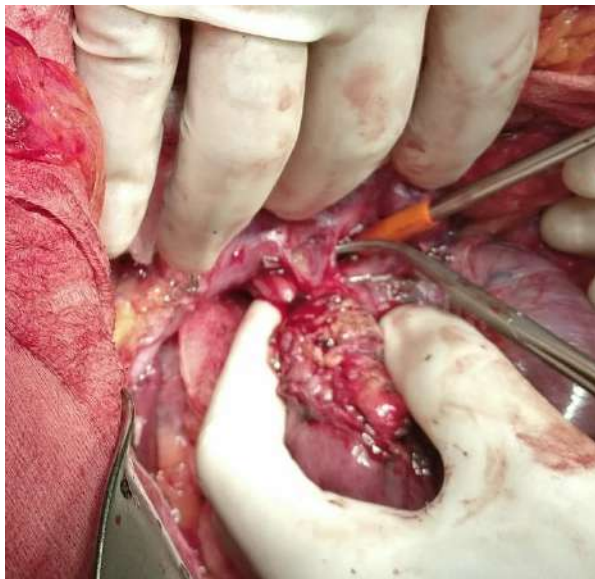
Figure 1. Overall Survival and Cumulative Incidence of Locoregional Progression



A, Kaplan-Meier estimate of overall survival rates. B, Cumulative incidence of locoregional progression rates. A-RT indicates ablative radiation therapy.

Figure 2. Overall Survival and Cumulative Incidence of Locoregional Progression by CA19-9 Percent Change





Aggressive chemotherapy + Dose escalated SBRT + R0 resection (venous / arterial reconstruction)

4-6# FOLFIRINOX

+

High dose SBRT



Better Overall outcomes !!



Early
initiation of
systemic
treatment

- FOLFIRINOX /NAB-Pacli
- 4-8#

Shortening
the time
taken to
deliver CTRT

- SBRT
- High precision RT
- More effective RT higher doses upto 75Gy/1 week

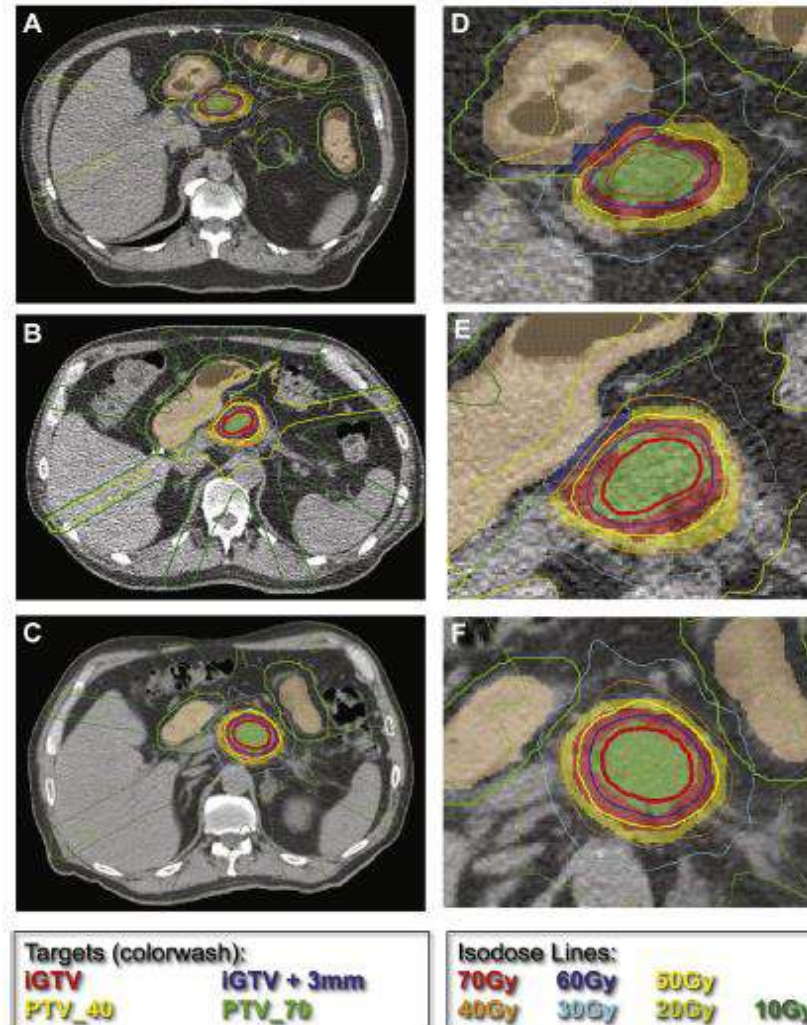
NACT- Advantages

1. Increases the proportion of patients with resectable disease receiving multimodality therapy.
2. May reduce tumor volume and downstage tumors enabling surgical resection with a lower risk of an R1 resection.
3. May also allow earlier treatment of radiographically occult micrometastasis.
4. May identify patients with a favorable cancer biology that have the greatest benefit from surgical resection.

Dose escalation for LAPC: How high can we go?

Taniguchi 2018 MDAC

- 20 patients treated with either SBRT or dose-escalated hypofractionated IMRT (DE-IMRT) were re-planned
- 70 Gy/5# - GTV
- 40 Gy/5#- PTV



Mean iGTV coverage

50 Gy - 91% (0.07%),
60 Gy - 61.3% (0.08%)
70 Gy - 24.4% (0.05%)

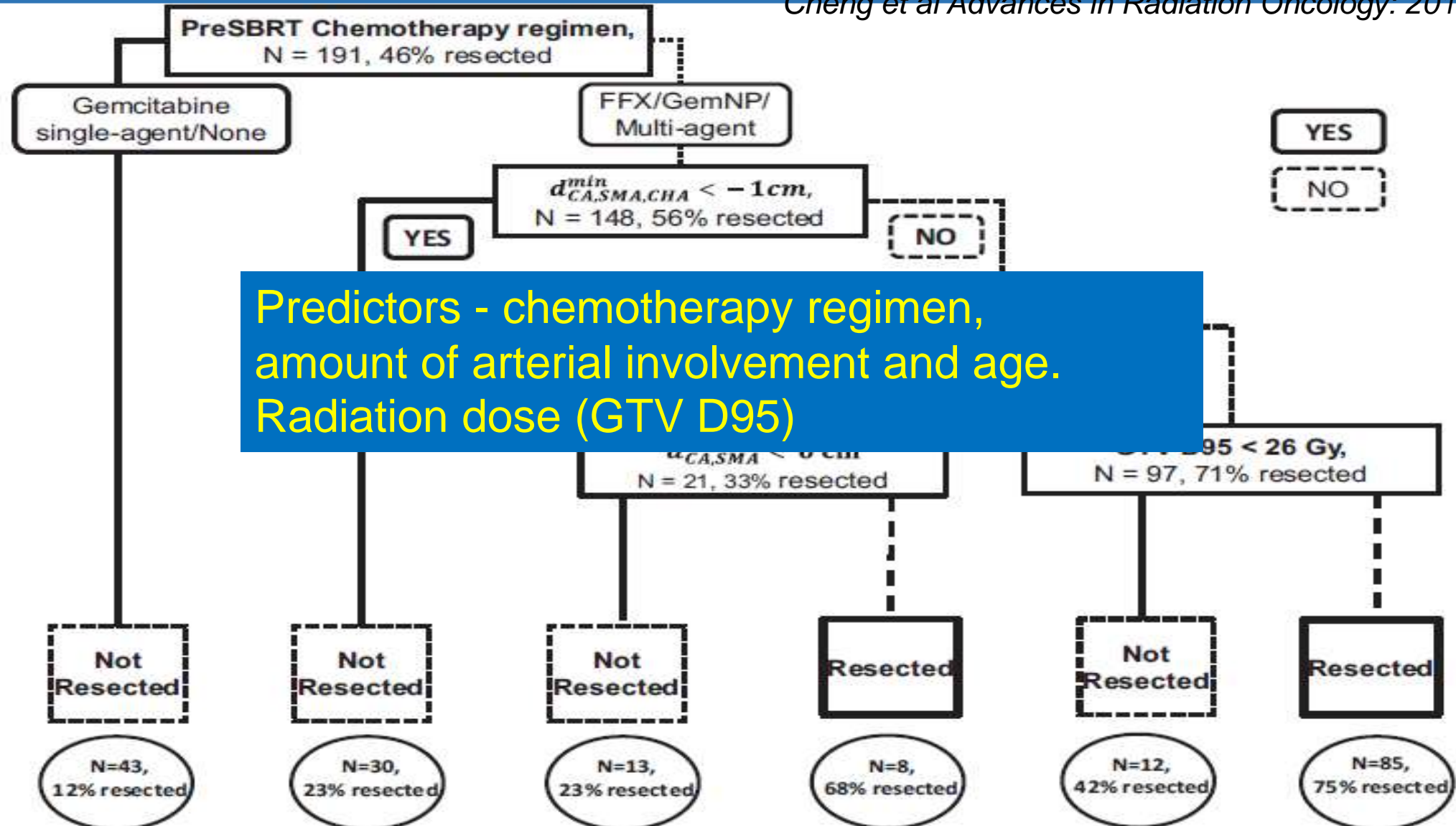
Max PTV coverage

70 Gy - 33%.

60 Gy - 77.5%

Predicting response to SBRT and Sx resection

Cheng et al *Advances in Radiation Oncology*: 2018



Different combined regimens of chemotherapy with SBRT for LAPC

Factors associated with OS

Treatment modality							
Nonchemotherapy	33	11.2	10.5-11.8	<.001	1		<.001
Induction chemotherapy	45	12.2	11.3-13.0	0.60	0.37-0.99	-0.51	.046
Adjuvant chemotherapy	205	13.6	13.0-14.2	0.42	0.28-0.62	-0.88	<.001
Induction and adjuvant chemotherapy	136	13.3	12.5-14.1	0.50	0.33-0.76	-0.69	.001
BED ₁₀							
≥60 Gy	225	14.1	13.1-15.1	<.001	1		<.001
<60 Gy	194	11.4	10.0-11.5	2.59	2.06-3.26	0.95	

Factors associated with PFS

Nonchemotherapy			5.0-6.2	<.001	1		<.001
Induction chemotherapy		6.4	6.0-6.8	0.50	0.31-0.79	-0.70	.003
Adjuvant chemotherapy	205	8.6	8.2-9.0	0.28	0.19-0.40	-1.29	<.001
Induction and adjuvant chemotherapy	136	8.1	7.4-8.8	0.33	0.22-0.49	-1.10	<.001

Giving chemotherapy in NA and adj improves survival

CONKO-007: Chemoradiotherapy vs Chemotherapy Alone for Unresectable Locally Advanced Pancreatic Cancer

CCO Independent Conference Highlights*

of the *2022 ASCO Annual Meeting, June 3-7, 2022, Chicago, Illinois*

*CCO is an independent medical education company that provides state-of-the-art medical information to healthcare professionals through conference coverage and other educational programs.



CONKO-007: Study Design

- Randomized phase III trial

Patients with unresectable locally advanced pancreatic cancer; no prior radiotherapy or chemotherapy; ECOG PS ≤2 (N = 402)

Induction CT: Gemcitabine or FOLFIRINOX*
Randomized (n = 336)

CRT: Gemcitabine + RT†
(n = 167)

CT: Gemcitabine or FOLFIRINOX*
(n = 169)

Computed tomography scan for evaluation of resectability; if R0 resectable, could proceed to surgery; if not, could receive additional chemotherapy

*Gemcitabine 1000 mg/m²/d on Days 1, 8, 15, 29, 36, 43, 57, 64, and 71 or FOLFIRINOX on Days 1, 15, 29, 43, 57, and 71.

†Irradiation 28 x 1.8 Gy with total dose 50.4 Gy; gemcitabine 300 mg/m²/d on Days 1, 8, 15, 22, and 29 followed by gemcitabine 1000 mg/m²/d on Days 57, 64, and 71. †Primary endpoint was changed from OS after interim analysis due to insufficient recruitment.

- Primary endpoint: R0 resection rate†
- Secondary endpoints: OS, DFS, rate of resections, survival following resection
- Median follow-up: 55.13 mo

CONKO-007: R0 Resection Rate, All Randomized Patients

Outcome, n (%)	CT (n = 167)	CT + CRT (n = 169)	P Value
Resection performed	60 (36)	62 (37)	.91
pCR	1 (0.6)	11 (7)	.0055
Resection			
▪ R0	30 (18)	43 (25)	.1126
▪ R1	16 (10)	5 (3)	.0133
▪ R2, Rx	14 (8)	14 (8)	1.0000
CRM			
▪ Negative	15 (9)	29 (17)	.0348
▪ Positive	27 (16)	11 (7)	.0057
▪ Missing data	4 (2)	8 (5)	
Deceased with 30 days post resection	5 (3)	4 (2)	.7494

CONKO-007: R0 Resection Rate, Patients Who Underwent Surgery After Randomized Treatment

Outcome, n (%)	CT (n = 60)	CT + CRT (n = 62)	P Value
pCR	1 (2)	11 (18)	.0043
Resection			
▪ R0	30 (50)	43 (69)	.0418
▪ R1	16 (27)	5 (8)	.0081
▪ R2, Rx	14 (23)	14 (23)	1.0000
CRM			
▪ Negative	15 (25)	29 (47)	.0147
▪ Positive	27 (45)	11 (18)	.0016
▪ Missing data	4 (7)	8 (13)	
Deceased with 30 days post resection	5 (8)	4 (6)	.7413

CONKO-007: OS by Subgroups

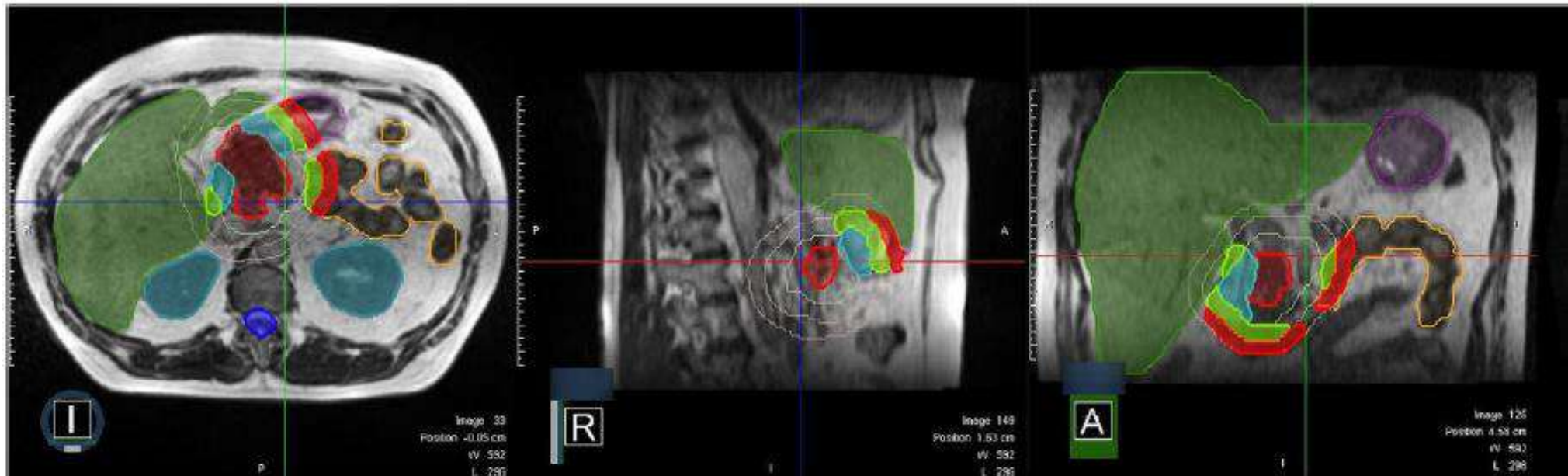
Outcome	OS, Mo	5-Yr OS, % (Range)	HR (95% CI), CT vs CT + CRT	P Value
Surgery				
▪ No (n = 214)	14	0	0.573 (0.443-0.743)	<.001
▪ Yes (n = 122)	19	17.5 (11.1-27.7)		
All surgical patients (N = 122)				
▪ CT arm (n = 60)	19	12.0 (5.3-27.5)	0.896 (0.595-1.350)	.601
▪ CT + CRT arm (n = 62)	20	24.0 (14.7-39.2)		
All surgical patients treated with FOLFIRINOX (N = 112)				
▪ CT arm (n = 56)	21	13.0 (5.7-29.6)	0.857 (0.555-1.324)	.487
▪ CT + CRT arm (n = 56)	22	26.9 (16.7-43.5)		
Resection status				
▪ R0 (n = 73)	26	27.3 (17.4-43.8)	R0 vs R1: 2.155 (1.249-3.717)	.006
▪ R1 (n = 21)	17	8.0 (1.4-45.0)	R0 vs incomp/no: 2.486 (1.786-3.460)	<.001
▪ Incomplete/no surgery (n = 242)	16	0	R0 vs no random: 4.163 (2.943-5.889)	<.001
▪ No randomization (n = 159)	9	0	R1 vs incomp/no: 1.154 (0.710-1.874)	.563
Resection status				
▪ CRM- (n = 44)	36	35.9 (22.6-57.0)	CRM- vs CRM+: 2.293 (1.356-3.876)	.002
▪ CRM+ (n = 38)	18	9.0 (2.6-31.7)	CRM- vs incomp/no: 3.115 (2.034-4.770)	<.001
▪ Incomplete/no surgery (n = 242)	16	0	CRM- vs no random: 5.197 (3.352-8.058)	<.001
▪ No randomization (n = 159)	9	0	CRM+ vs incomp/no: 1.358 (0.926-1.992)	.117

Future directions

- MRI guided

Stereotactic MR-guided adaptive radiation therapy (SMART) for pancreatic cancer

At each fraction, OAR (re-)contouring is done within a distance of 3 cm from the PTV surface allows good OAR sparing and adequate target coverage while requiring only limited online (re-)contouring from clinicians.



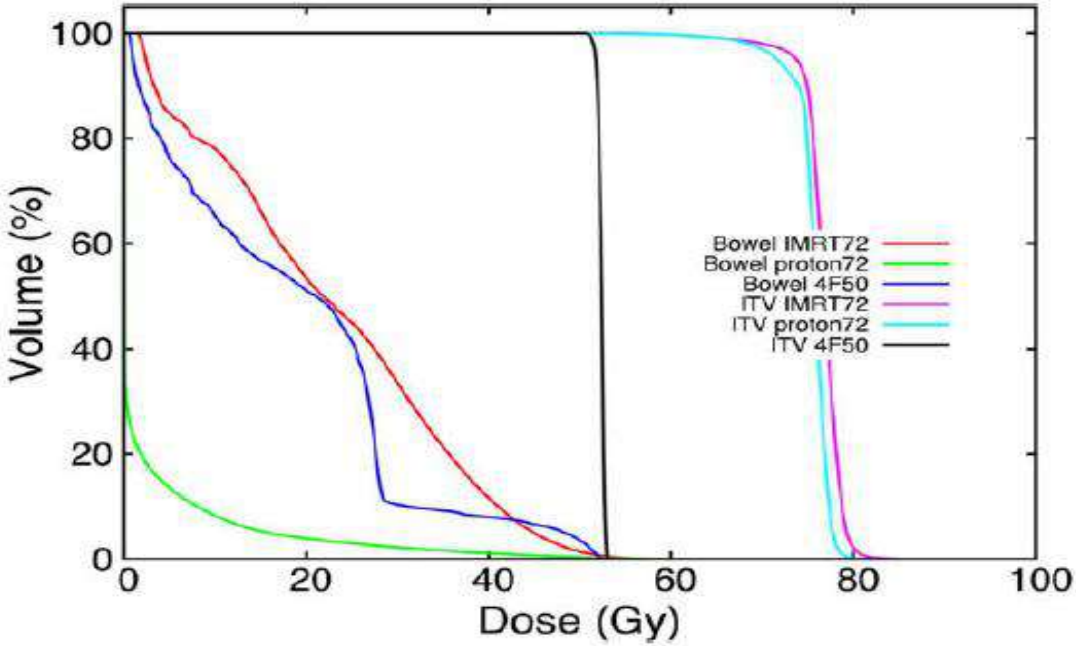
Dose escalation with proton or photon radiation treatment for pancreatic cancer[☆]

Myriam Bouchard^a, Richard A. Amos^a, Tina M. Briere^a, Sam Beddar^a, Christopher H. Crane^{b,*}

^aDepartment of Radiation Physics, The University of Texas M.D. Anderson Cancer Center, Houston, USA

Radiotherapy and Oncology 92 (2009) 238–243

^bDepartment of Radiation Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, USA



optimal choice of radiation therapy modality for safe dose escalation depends on the pancreatic tumor position in relation to OAR anatomy. IMRT and passive scattering PT showed advantageous results, but for different tumor positions. 3DCRT plans presented considerably inferior target coverage compared

Fig. 5. Bowel and internal target volume dose–volume histograms for tumor position #1, comparing 72-Gy IMRT, 72-Gy PT and 50-Gy four-field box.

Percentages of ITVs and CTVs receiving doses >72 Gy ($V_{72\text{Gy}}$) according to tumor positions.

Position #	ITV $V_{72\text{Gy}}$			CTV $V_{72\text{Gy}}$		
	IMRT	Protons	3DCRT	IMRT	Protons	3DCRT
Initial (#1)	97.1%	94.4%	40.9%	99.6%	99.6%	51.0%
Head (#1–3)	75.9 ± 20.0%	86.5 ± 6.2%	37.7 ± 29.8%	78.6 ± 20.9%	98.9 ± 1.6%	44.2 ± 32.6%
Body (#4–7)	93.1 ± 3.1%	77.8 ± 4.3%	21.0 ± 10.3%	99.0 ± 1.1%	94.5 ± 3.3%	26.9 ± 11.8%
Tail (#8–11)	86.2 ± 14.1%	80.8 ± 6.6%	24.1 ± 17.8%	90.8 ± 15.4%	95.0 ± 4.1%	20.5 ± 24.0%

SBRT dose regimens

- 40-50Gy/ 5#
- 67.5Gy/15
- Is there a difference?
- BED is what matters
- BED >90 Gy desirable upto 100Gy

50Gy/5# vs 67.5/15# - ASTRO 2022

- Two institutes comparison
- No difference in outcomes

SBRT Pancreas

SOP

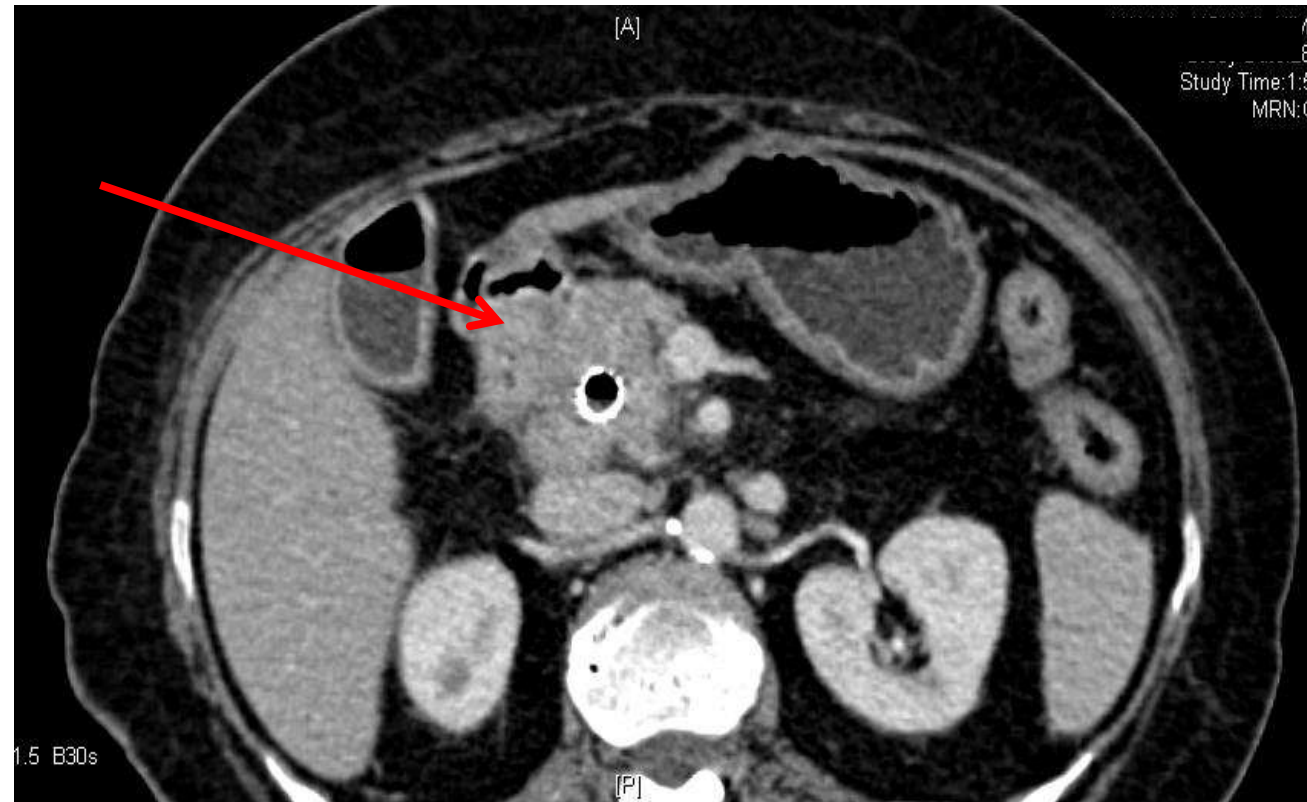
Patient selection

- Patients with active duodenal or gastric ulcers are not acceptable for SBRT.
- Patients with direct tumor invasion of the bowel or stomach based on endoscopy or if organ at risk (OAR) constraints cannot be met: Consider for Hypofractionated IGRT (HIGRT)
- Patients should have 4D CT simulation / fluoroscopy to assess tumor motion
- Patients should be treated with SBRT only if motion management techniques are available

Duodenal infiltration by tumor

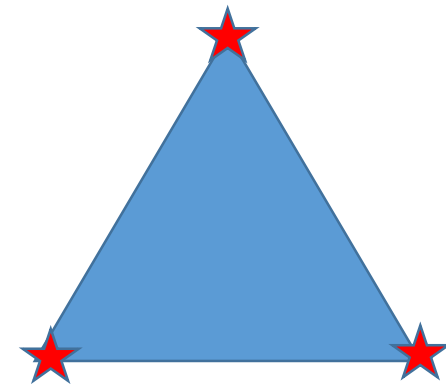
Not a contraindication for
SBRT
More fractionated
regimens preferred

MD Anderson/ Mayo
67.5/15#
55Gy / 10#
Keeping the BED >85Gy

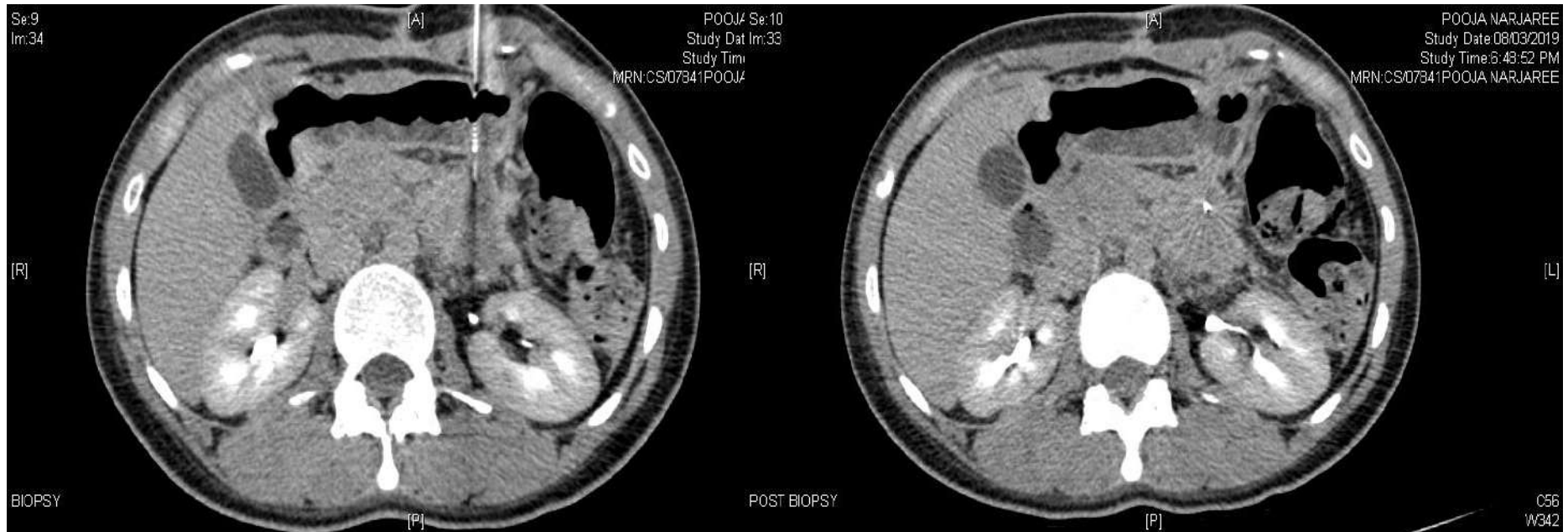


Fiducial placement

- 1-5 (preferably ≥ 3) fiducial markers (Civco, Visicoil, Gold anchor) should be placed for targeting purposes in or directly at the tumor periphery and/or within 1 cm of the tumor (normal pancreas) under EUS (preferred) or CT guidance.



CT guided Gold marker placement



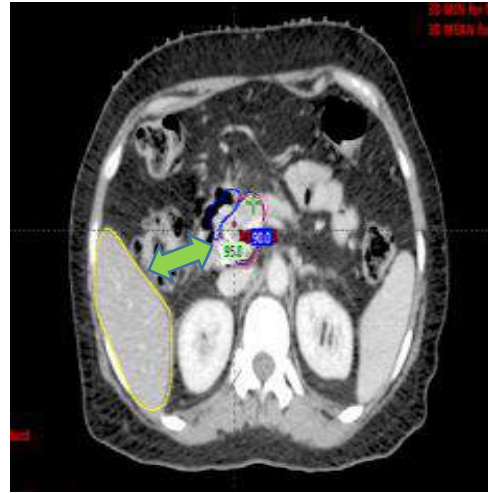
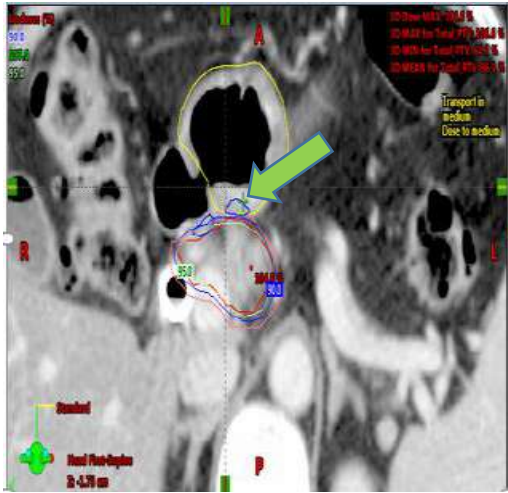
Simulation

- Counsel regarding the procedure and advise breathing exercises
- Supine position with a customized immobilization device (e.g. Vac-Lok)
- Empty stomach / four hours fasting/ Prokinetic and carminative protocol
- Oral contrast: Diatrizoate Meglumine 2.5ml diluted in 50ml of water is given 20 minutes prior to the scan. Ensure no unusual distension of stomach/duodenum/bowel.
- A 4DCT scan (when available) / Fluoroscopic tracking of markers - to assess respiratory motion. If the tumor motion > 5mm, respiratory motion management is required.

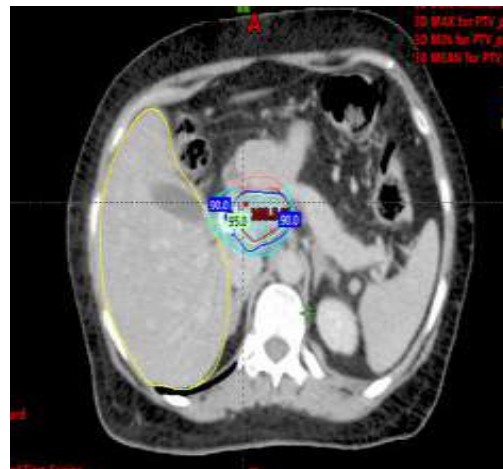
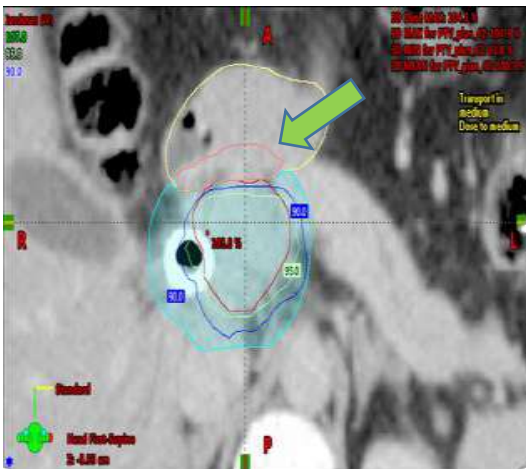


Dosimetric analysis
debh v/s dibh

DEBH



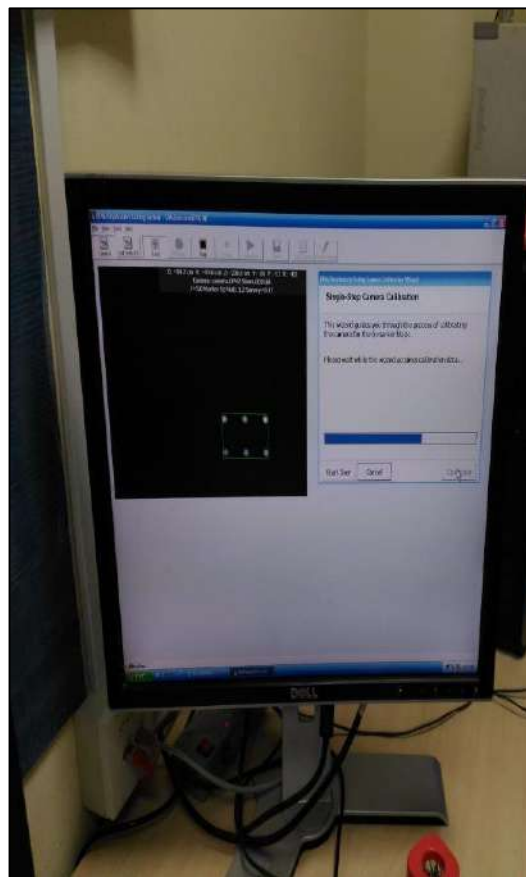
DIBH



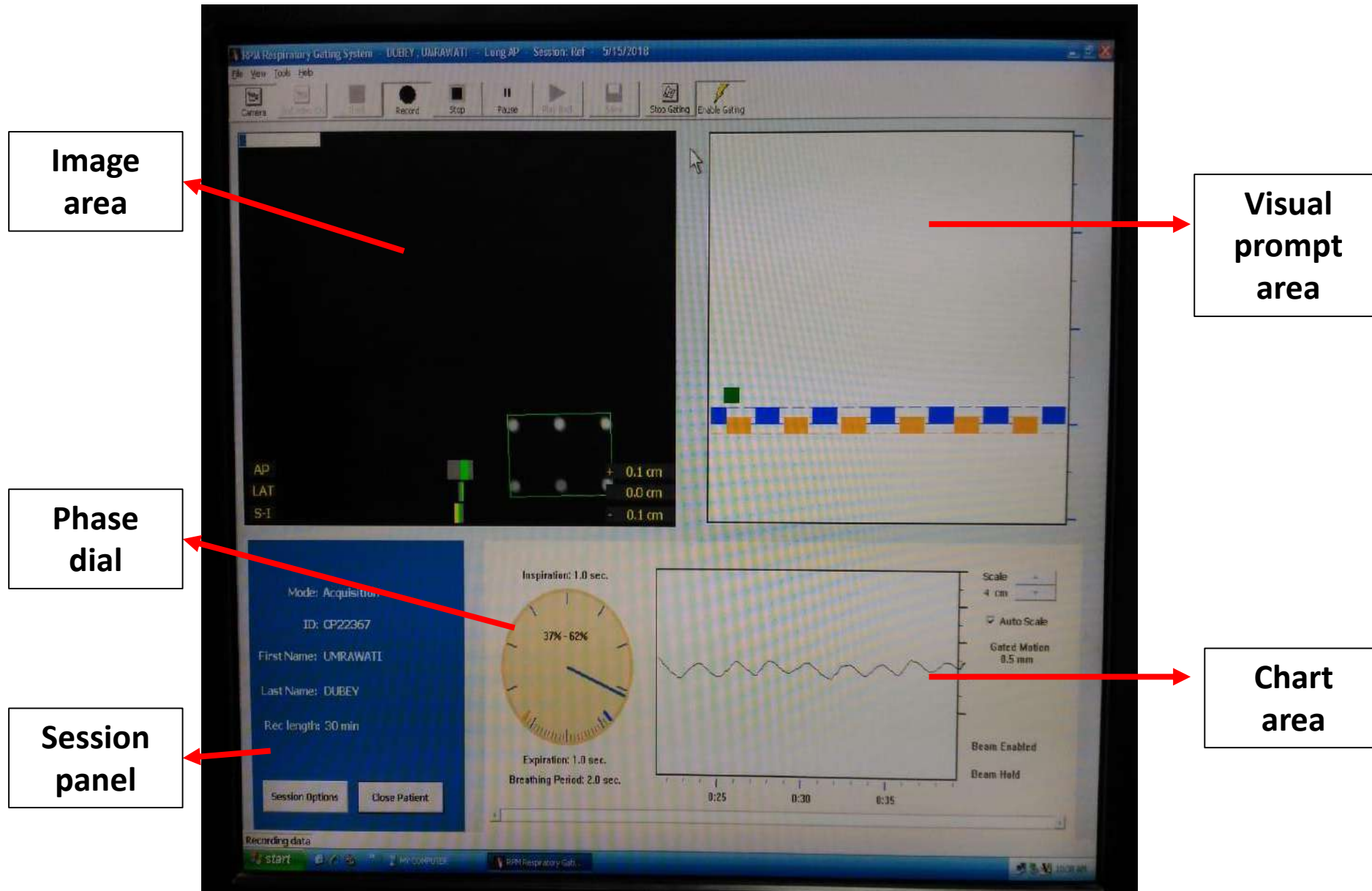
Variable	Mean	Std Dev	P Value
D15 Exp-D15Insp	3.46	4.1	0.421
D20 Exp-D20 Insp	5.95	9.72	0.085
D33 Exp-D33 Insp	0.49	0.84	0.1
D35 Exp- D35 Insp	0.33	0.16	0.075
D36 Exp- D36 Insp	0.08	0.17	0.145
B20 Exp- B20 Insp	17.49	51.69	0.312
B33 Exp- B33 Insp	5.6	14.25	0.245
S15 Exp- S15 Insp	12.42	11.41	0.007 Stomach
S20 Exp- S20 Insp	5.25	5.95	0.021 Stomach
L12 Exp- L12 Insp	51.8	38.17	0.002 Liver
K12 Exp- K12 Insp	4.01	12.1	0.321

P-value calculated using PAIRED T-test in Parametric variables normally distributed ($P < 0.05$)

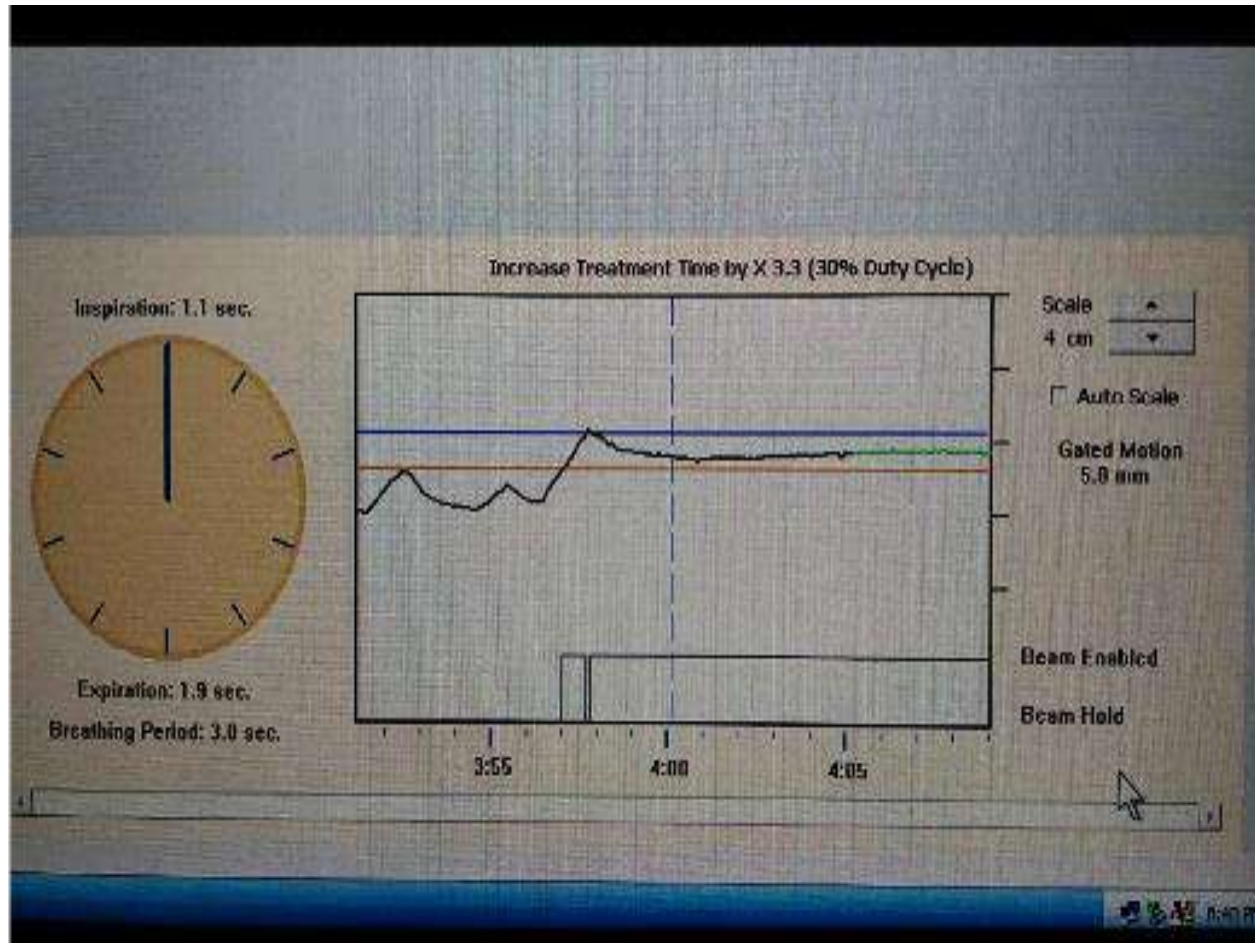
IR camera calibration



4DCT – tracking the pattern of respiration



Monitoring breath hold



Breath-hold technique

- Deep expiratory breath-hold (DEBH)
- Comfortable breath-hold (CBH)
- Deep inspiratory breath-hold (DIBH)

Basic Original Report

**Australasian Gastrointestinal Trials Group
(AGITG) and Trans-Tasman Radiation Oncology
Group (TROG) Guidelines for Pancreatic
Stereotactic Body Radiation Therapy (SBRT)**

Andrew Oar MBBS MIPH FRANZCR ^{a,b,*},

Parameter	Per protocol	Minor variation	Major variation
PTV40_EVAL D90%, %	≥ 100	90-99	<90
PTV40 D99%, Gy	>30	25-30	<25
CTV D99%, Gy	>33	30-33	<30
Max dose (D0.5 cm ³), %	110-130	130-140 OR <110	>140

40 Gy in 5 fractions (BED₁₀Z72 Gy, BED₃Z147 Gy) to as much of the PTV as possible. To meet dose constraints to

OARs, under coverage of the PTV near gastrointestinal structures is required. We recommend the dose to 90% of an evaluable PTV (PTV less gastrointestinal PRV) is greater than 100% of the prescription dose (40 Gy).

Compromises to coverage may be needed when tumors are

proximal to hollow viscous. If D90% (minimum dose covering 90% of the volume) is less than 90% of prescription

dose, reduced-dose SBRT, conventional chemoradiotherapy,

or chemotherapy alone should be considered

([Table 1](#)). Maximum doses (D0.5 cm₃) of 33 Gy in 5 fractions (BED₁₀Z 54 Gy, BED₃Z 103 Gy) to the duodenum and small bowel have a low incidence of toxicity

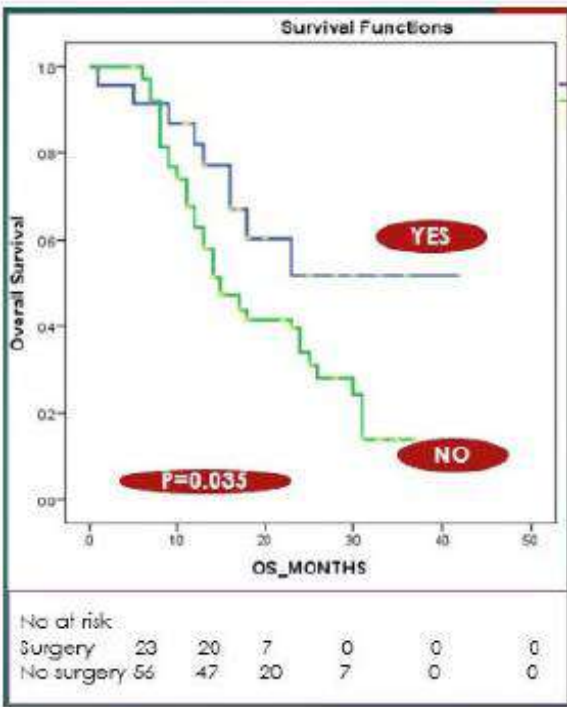
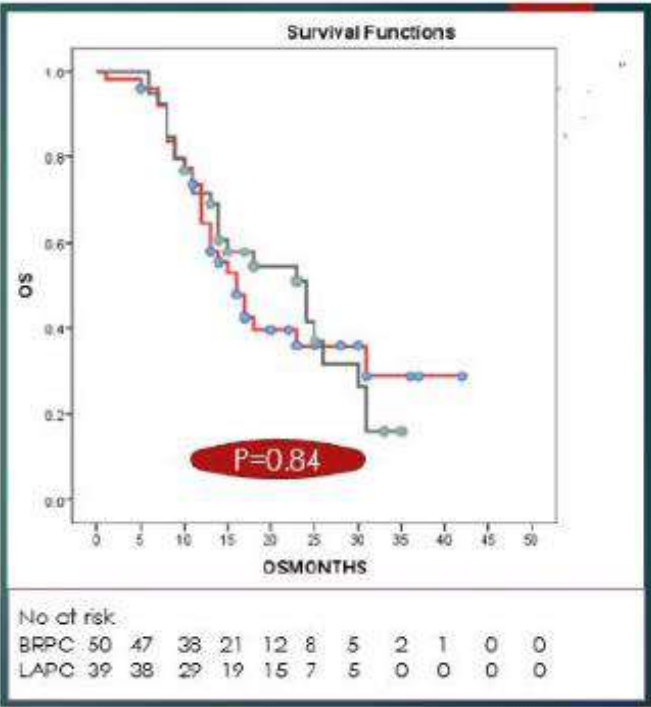
- SBRT should be delivered as 5 fractions
- with a maximum of 4 treatments per week, with 2
- consecutive days permitted but not 3.
- A minimum of
- 24 hours between fractions is also recommended.

RESEARCH ARTICLE

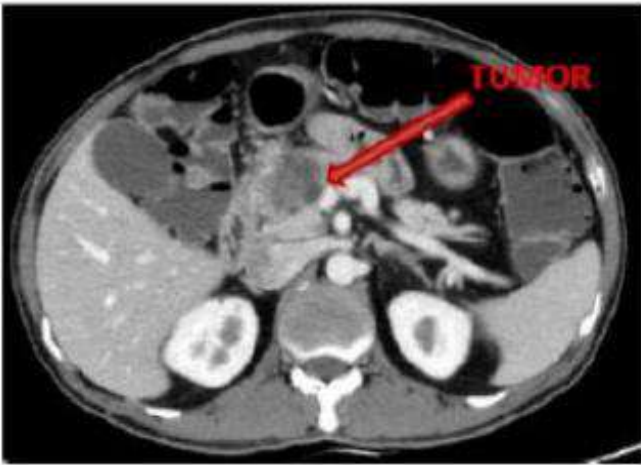
PEER REVIEWED | OPEN ACCESS

Predictors of outcome in patients receiving stereotactic body radiation therapy for borderline resectable and locally advanced pancreatic cancers

Akanksha Anup, Manish Bhandare, Vikram Chaudhari, Rahul Krishnatr
Shailesh Shrikhande, Vikas Ostwal, Anant Ramaswamy, Akshay Bahet
Mukta Ramadwar, Reena Engineer

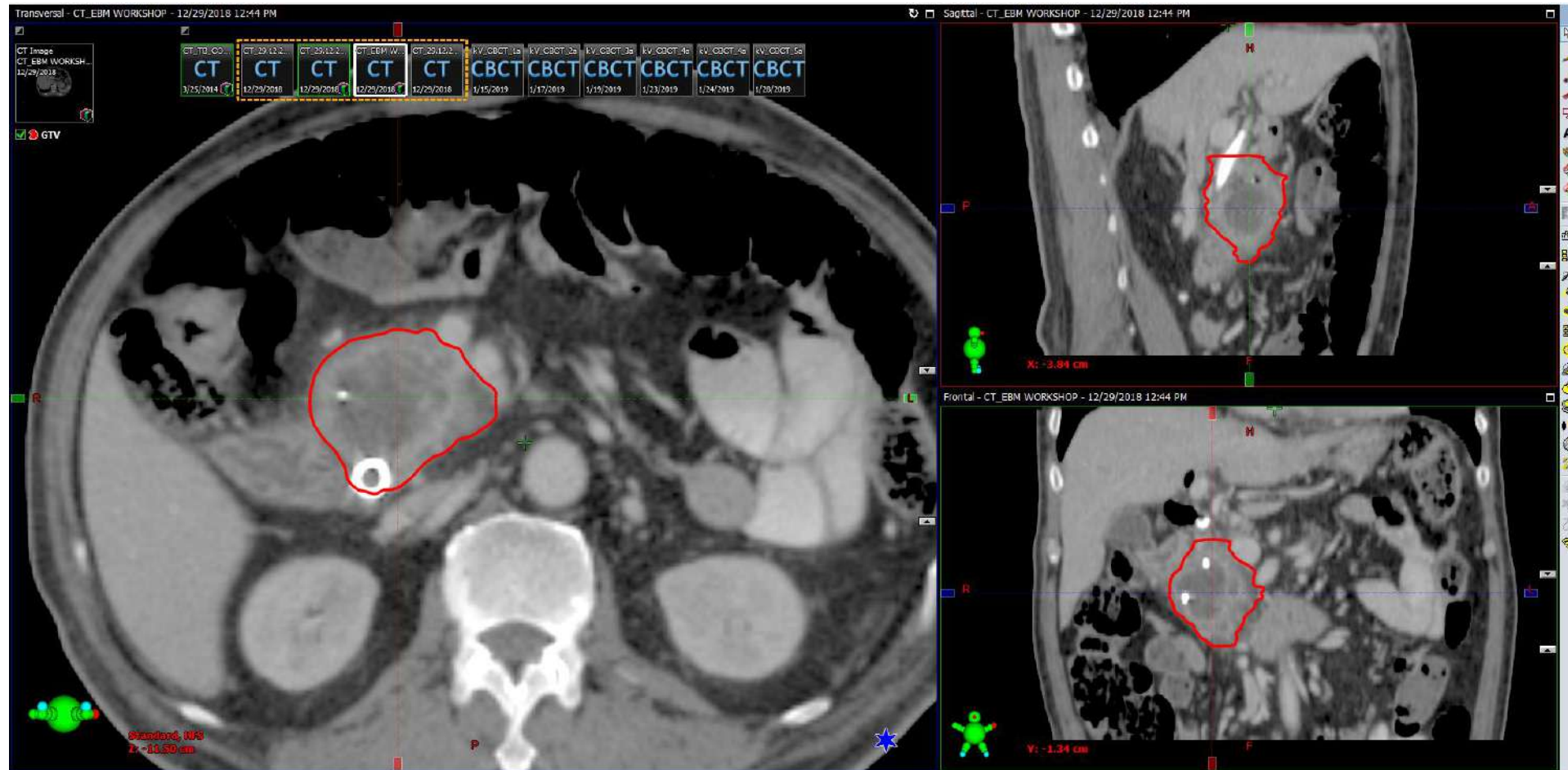


On multivariate analysis, Eastern Cooperative Oncology Group (ECOG) < 2 [hazard ratio (HR): 2.77 (1.2–6.2; 0.014)], head location [3.7 (1.44–9.6; 0.007)], and radiological response post-NACT-SBRT [4.38 (1.08–17.7; 0.039)] were significant predictors of outcome in both the cohorts. No grade ≥3 late radiotherapy (RT)-related toxicities were seen.

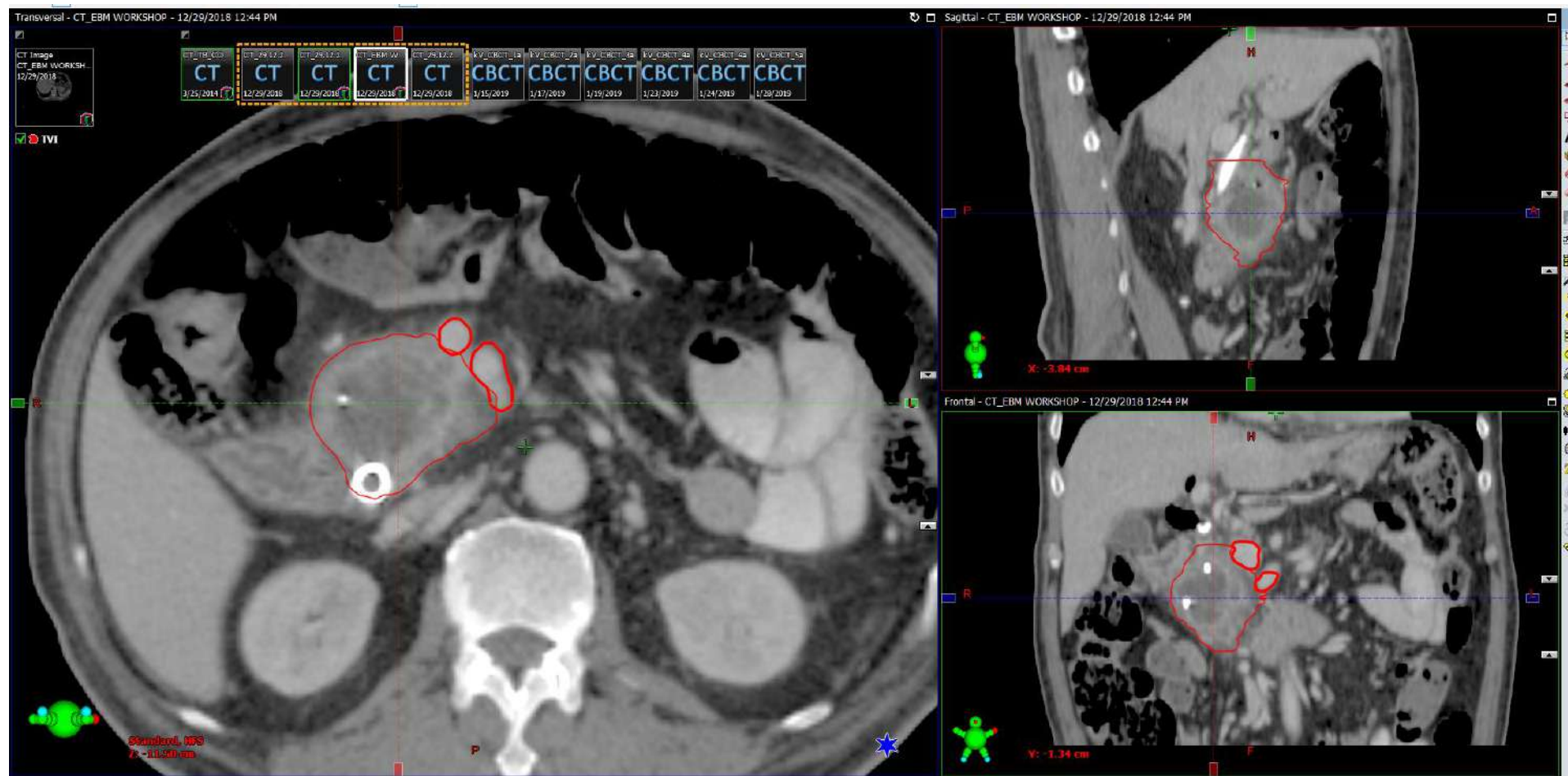


TARGET DELINEATION

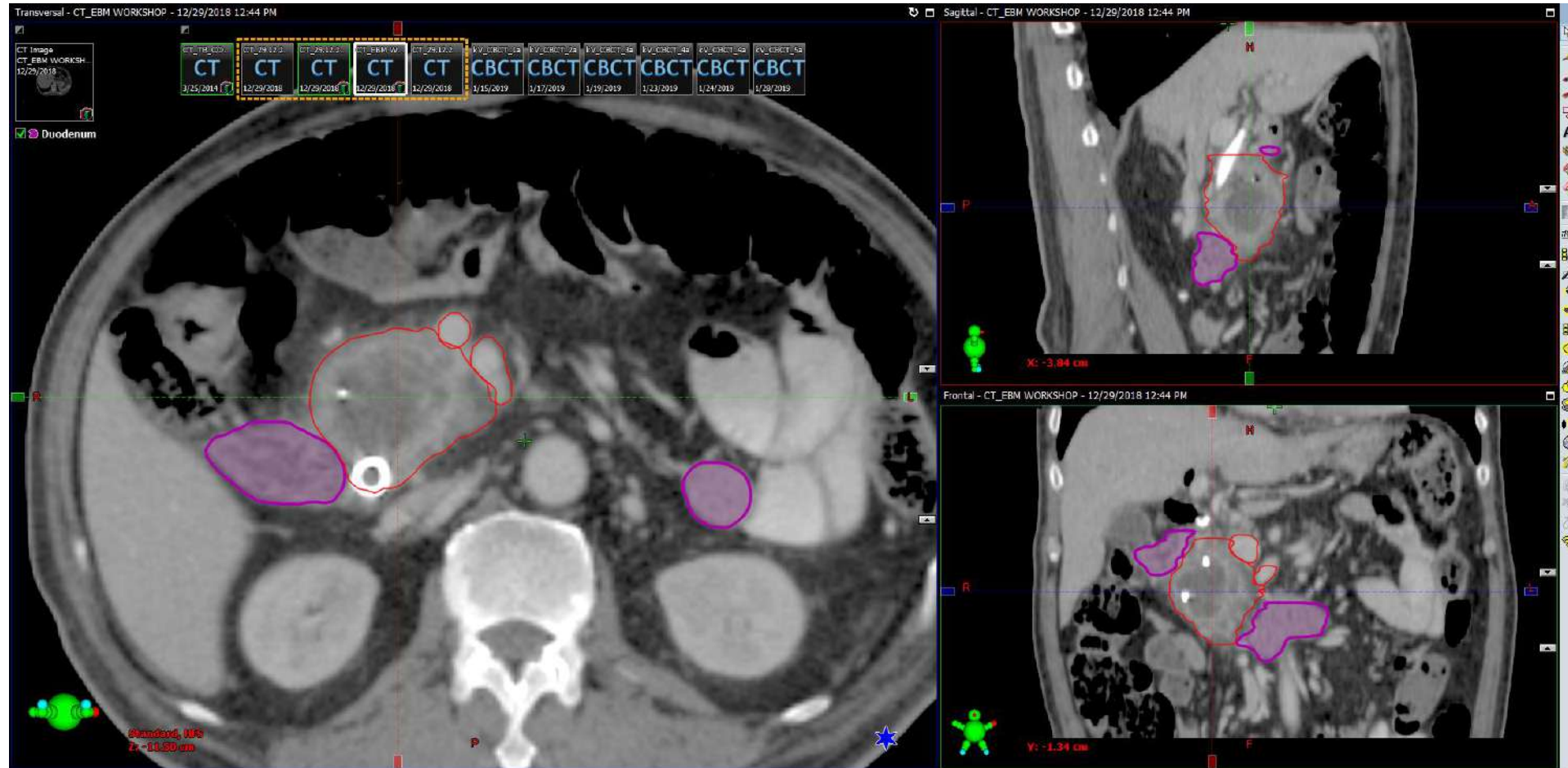
GTV



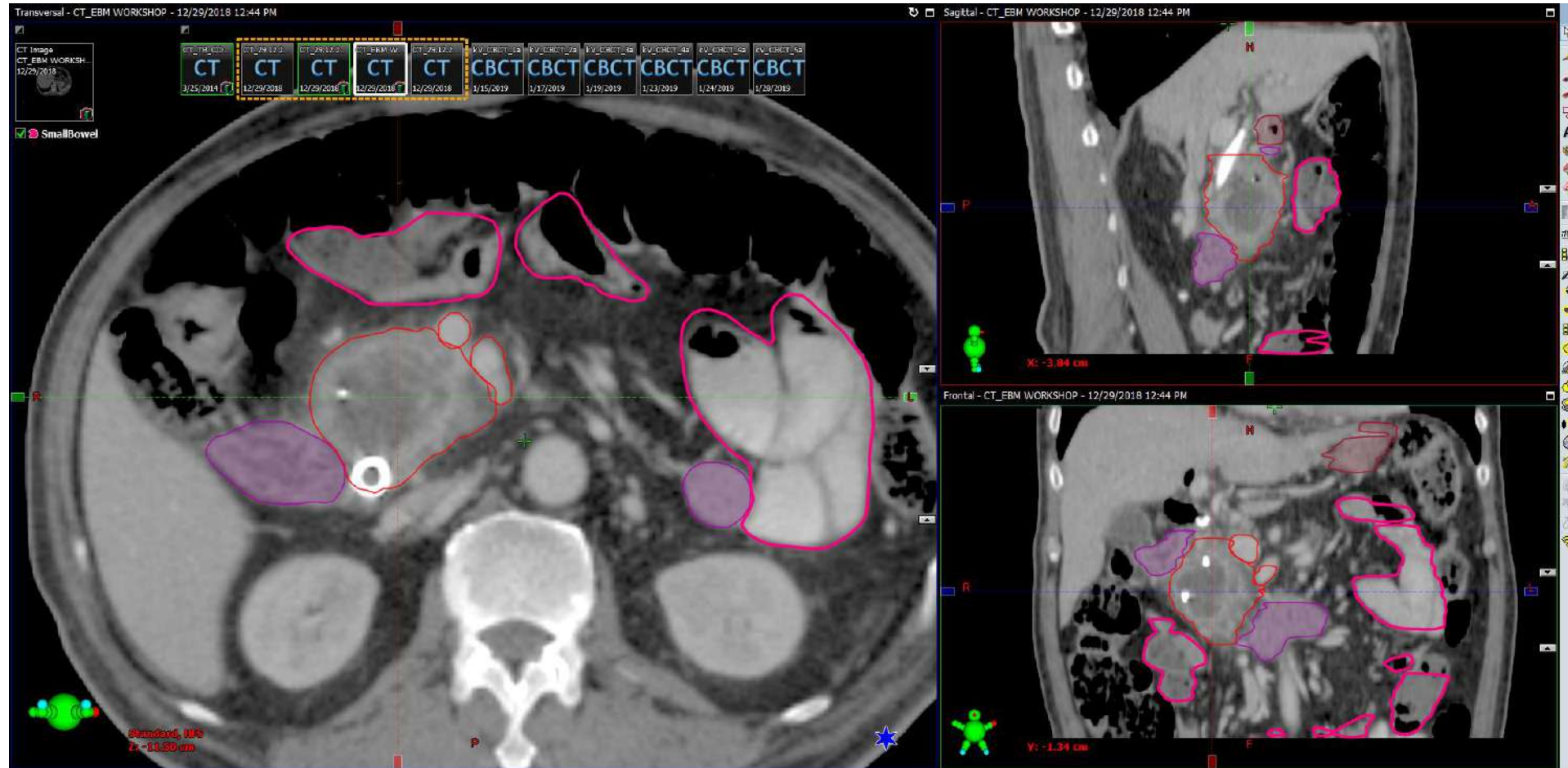
Vessels (Tumor vessel interface)



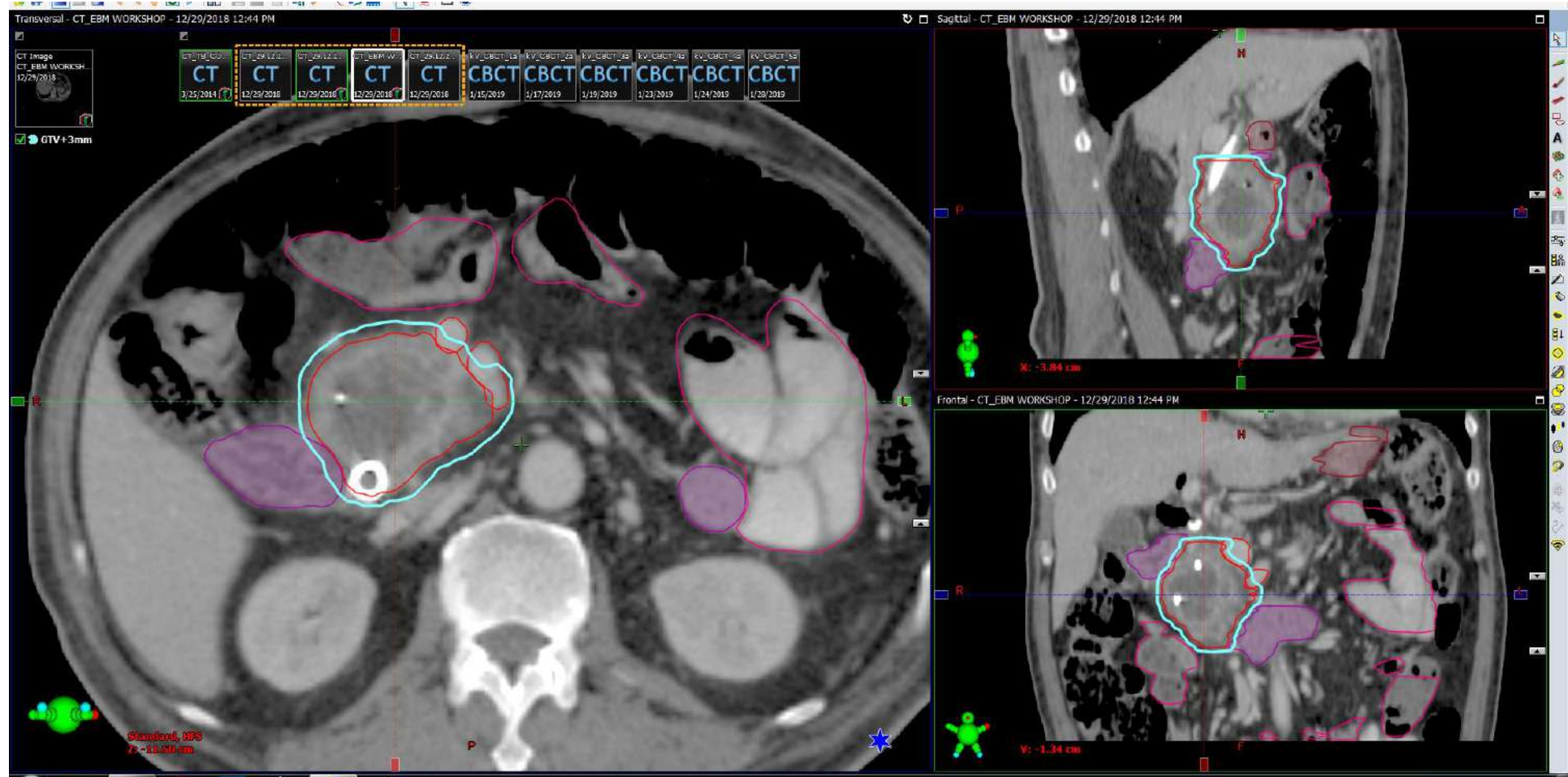
Duodenum



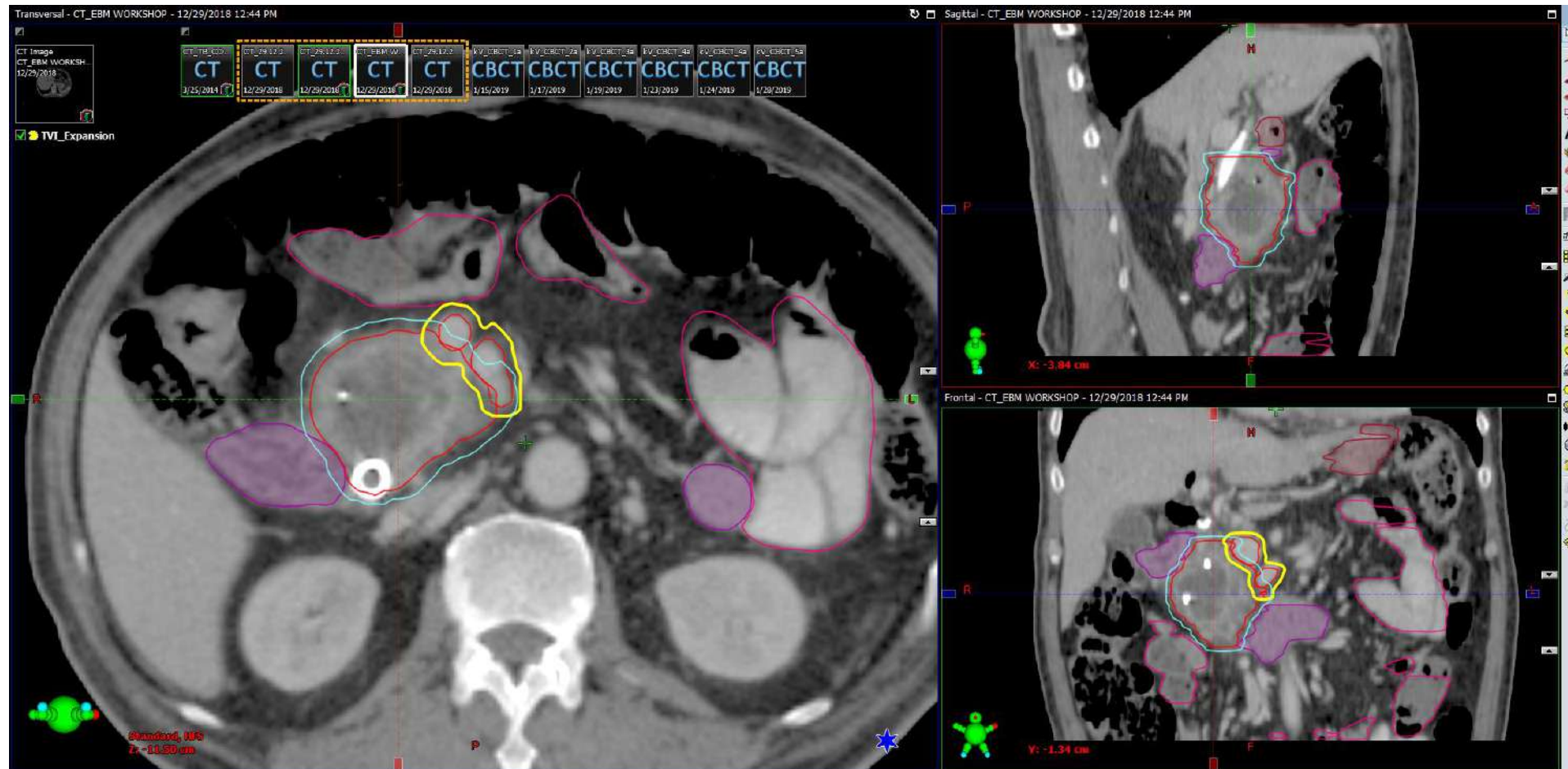
Small bowel



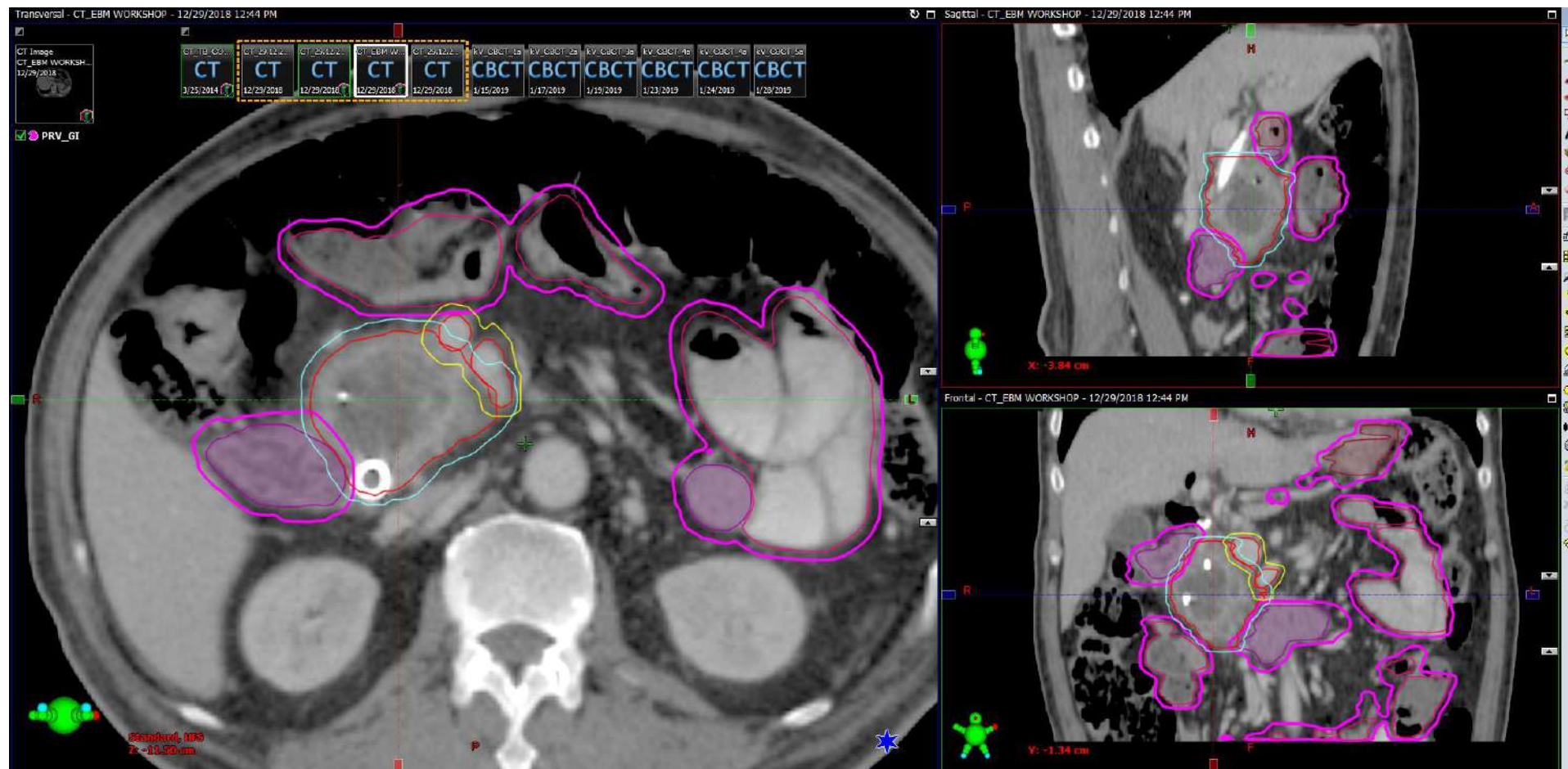
GTV + 3mm



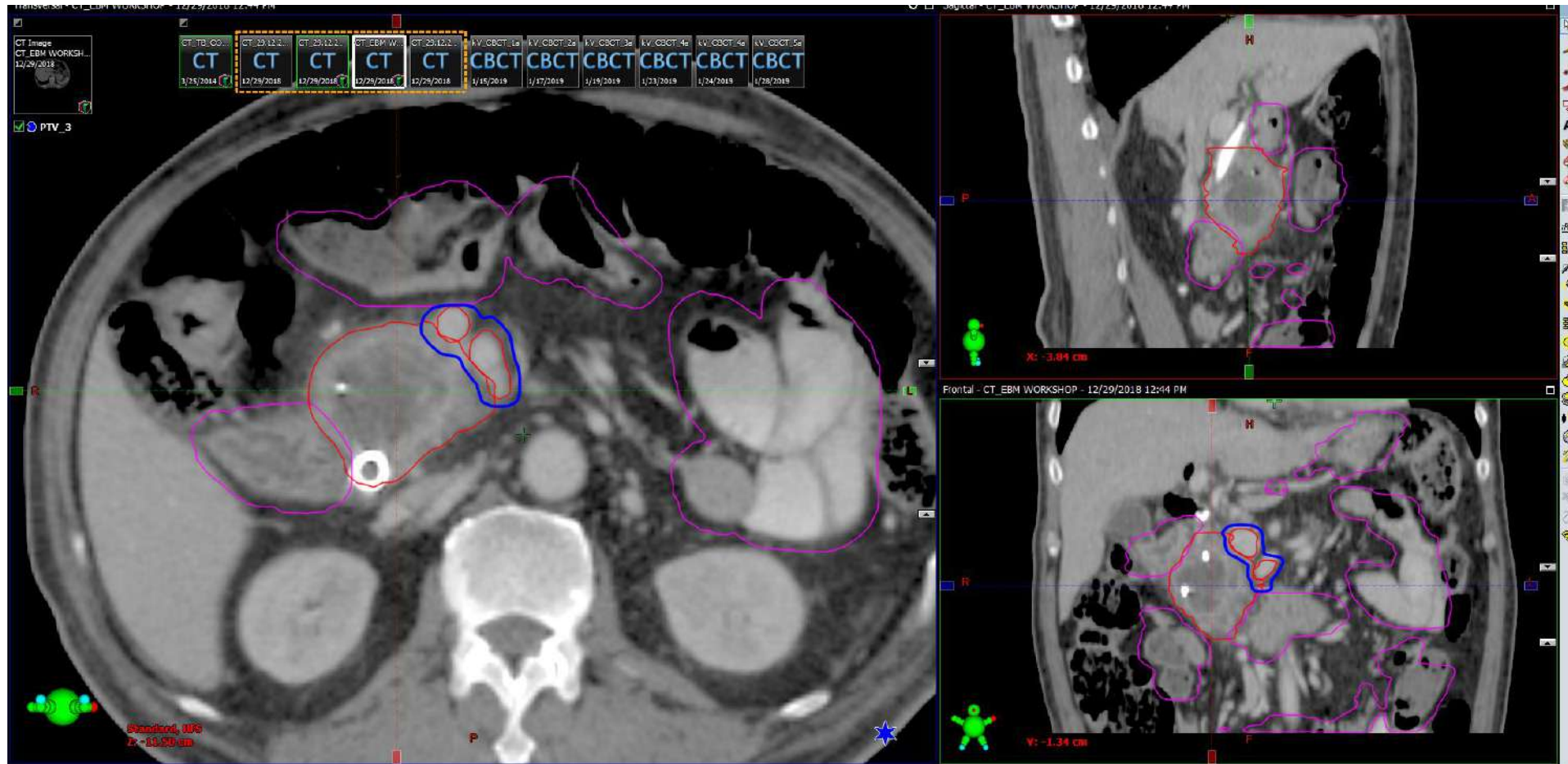
TVI + 3mm



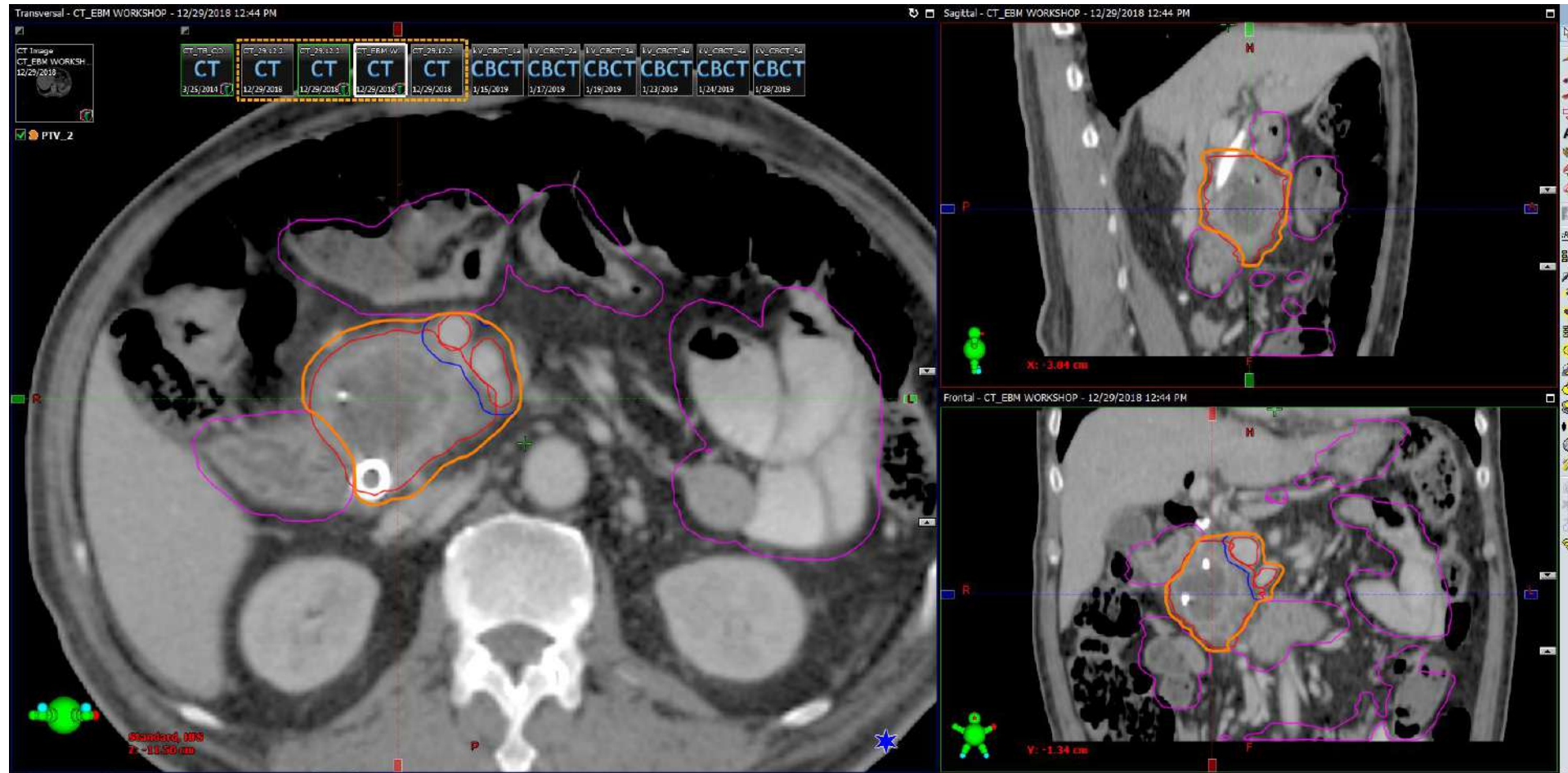
GI + 3mm (PRV GI)



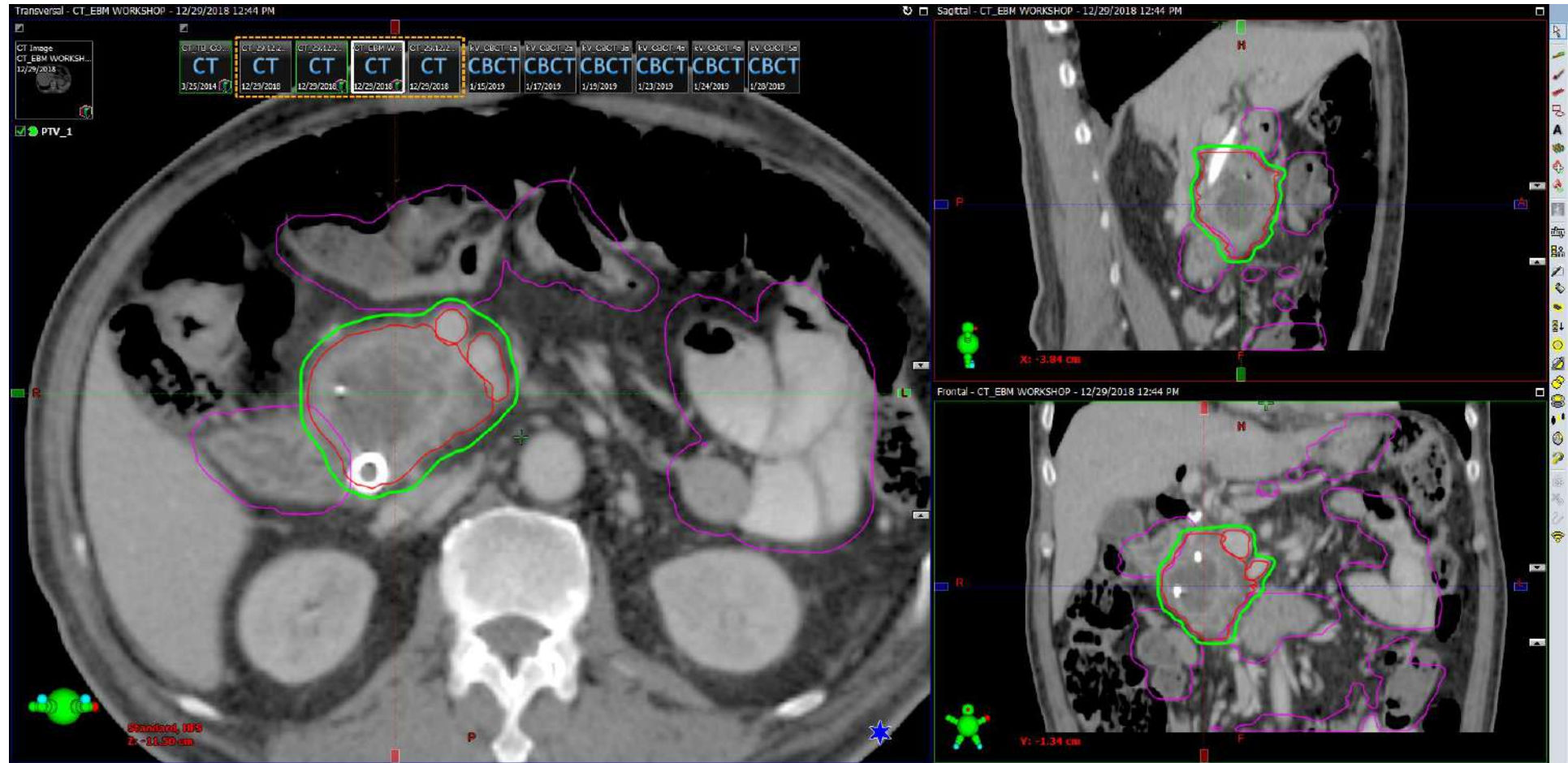
High Dose PTV



Intermediate Dose PTV



Low Dose PTV



Plan evaluation

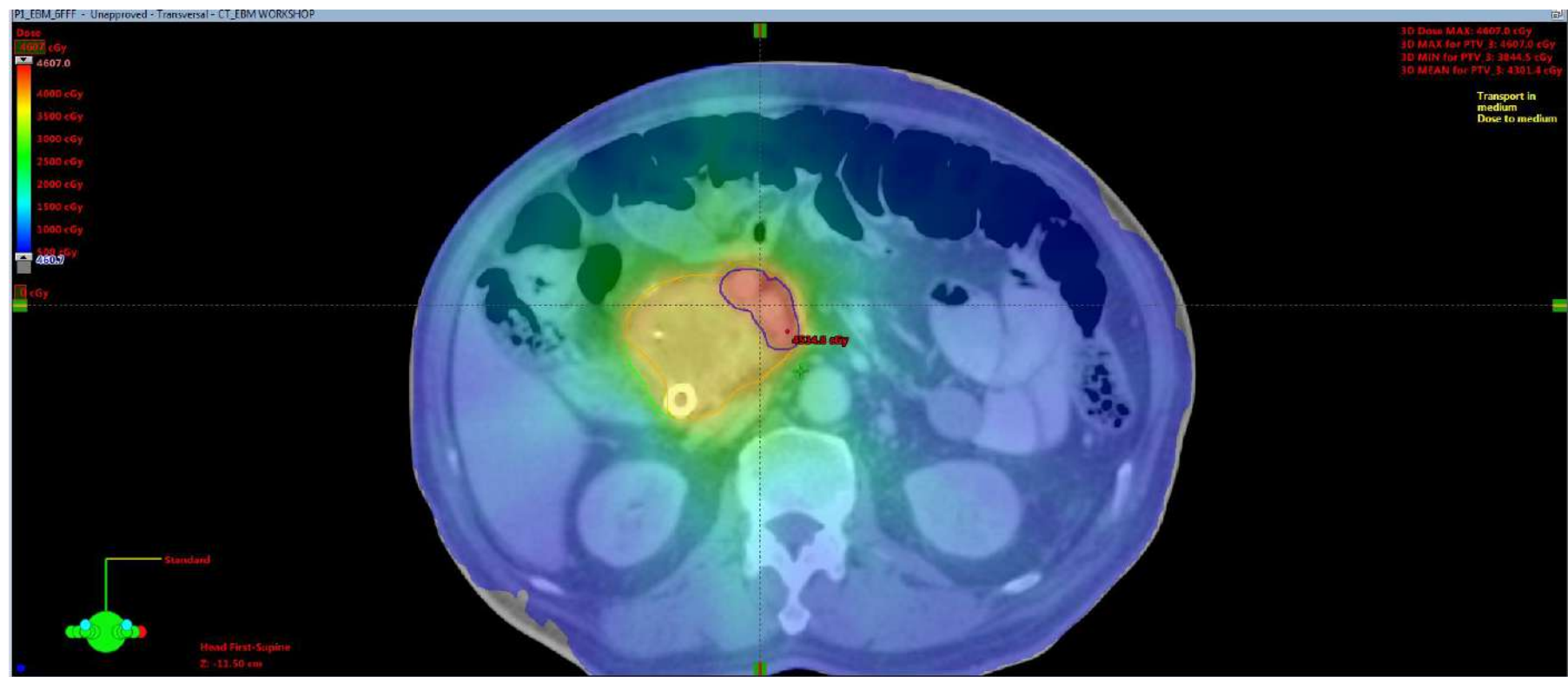
Dose prescription and fractionation		BED ($\alpha/\beta = 10$)	BED ($\alpha/\beta = 3$)
BRPC (ALLIANCE)			
	33Gy/5 # (SBRT)	54.8	105.6
	25Gy/5 # (HIGRT)*	37.5	66.7
BRPC (TMH)			
	36Gy/5 #	61.9	122
	42Gy/5 #	77.2	159
	45Gy/5 #	85.5	180
LAPC (TMH)	50Gy / 5 #	100	216
BRPC/ LAPC			
Frank duodenal infiltration	67.5Gy/15#	97.88	168

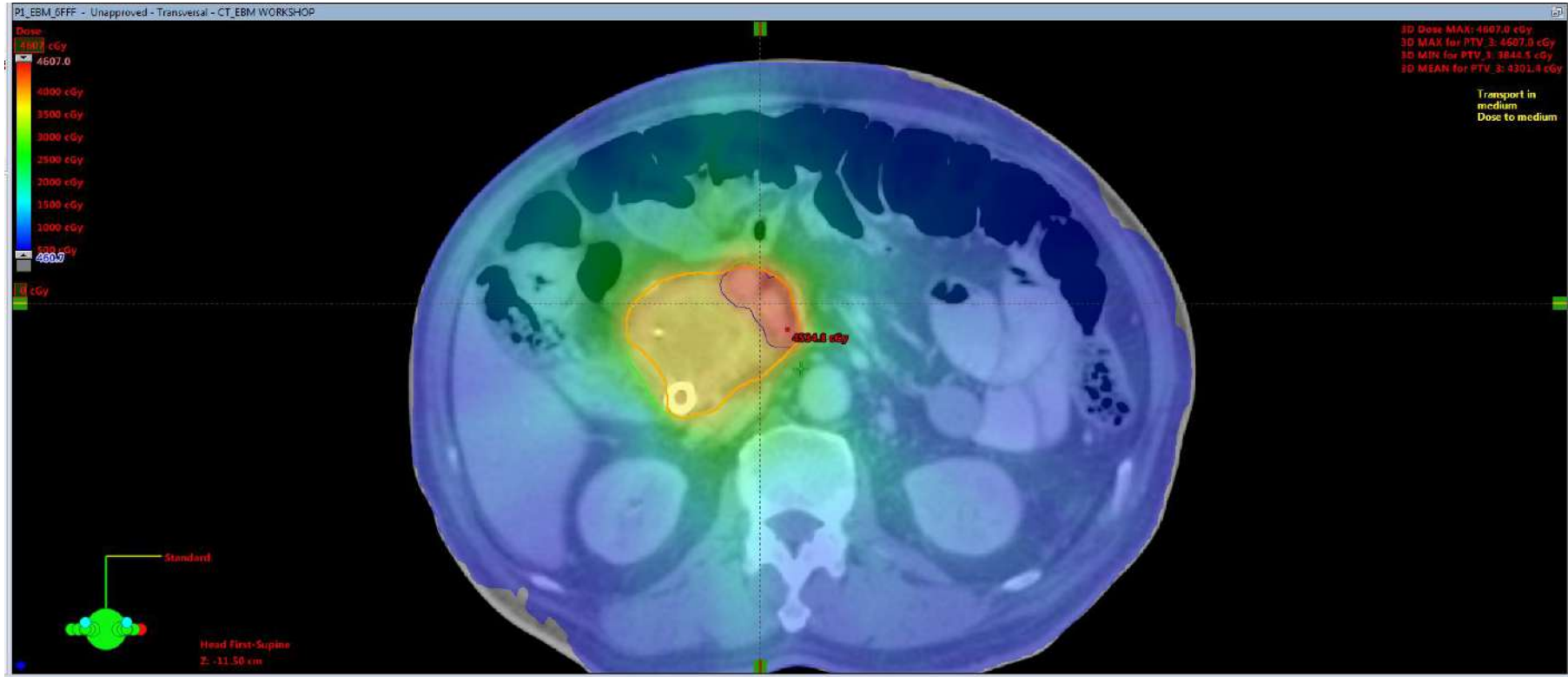
*(Large tumors, Mucosal infiltration, non-availability of IGRT/Motion management or if OAR constraints not achievable with 33Gy/5#)

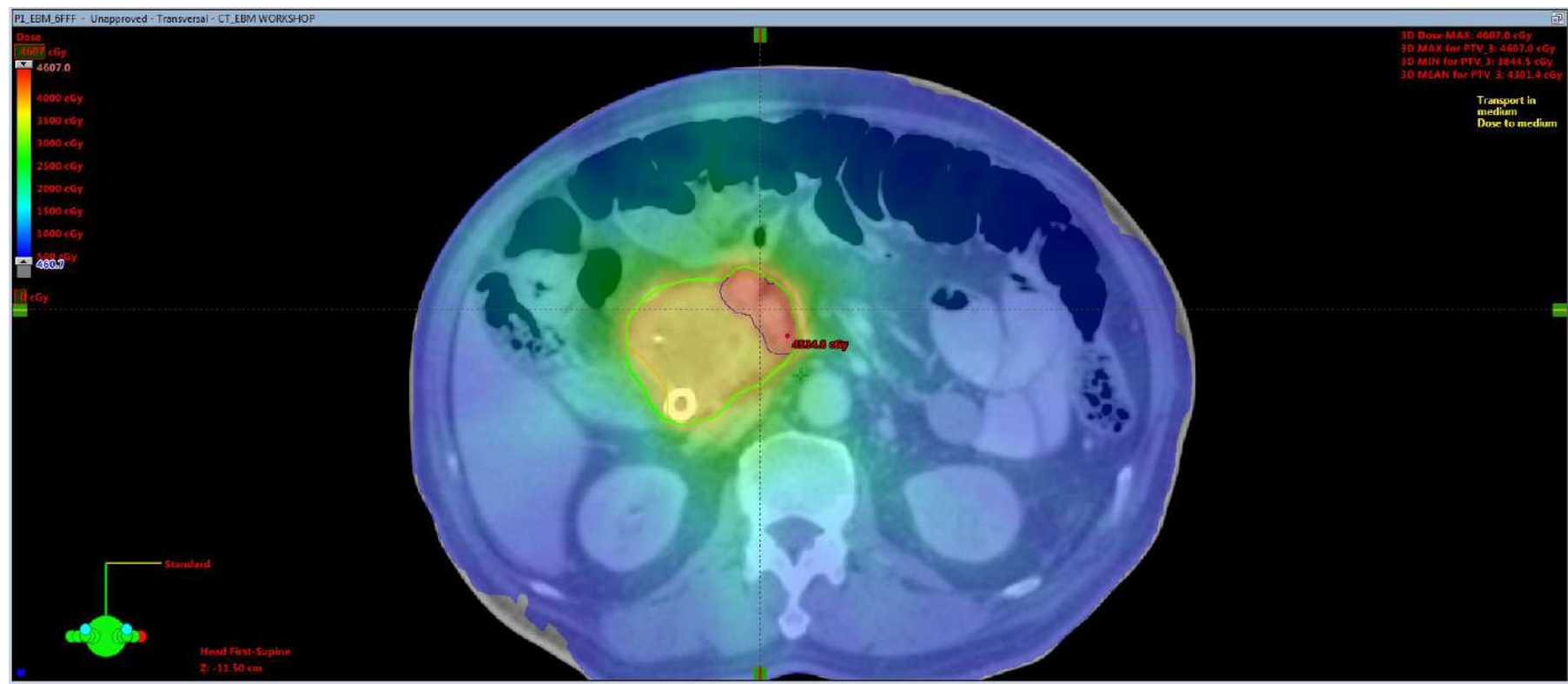
OAR constraints

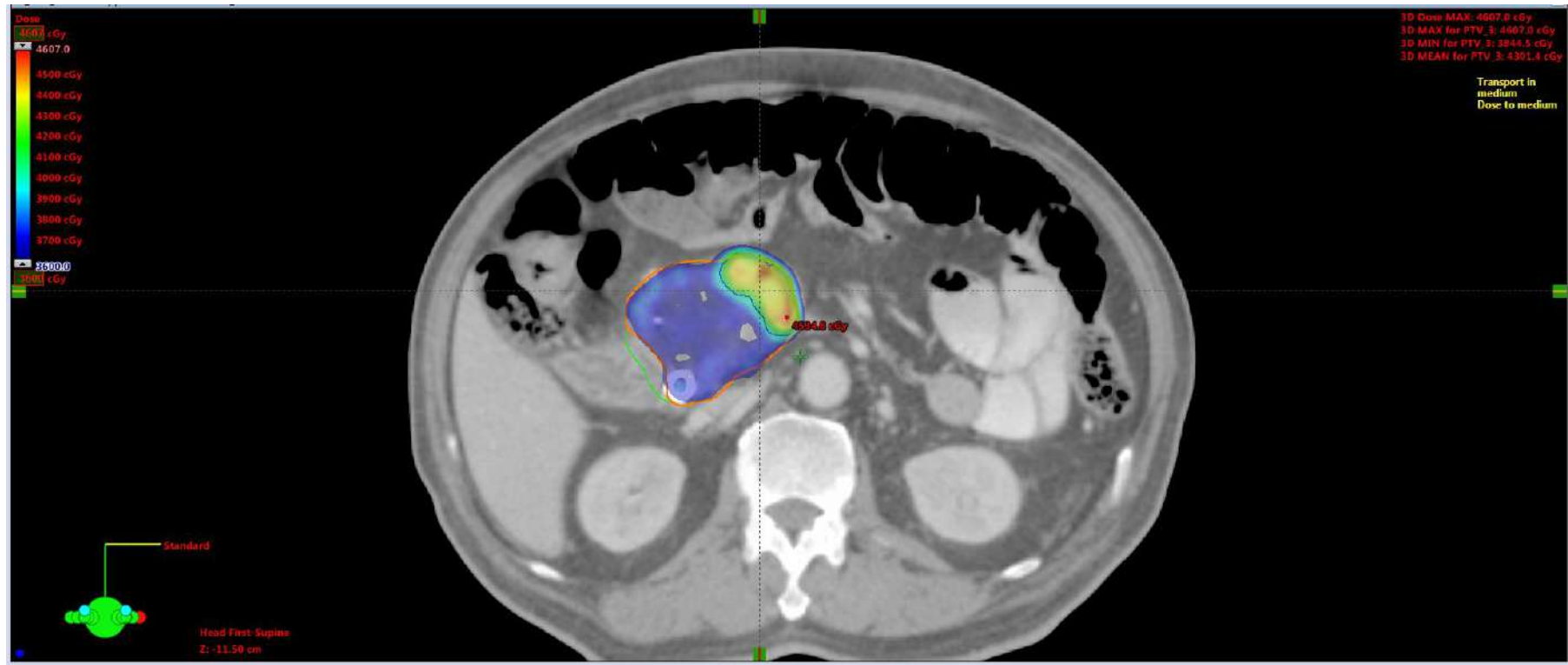
Duodenum Small bowel	V20 < 20 cc V35 < 1 cc* Dmax < 40Gy V20 < 20 cc
Stomach	V35 < 1 cc* Dmax < 40 Gy*
Kidneys	V12 < 25%*
Liver	V12 < 50%*
Spinal cord	V20 < 1cc*

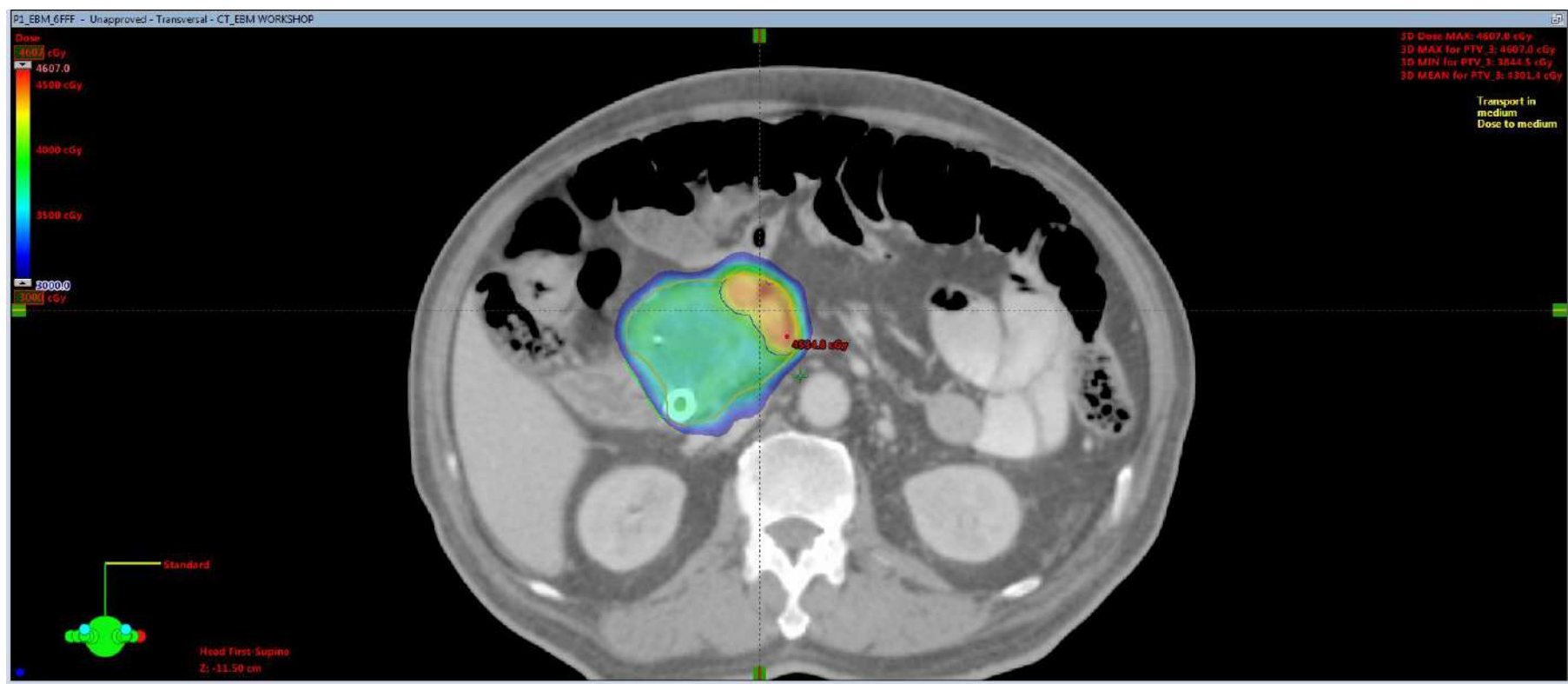
* Mandatory constraints

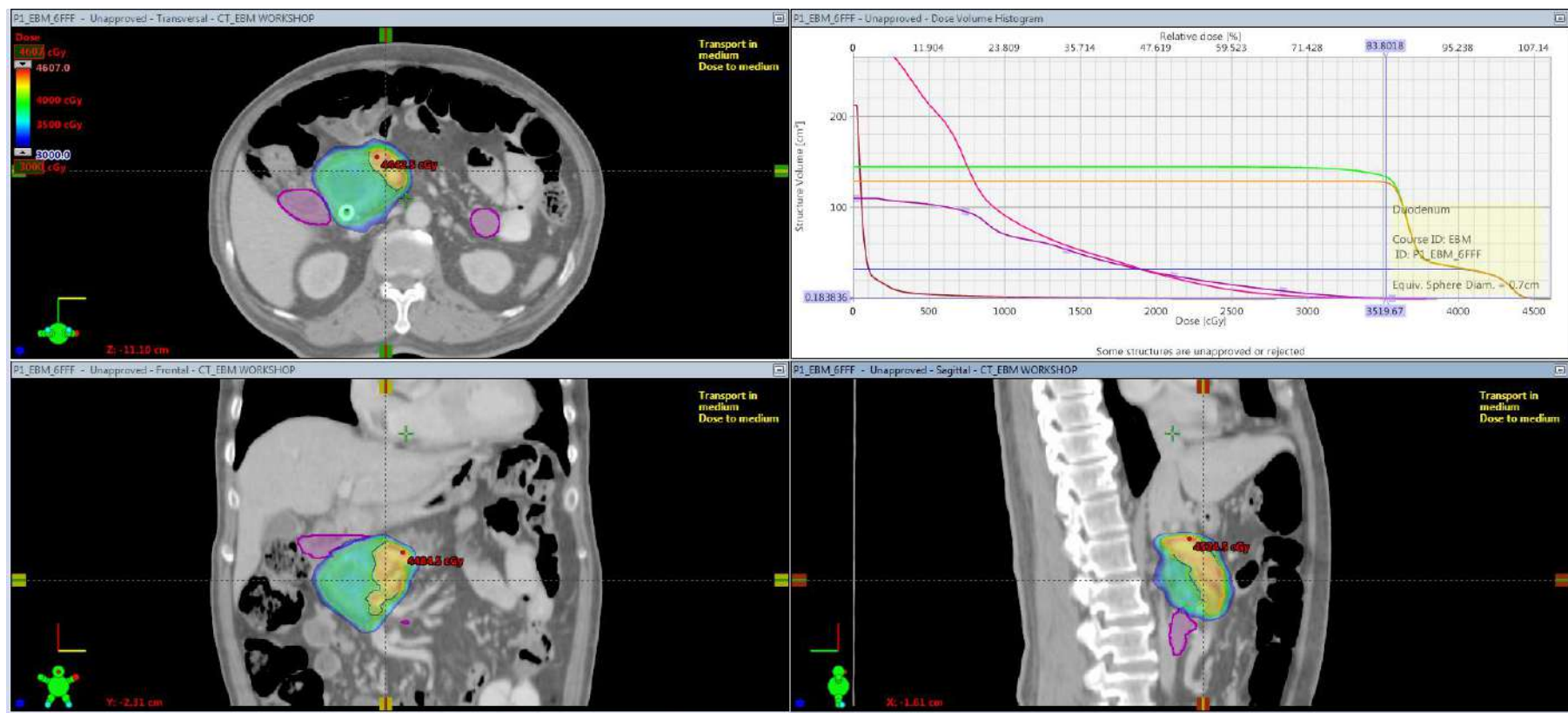




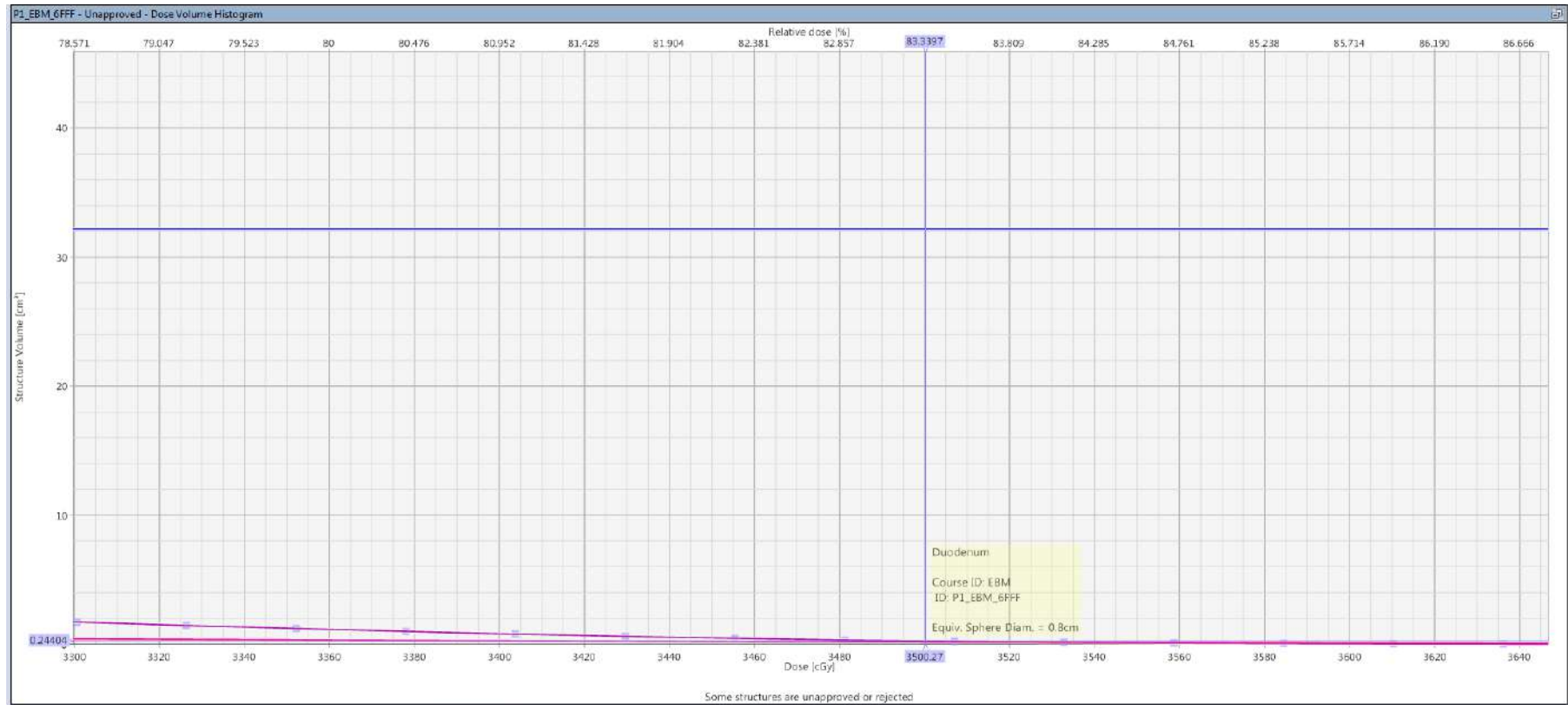




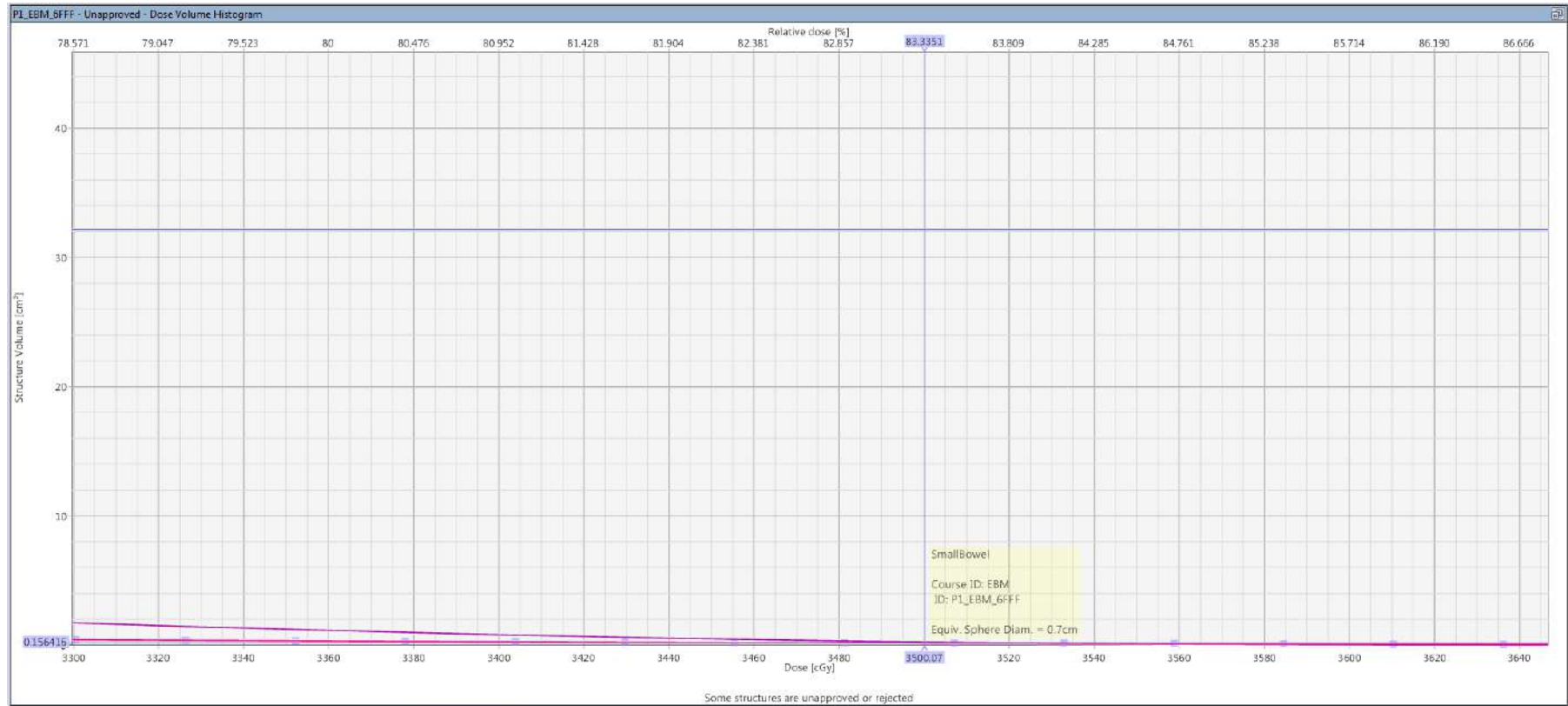




V 35 Duodenum <1cc



V 35 Bowel <1cc



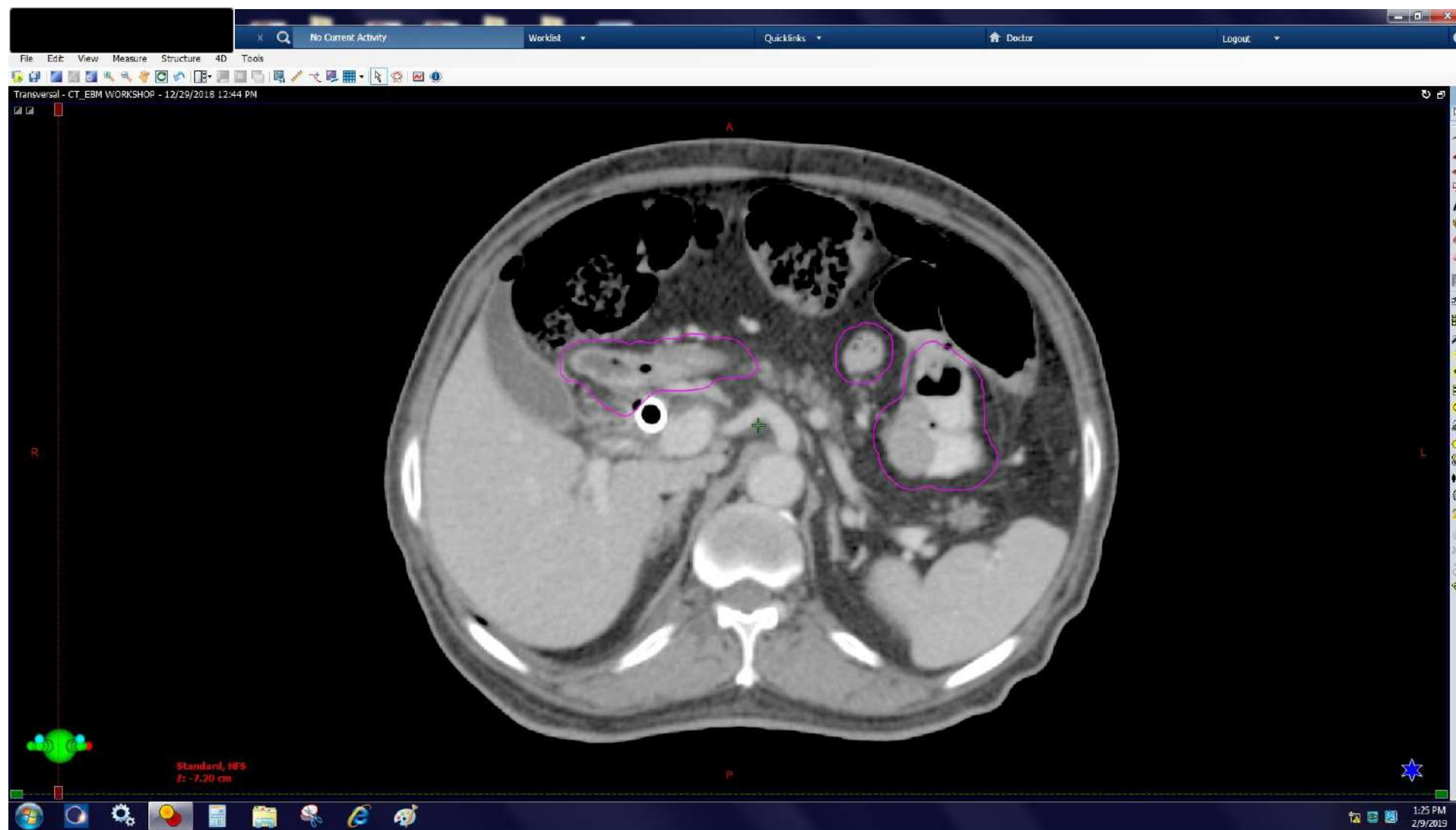
CASE 1

68Y/male, diabetic

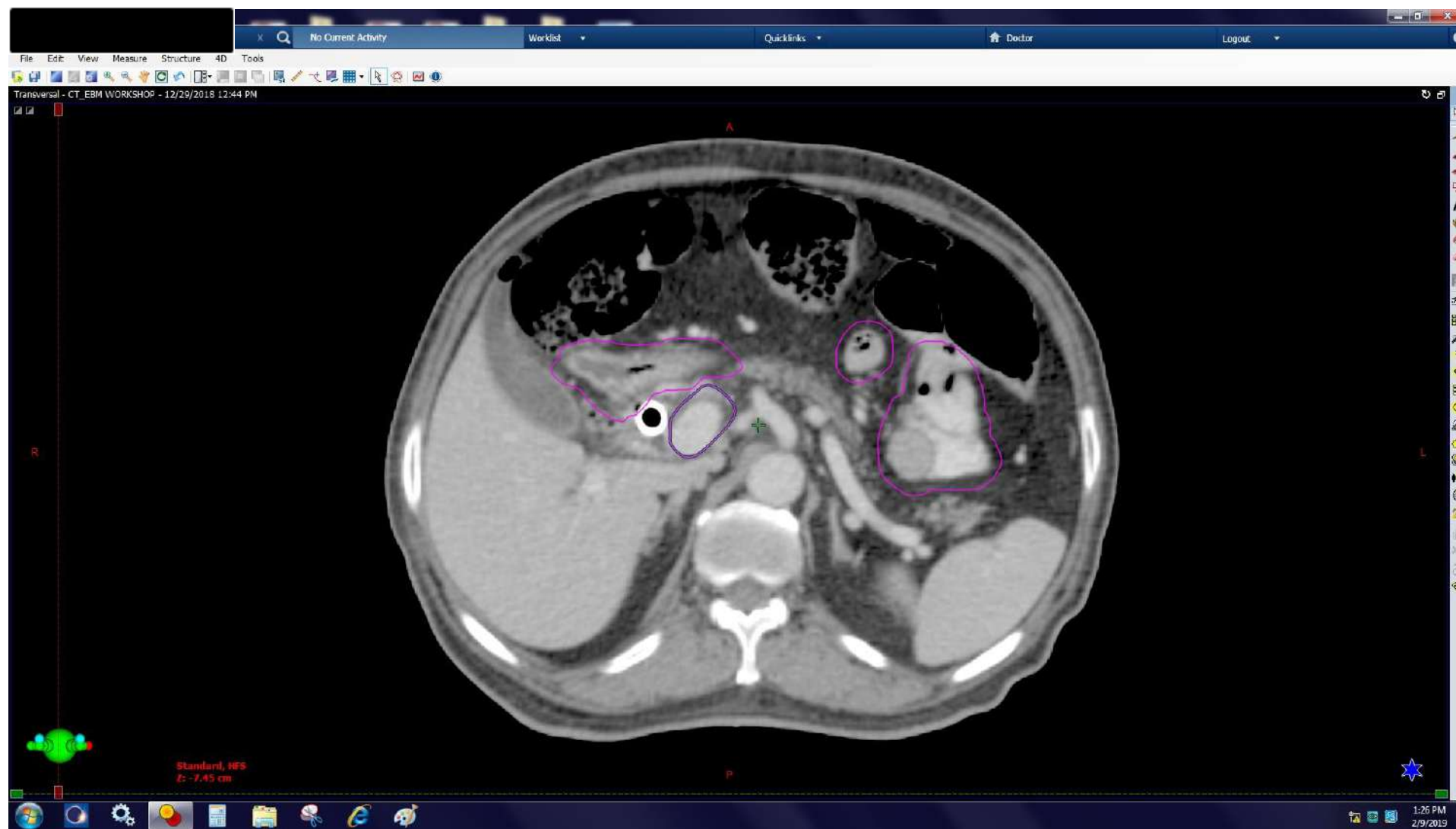
BRPC (Portal vein, SMV and SMA abutment)

Post 2 cycles Gemcitabine + Nab Paclitaxel

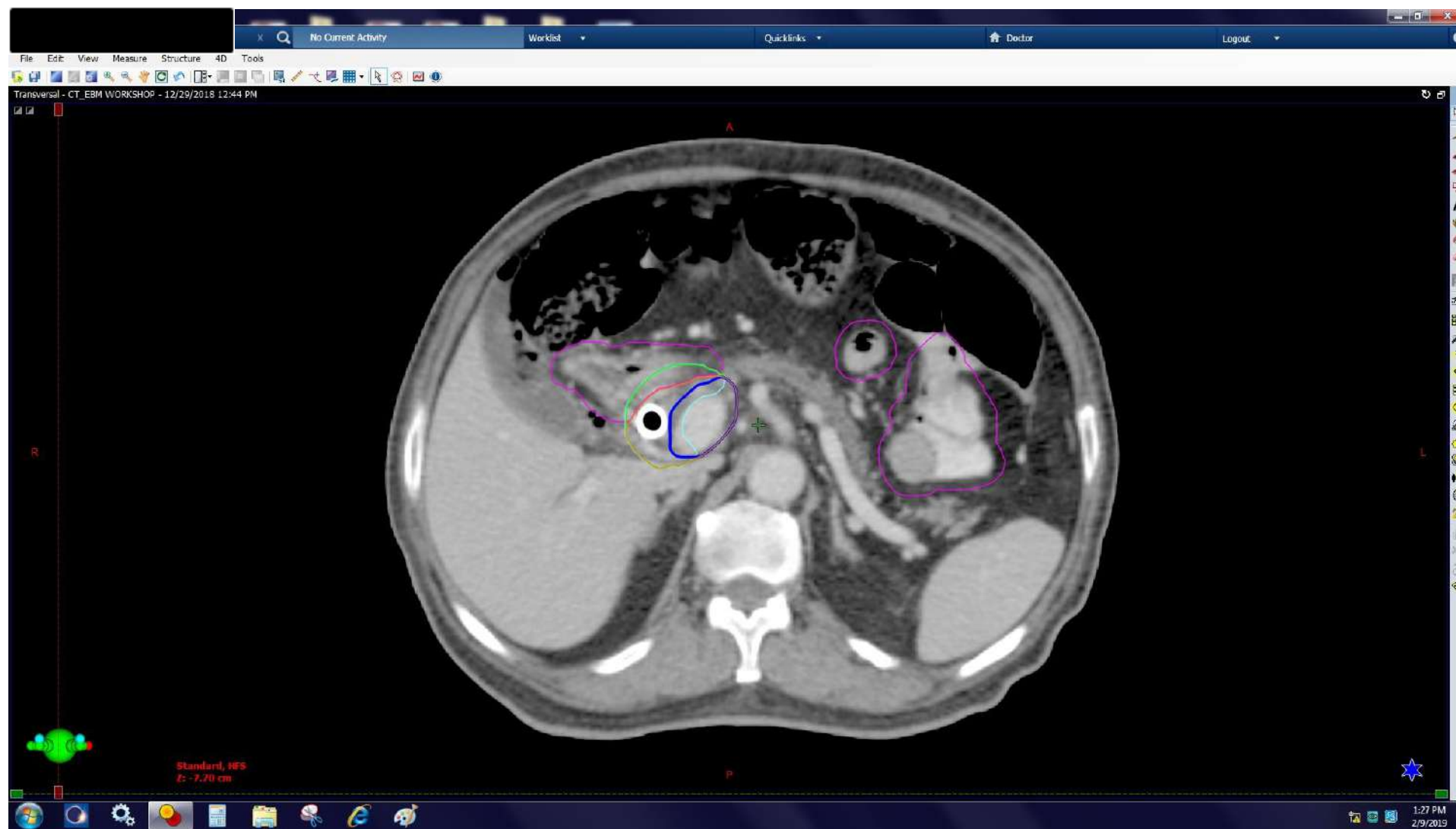




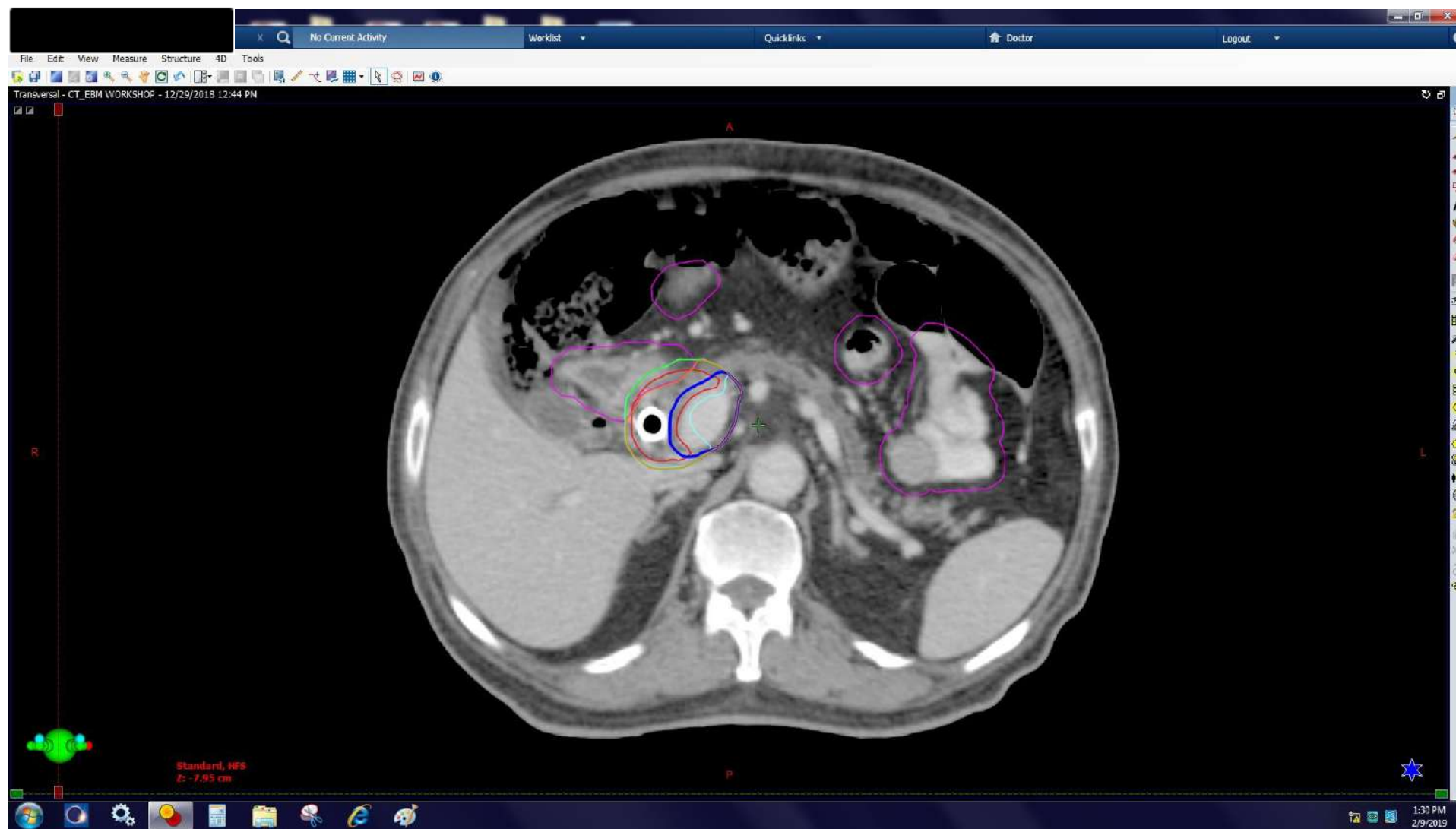
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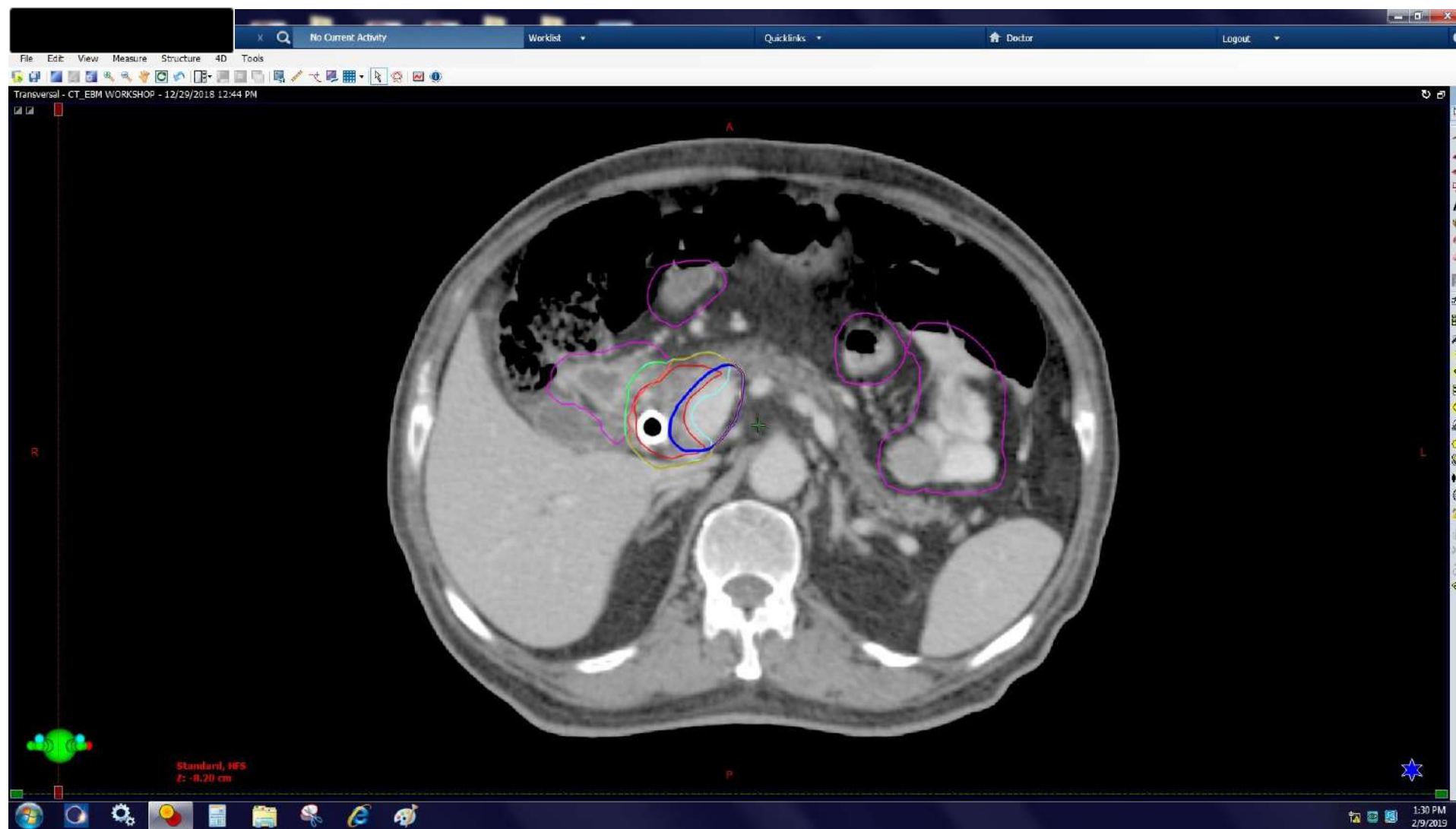
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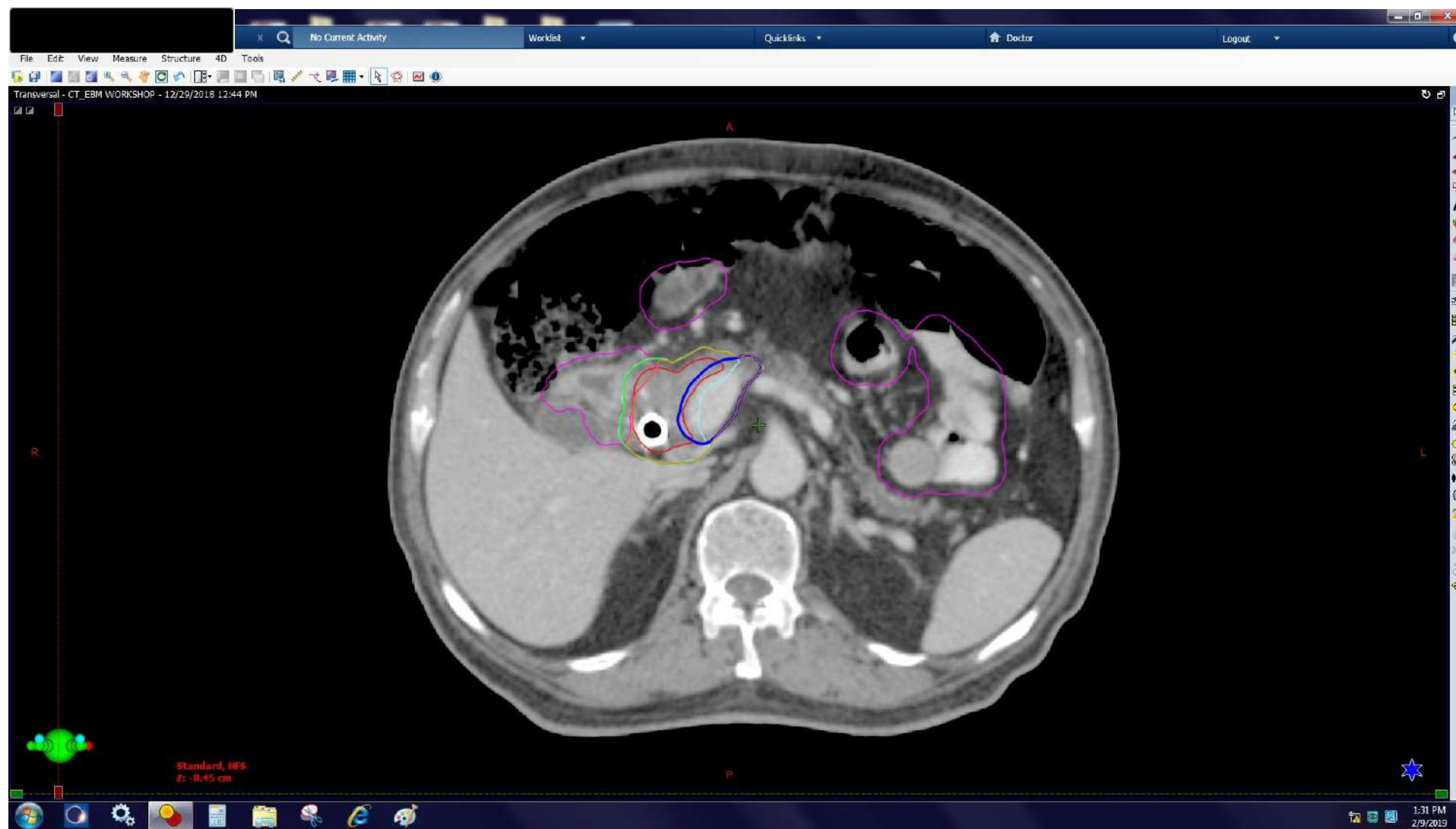
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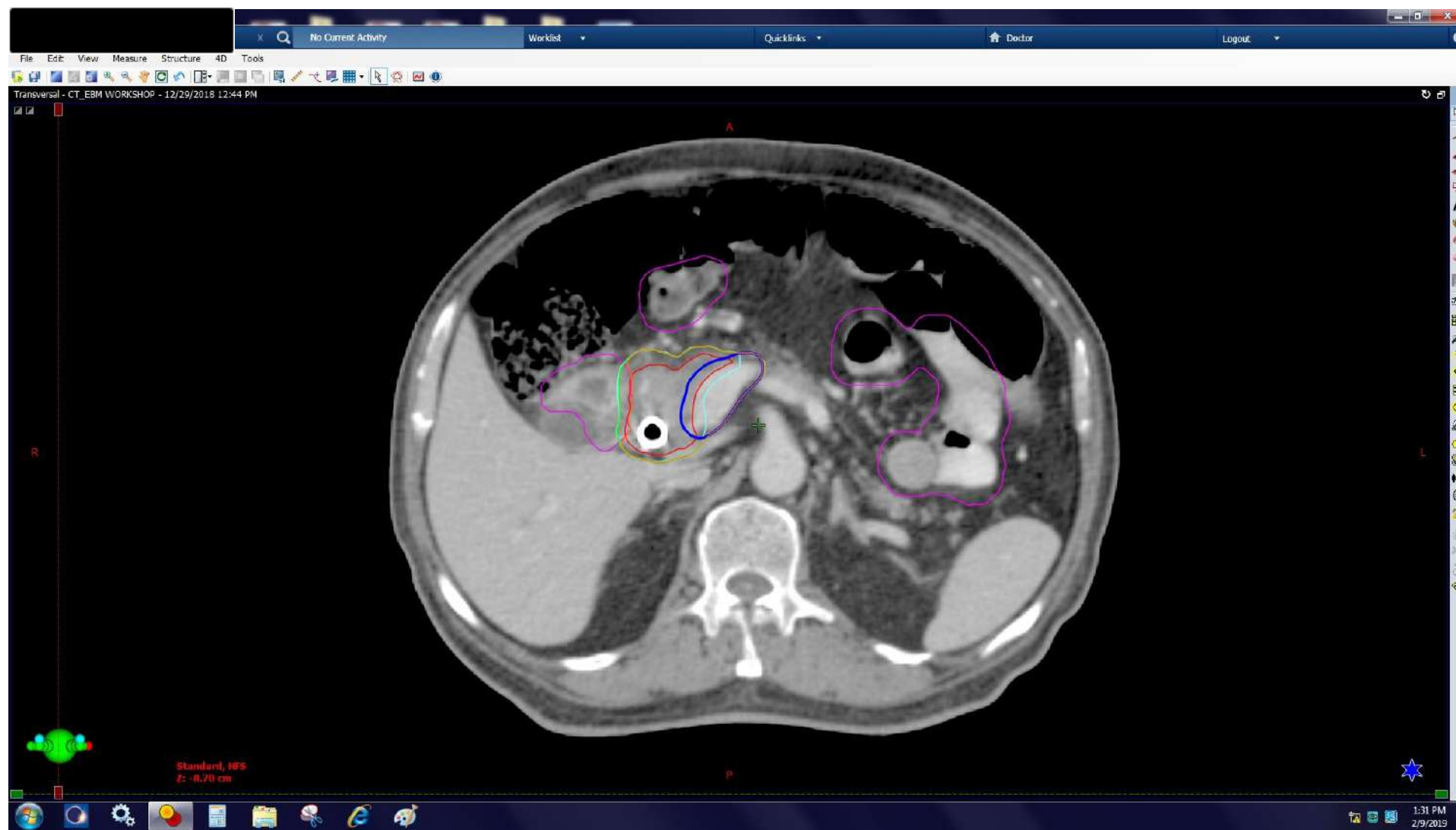
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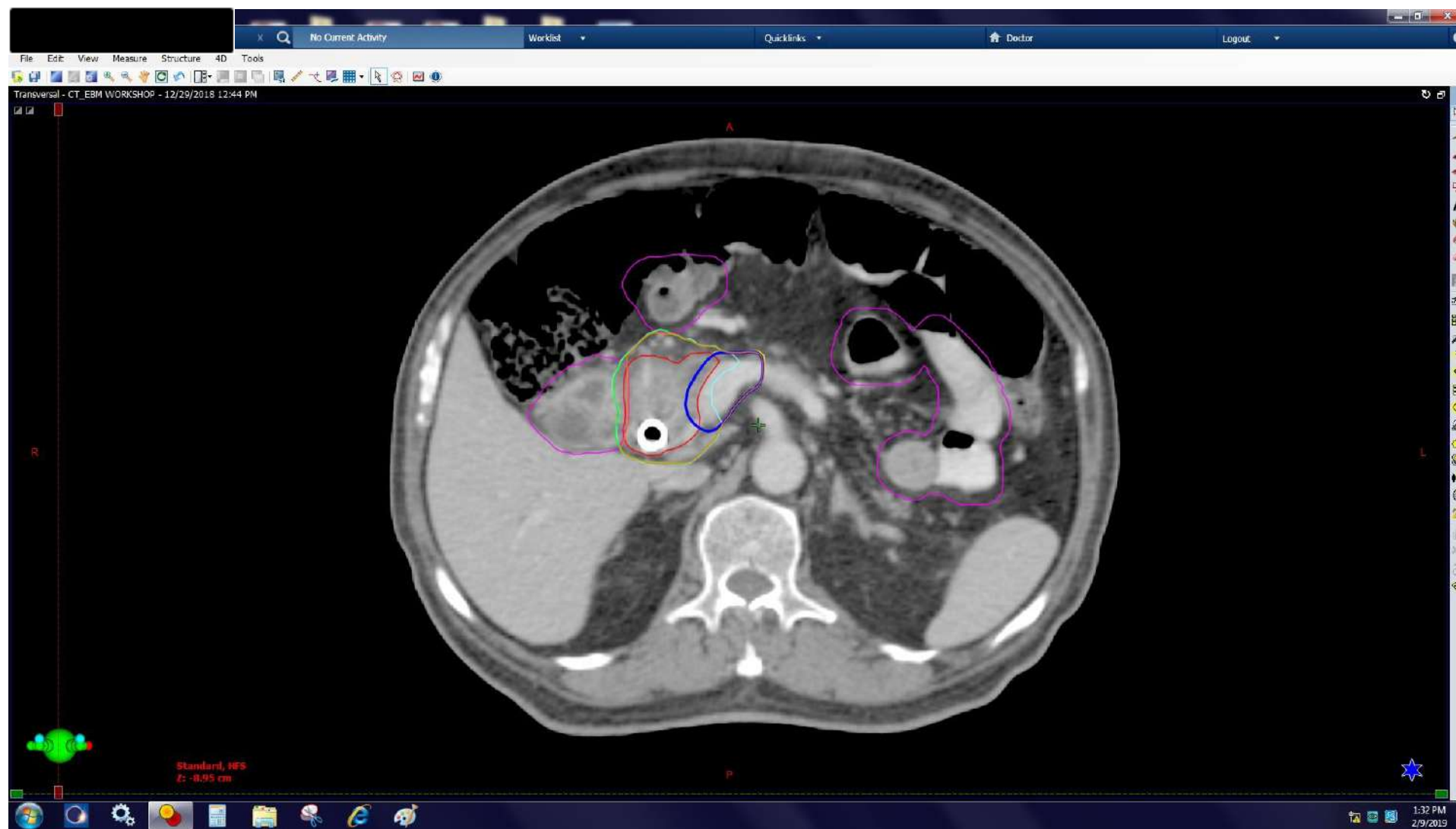
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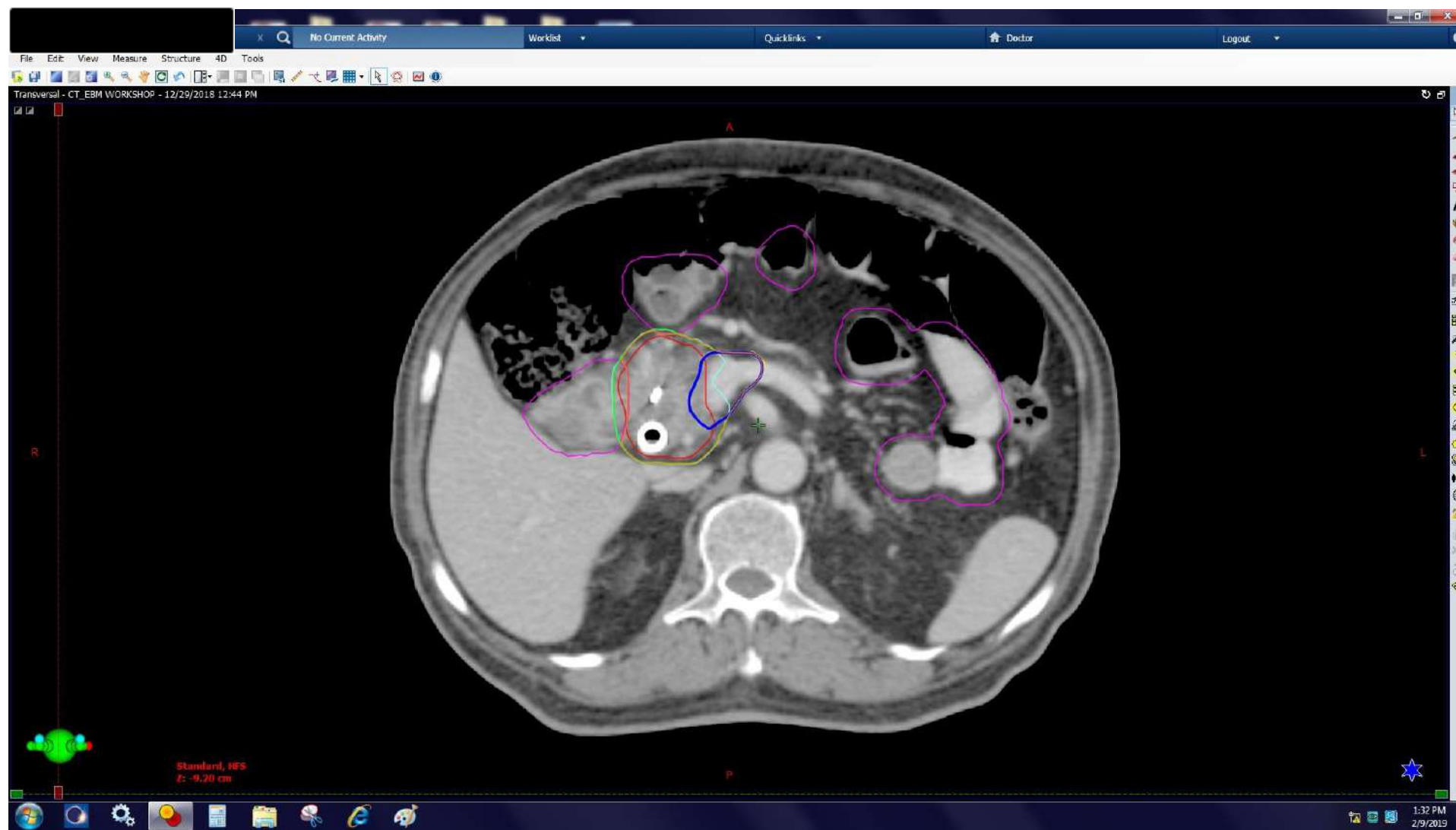
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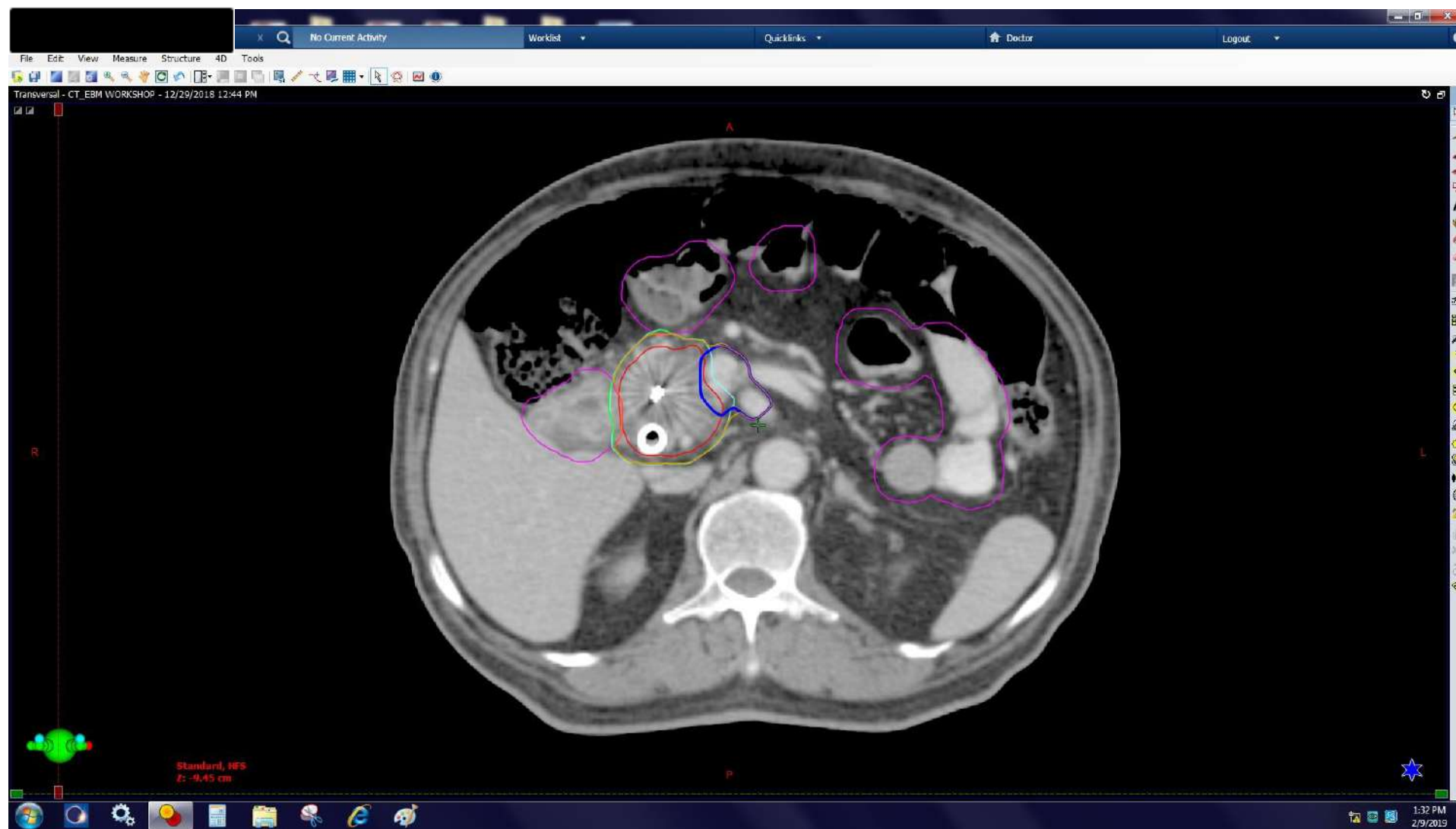
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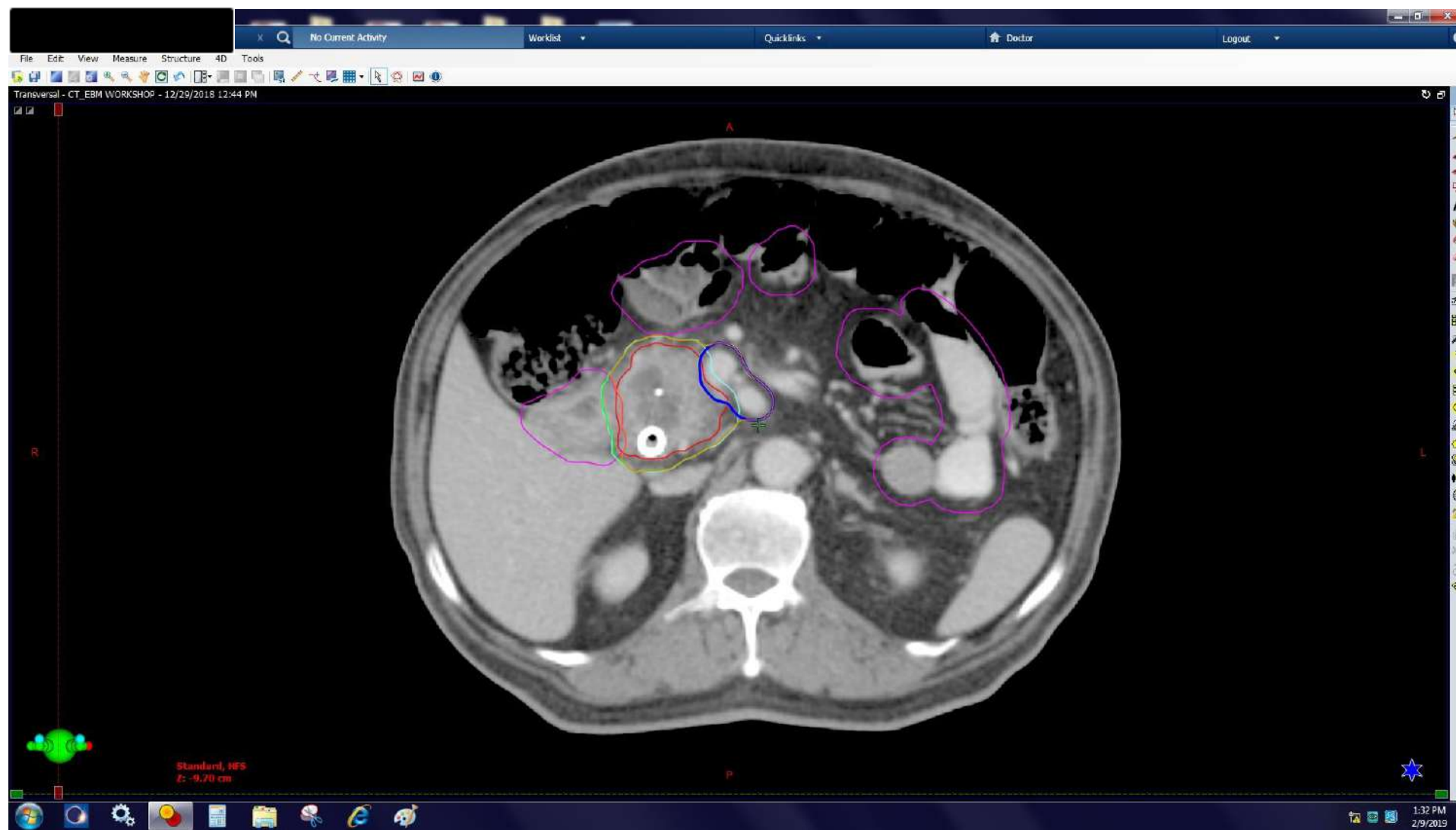
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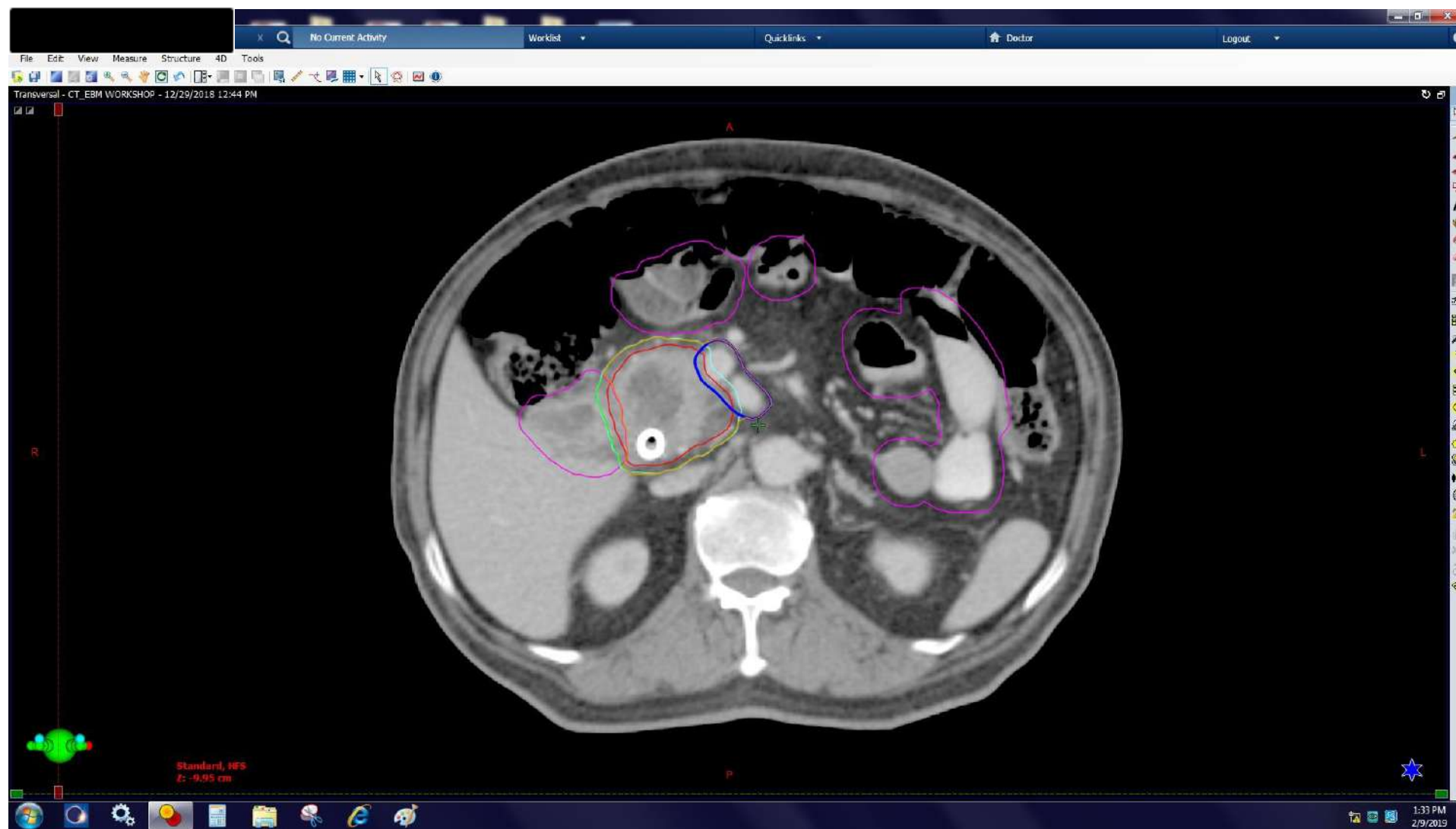
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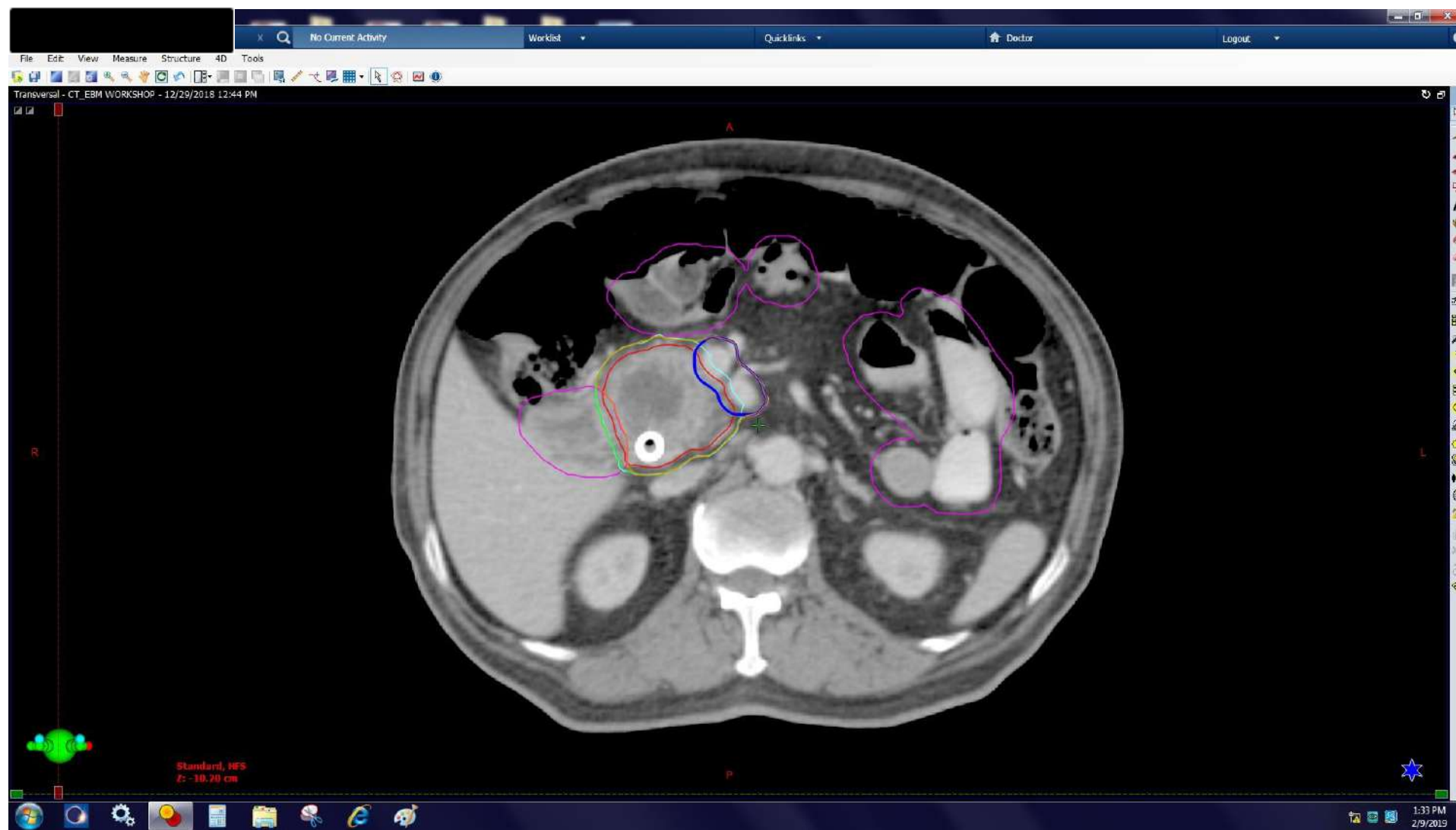
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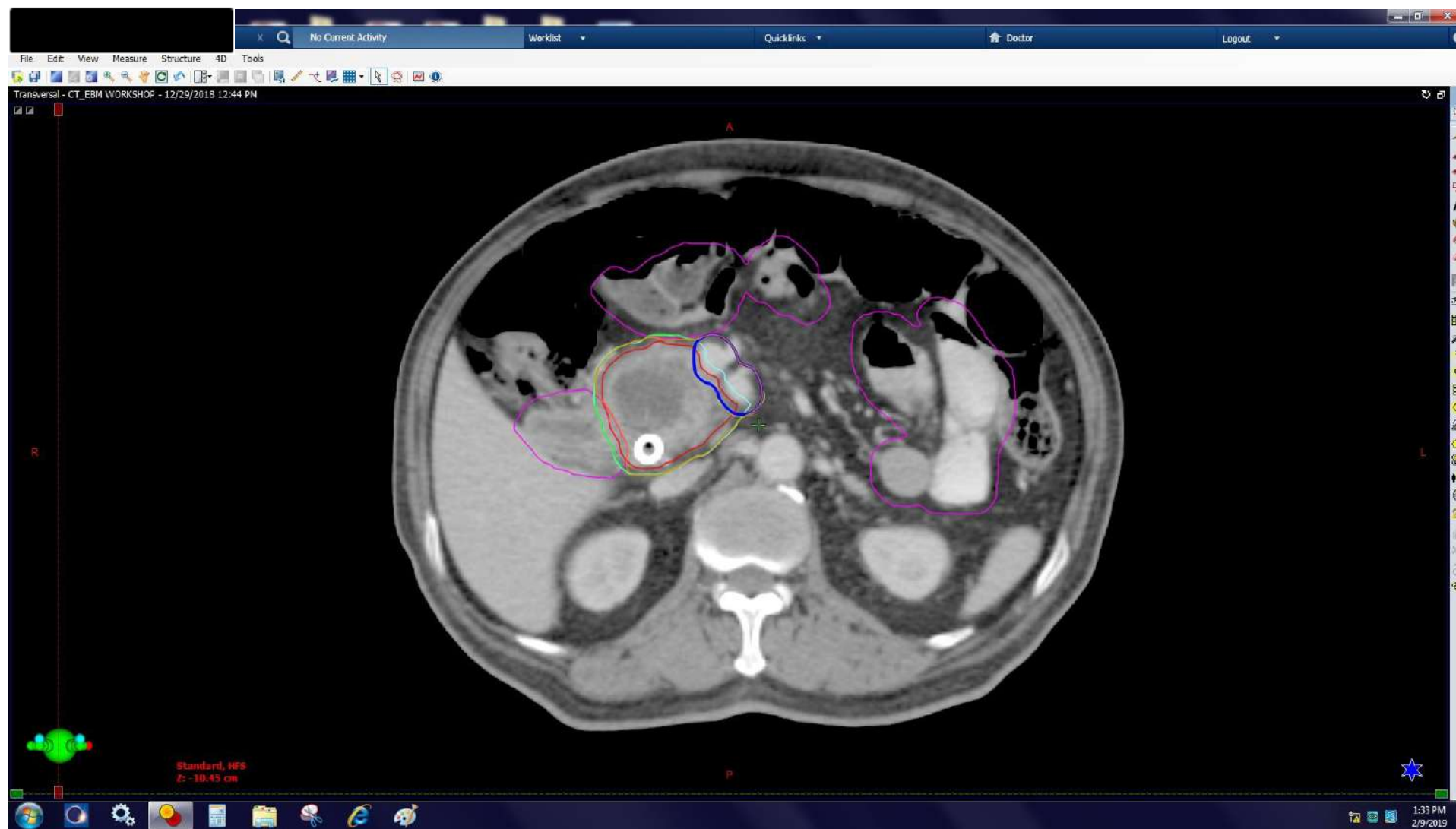
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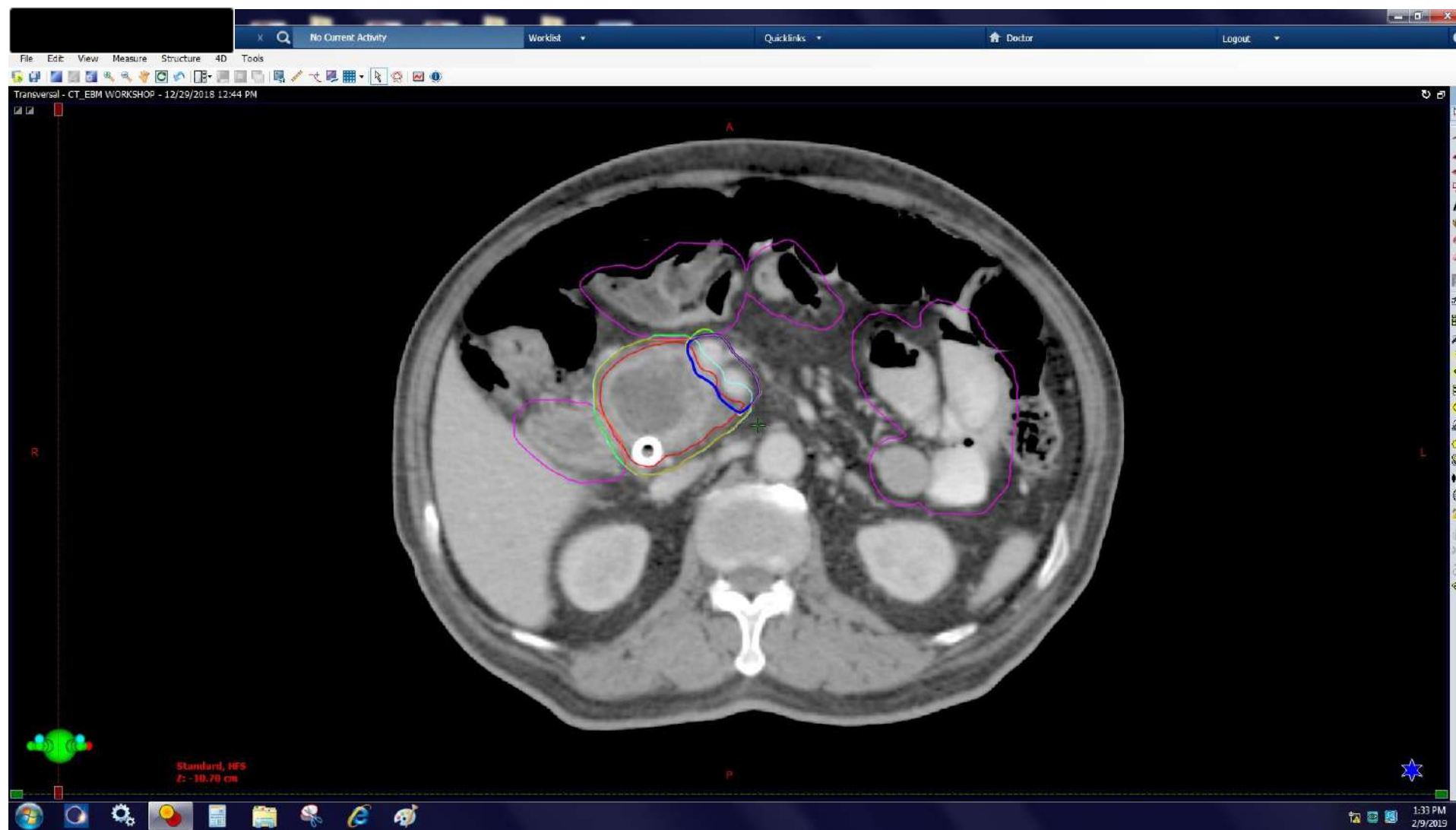
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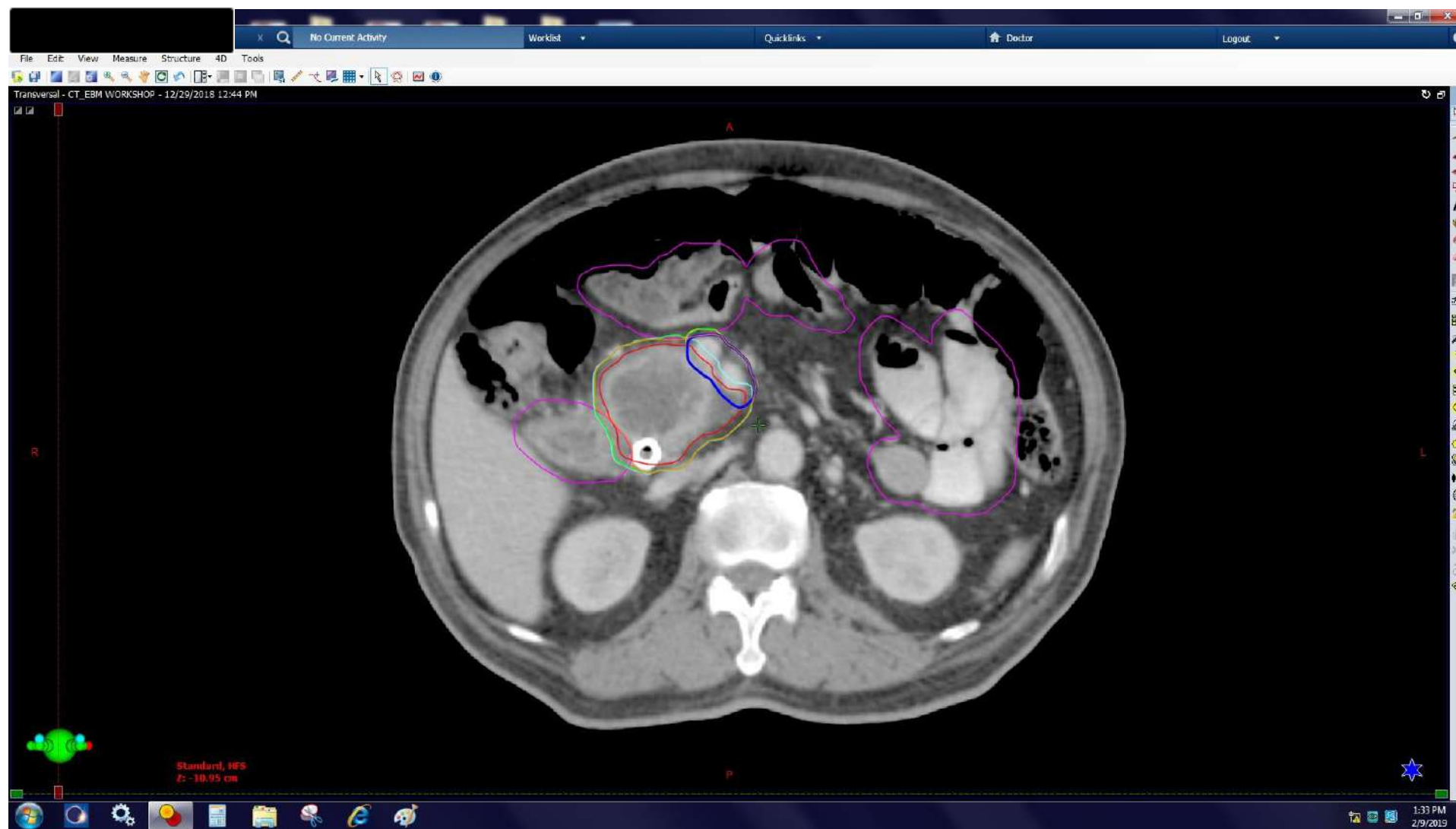
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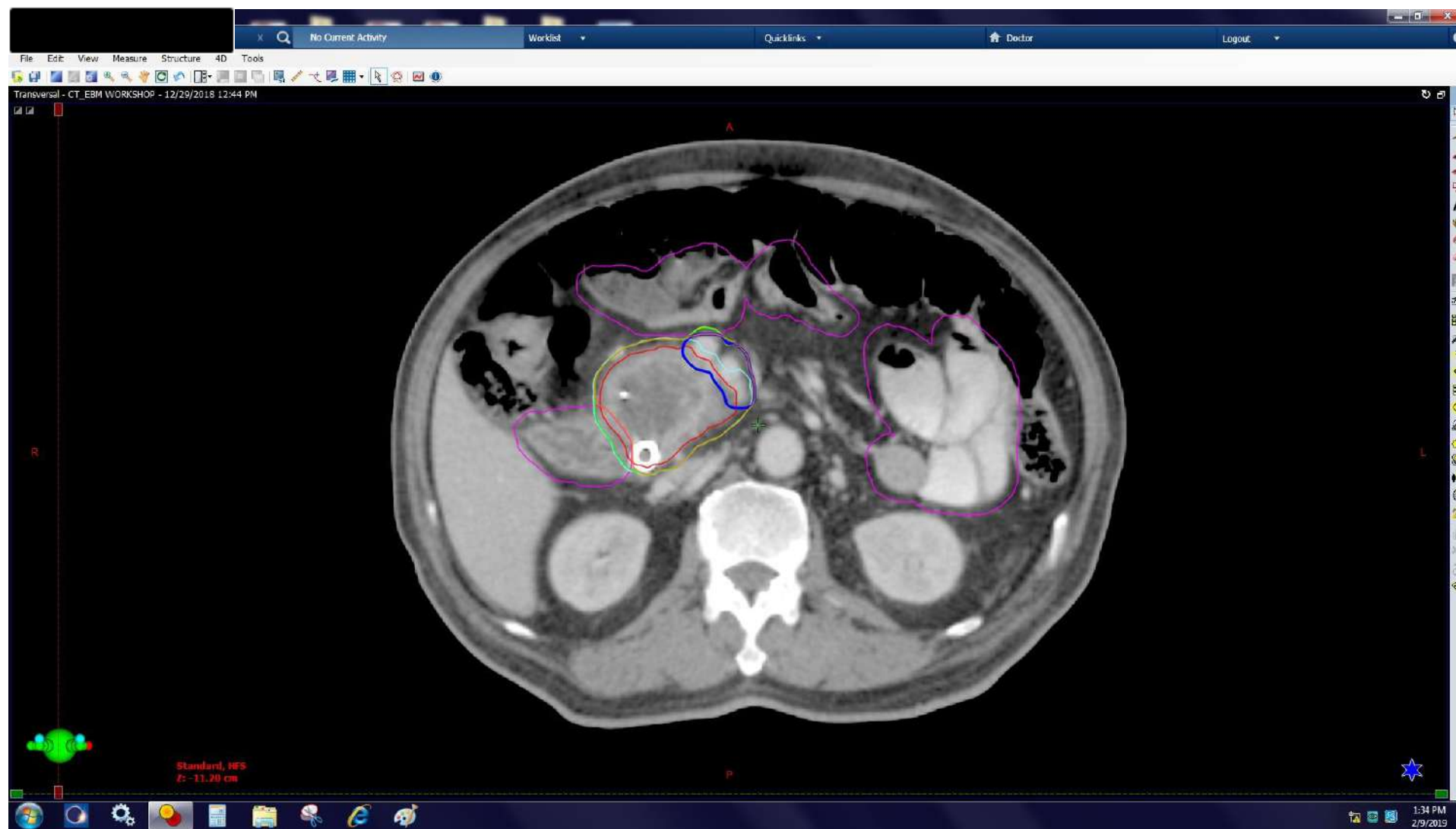
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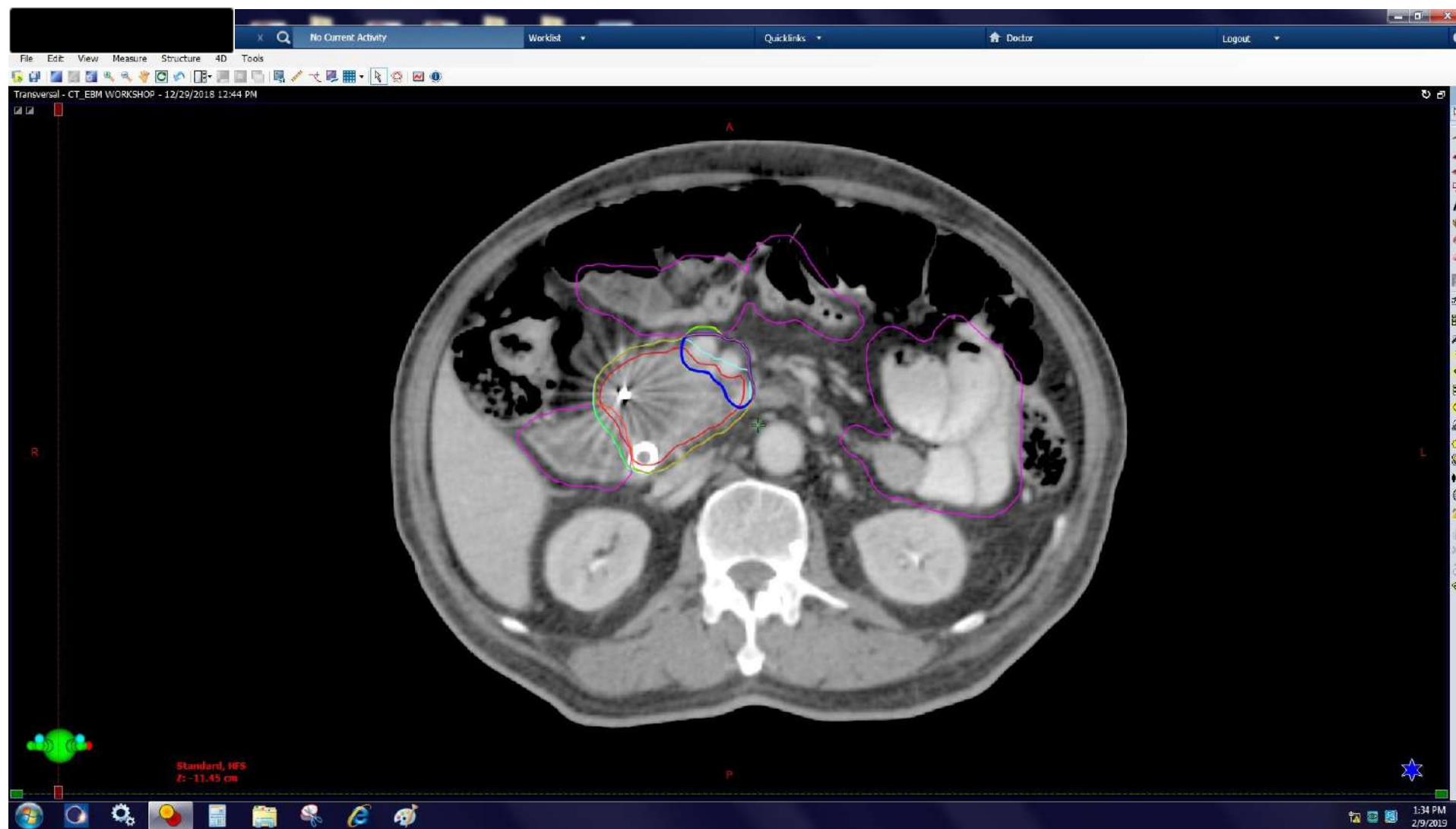
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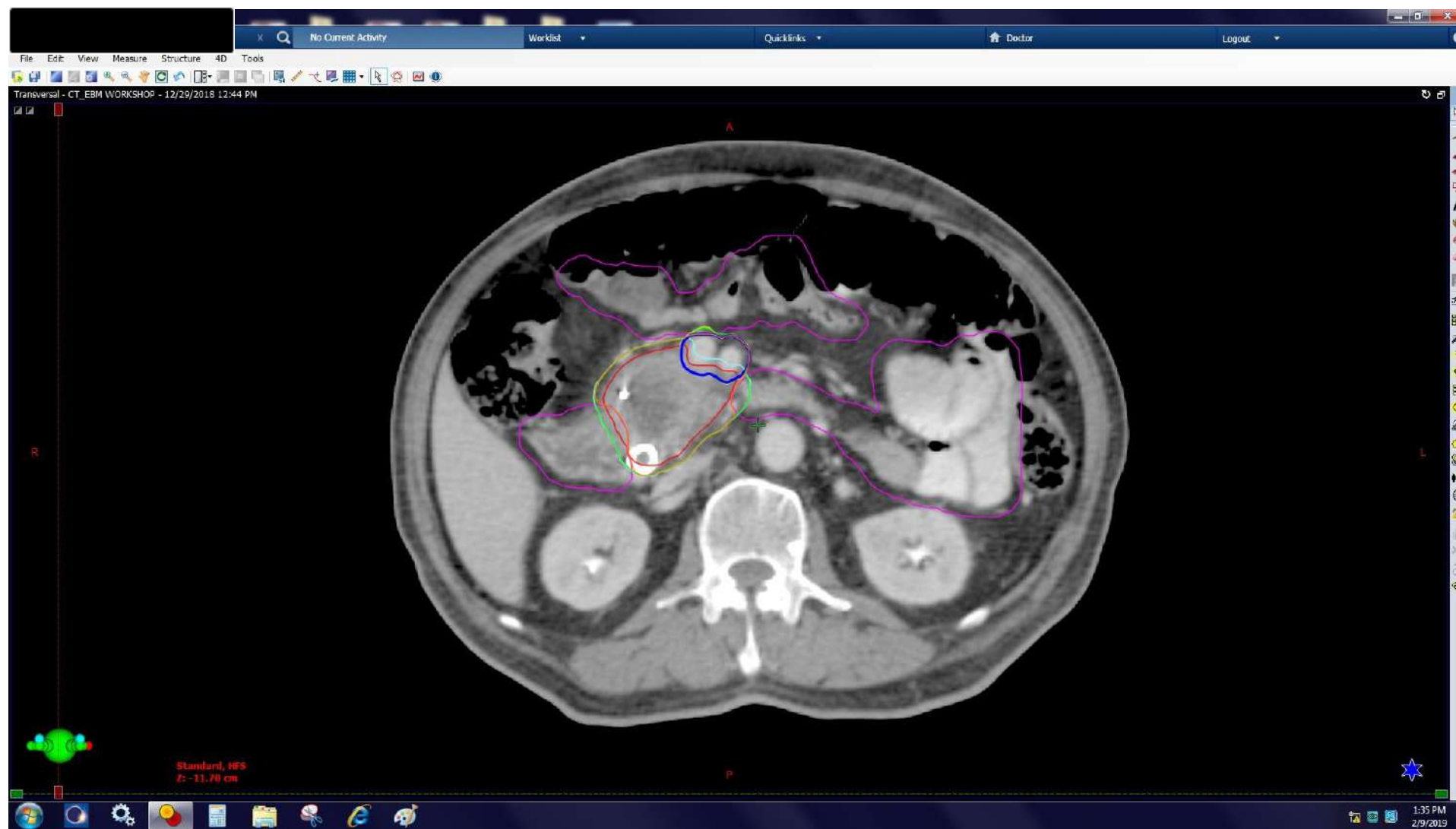
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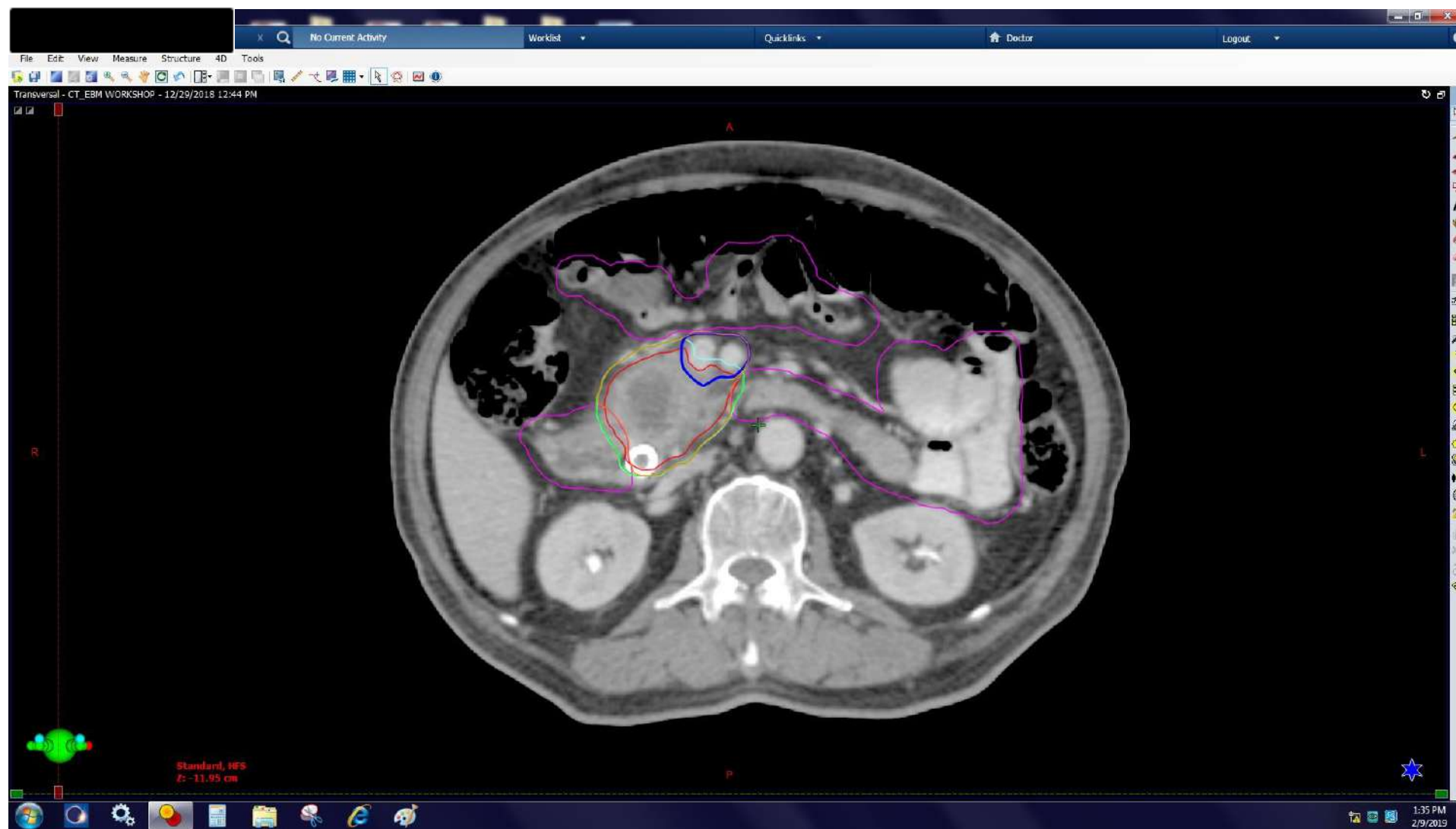
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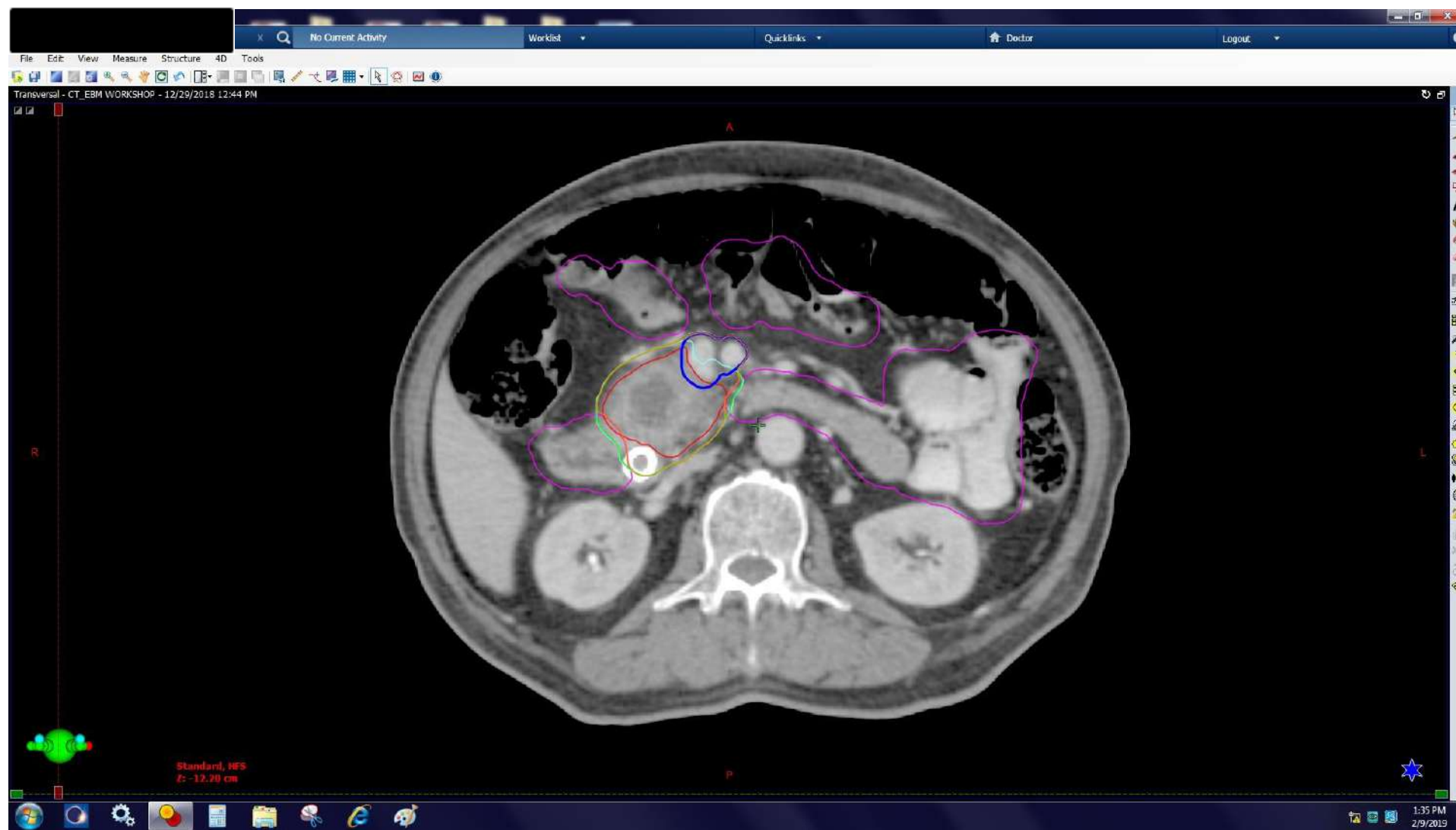
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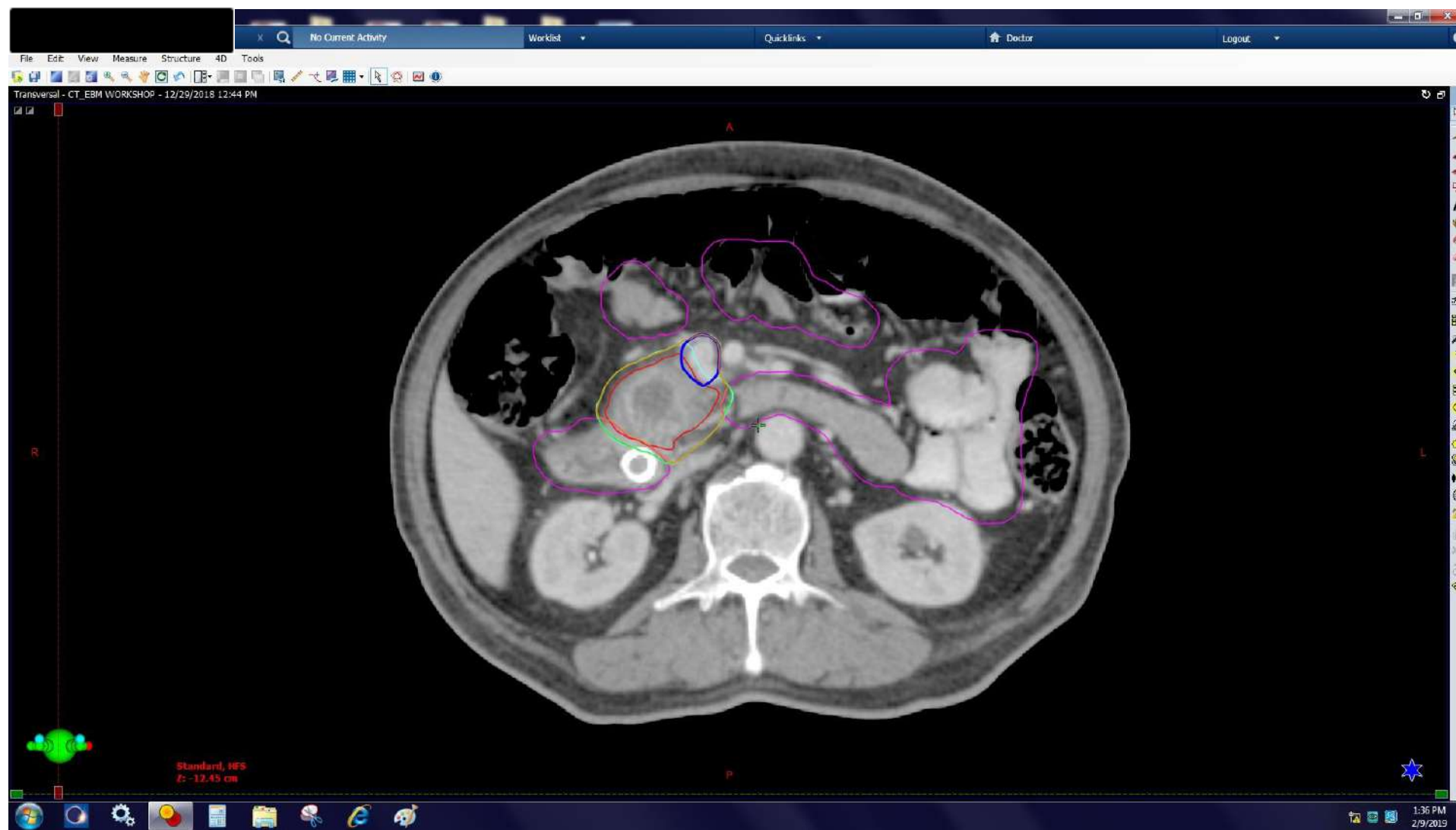
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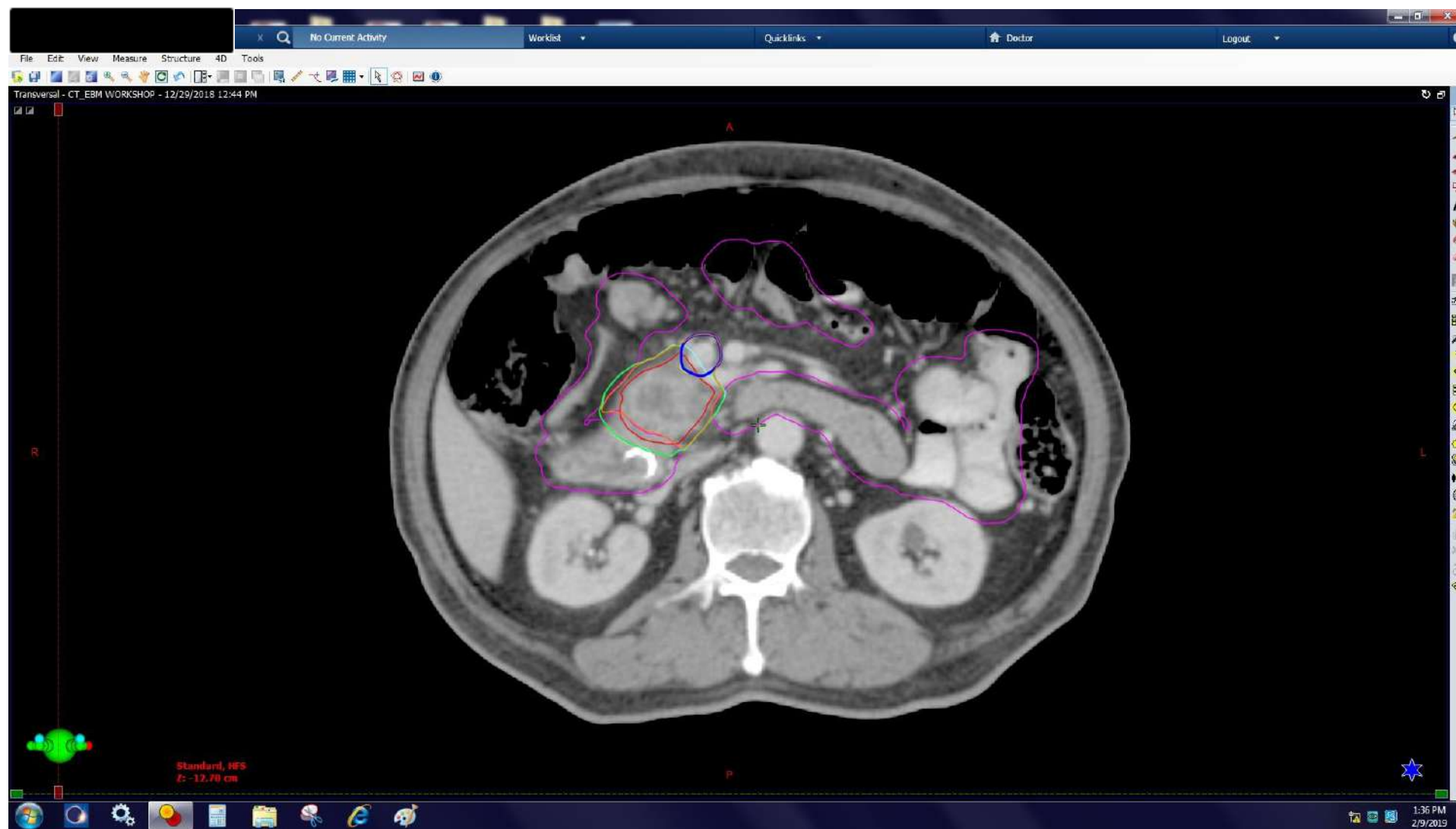
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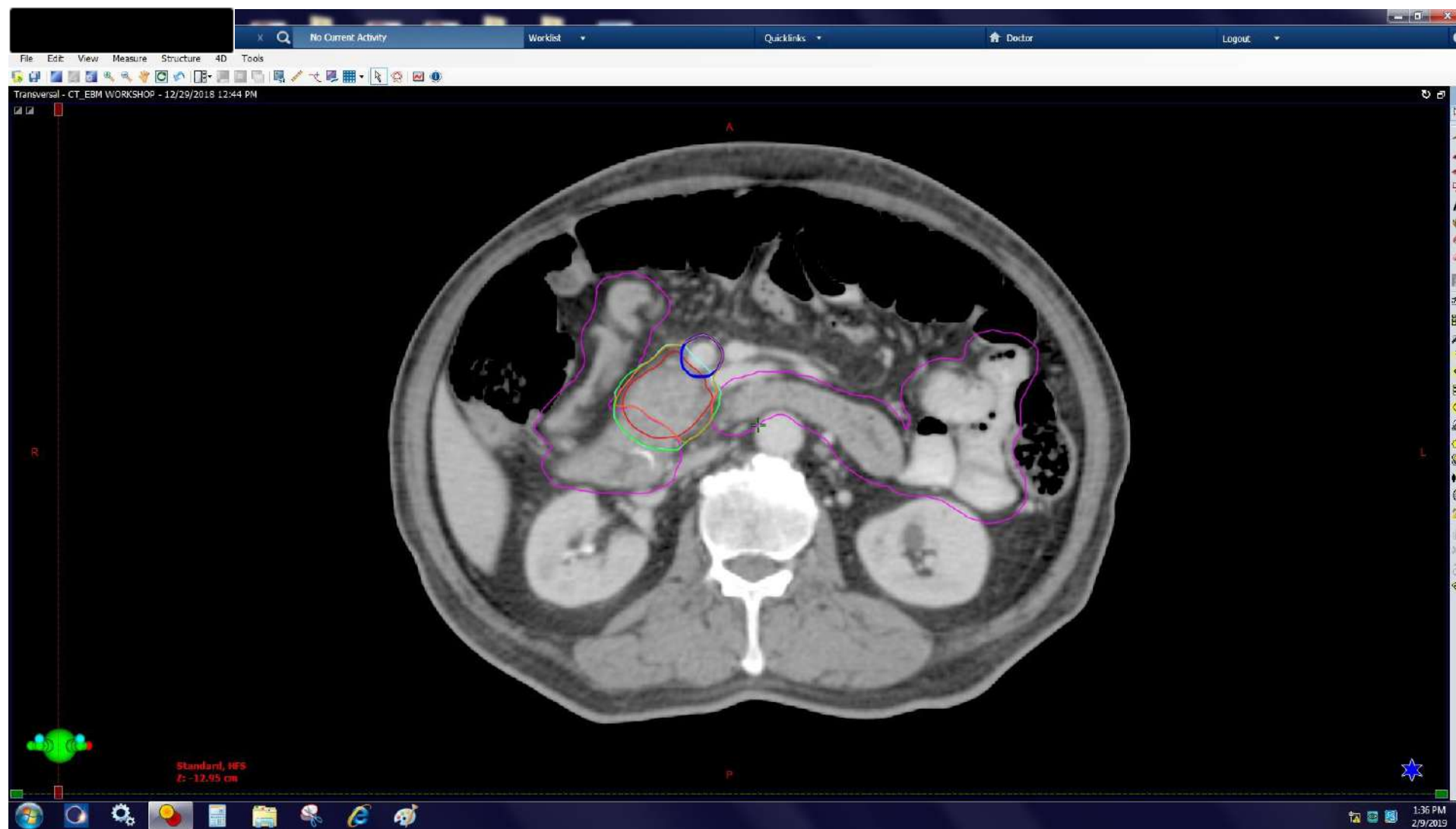
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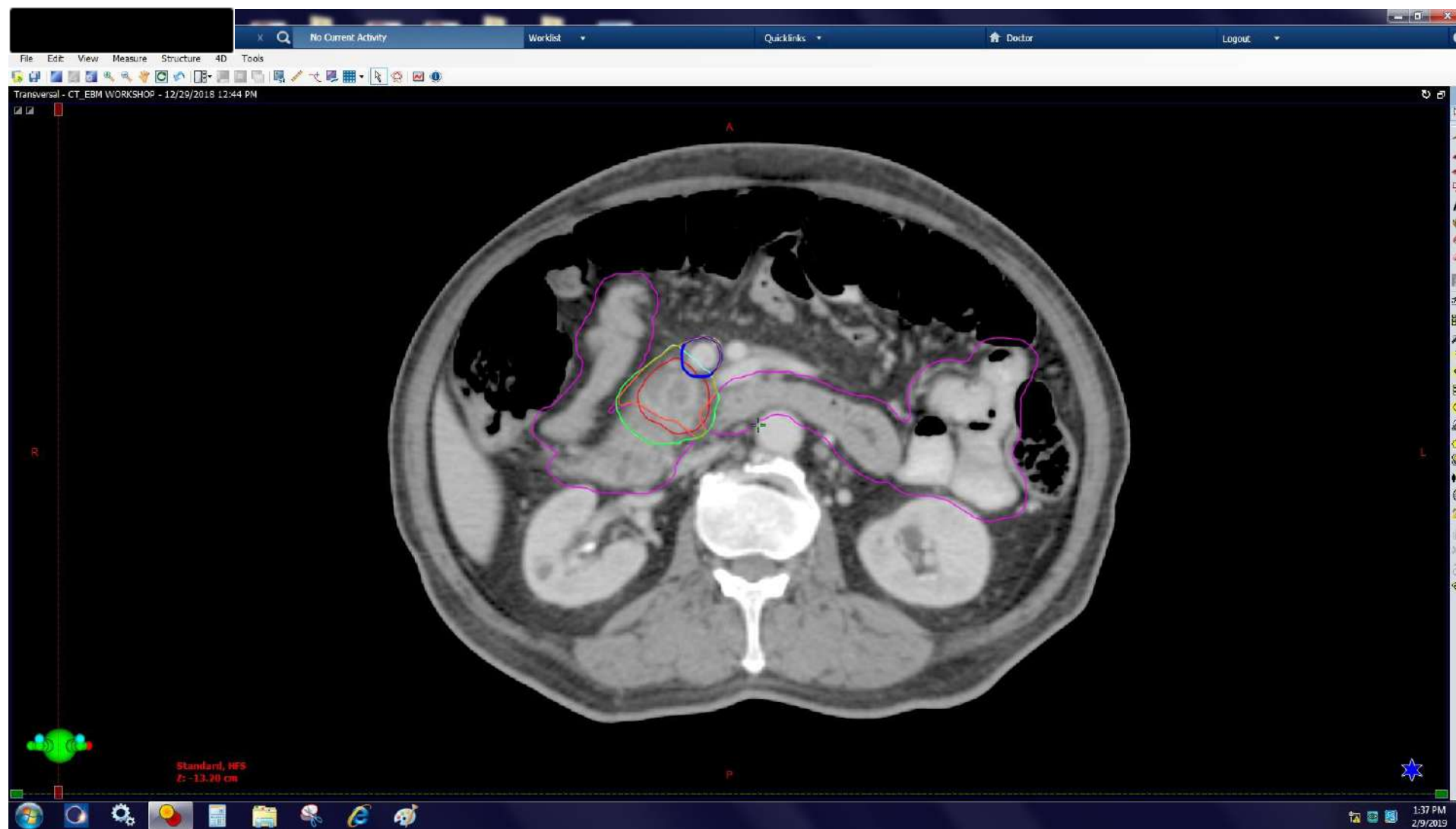
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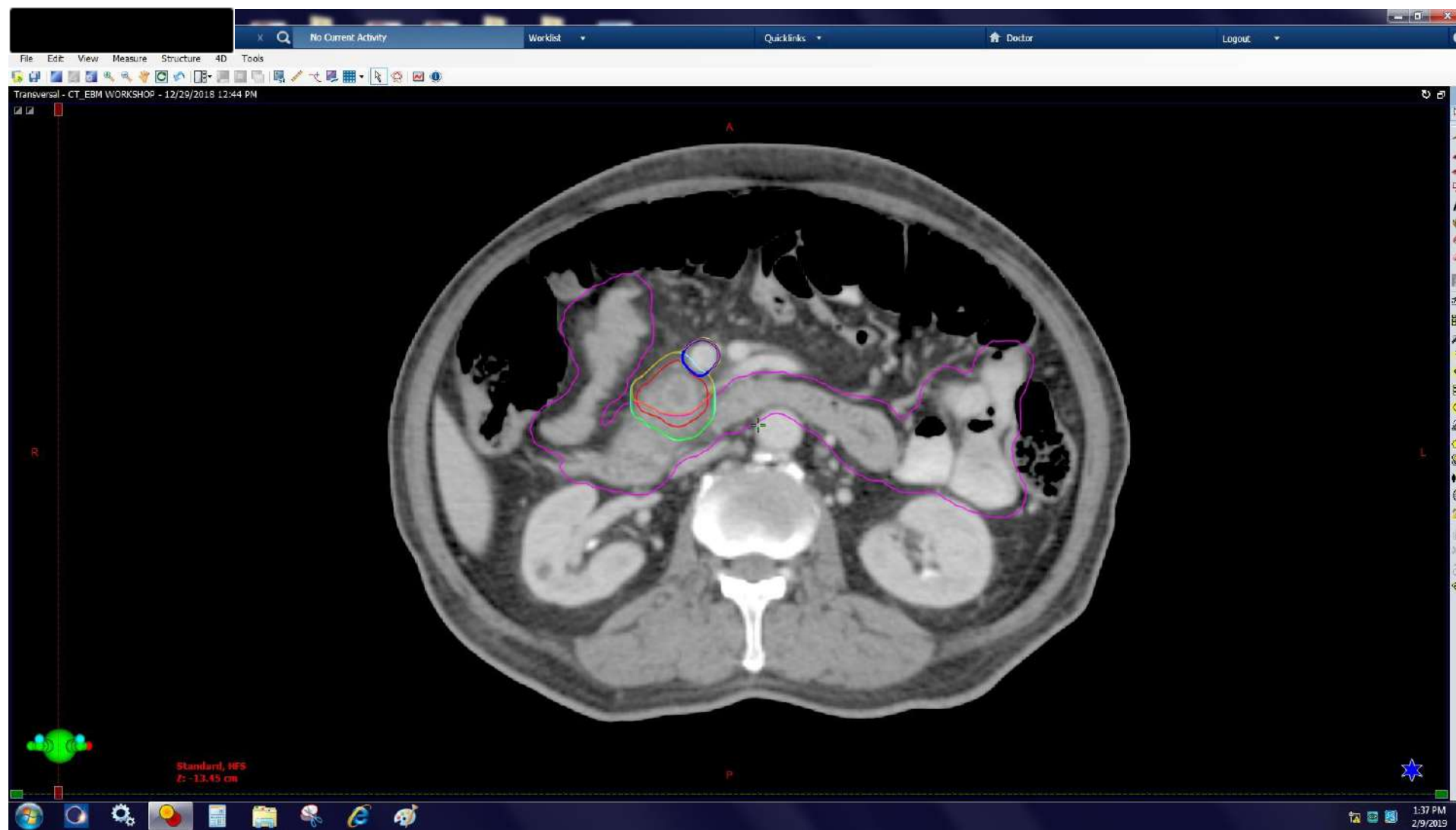
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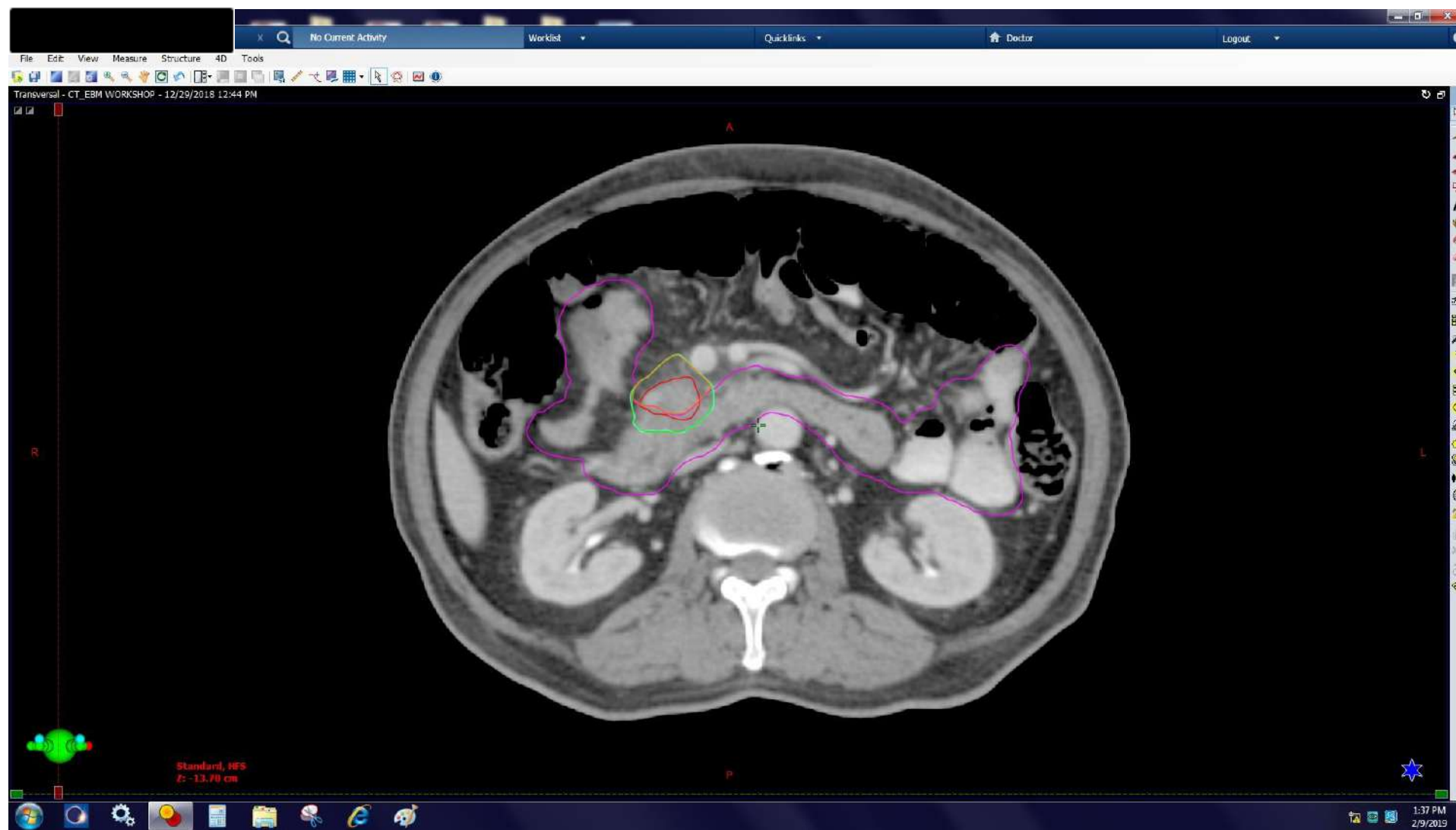
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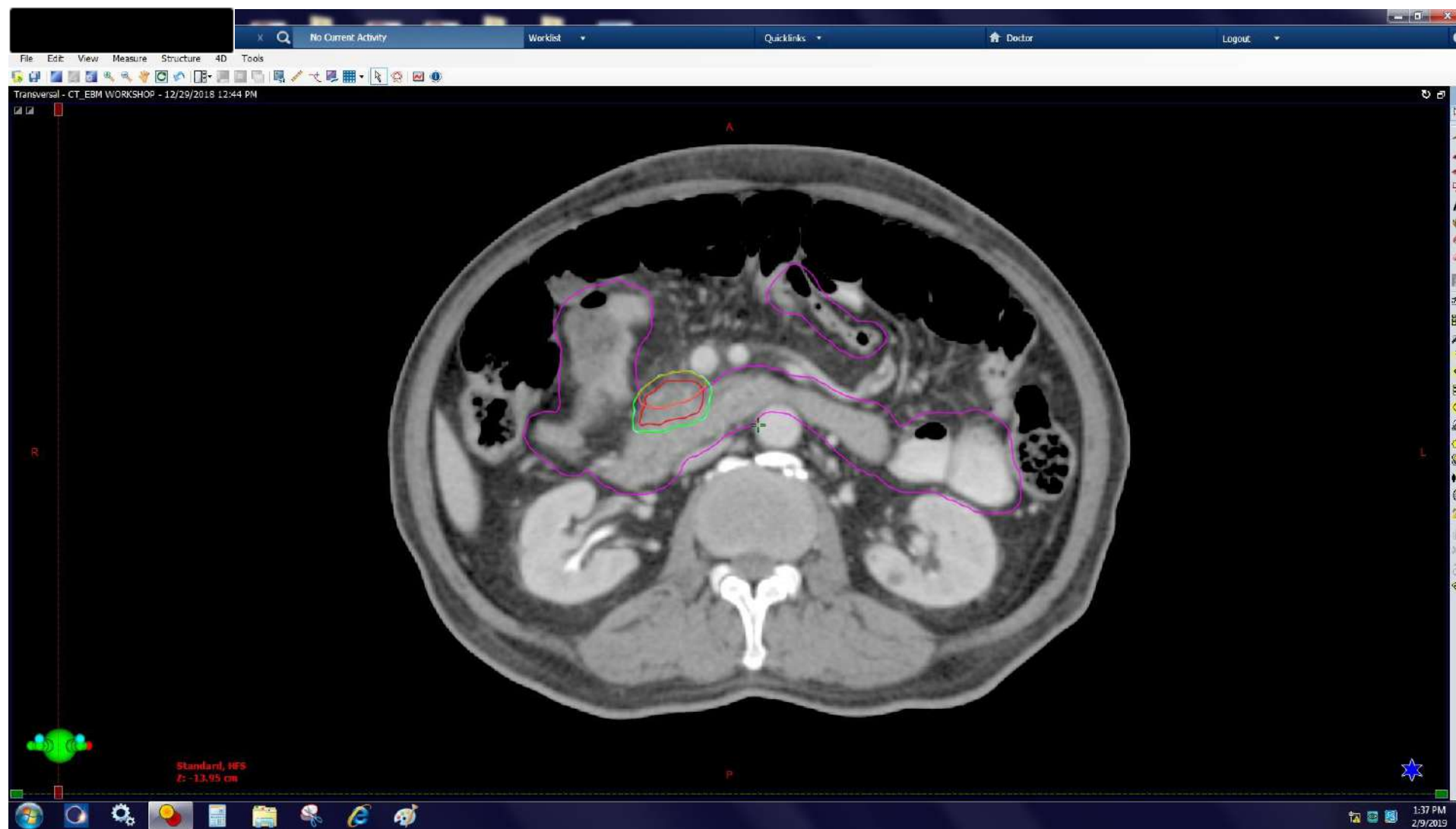
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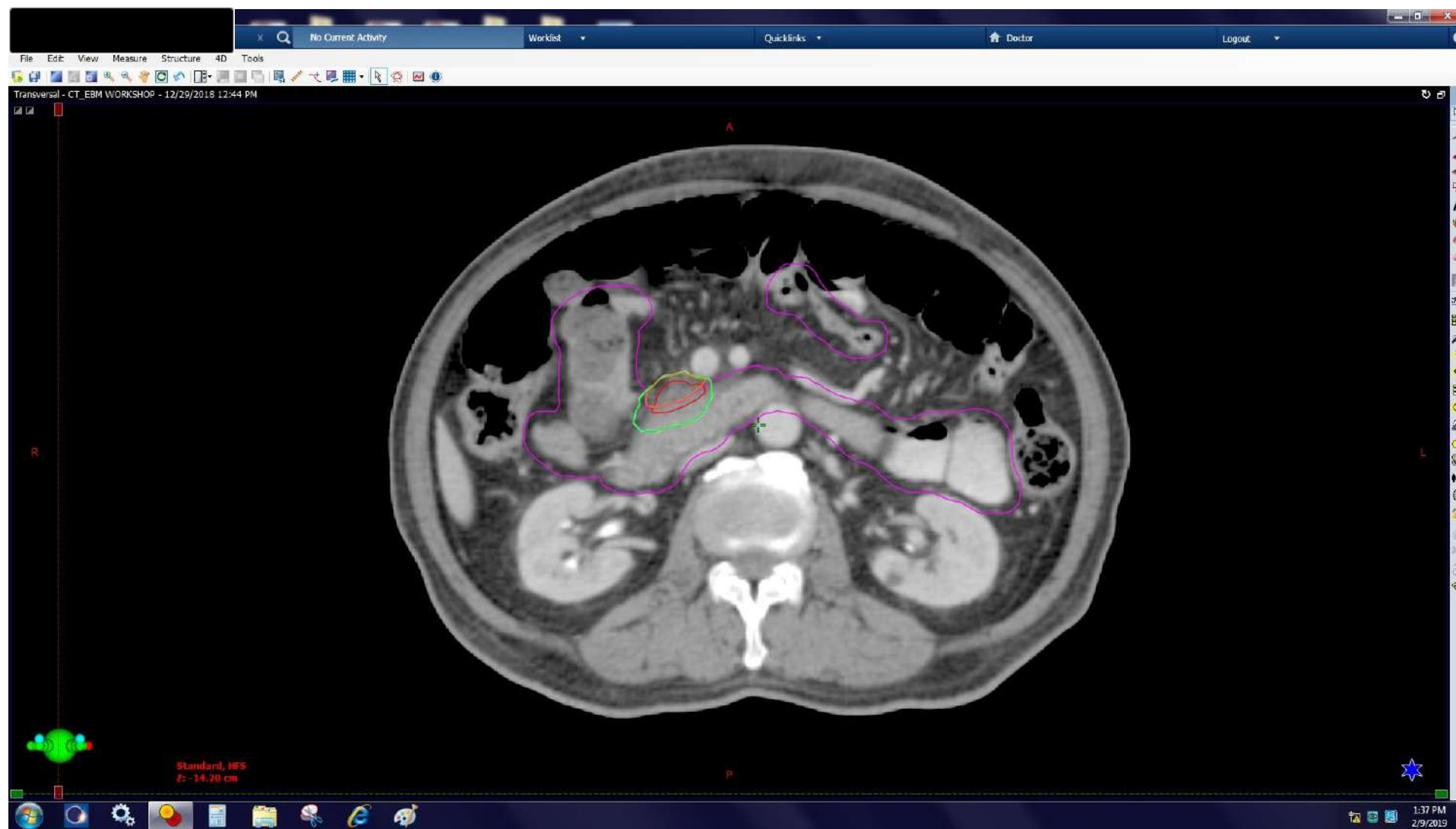
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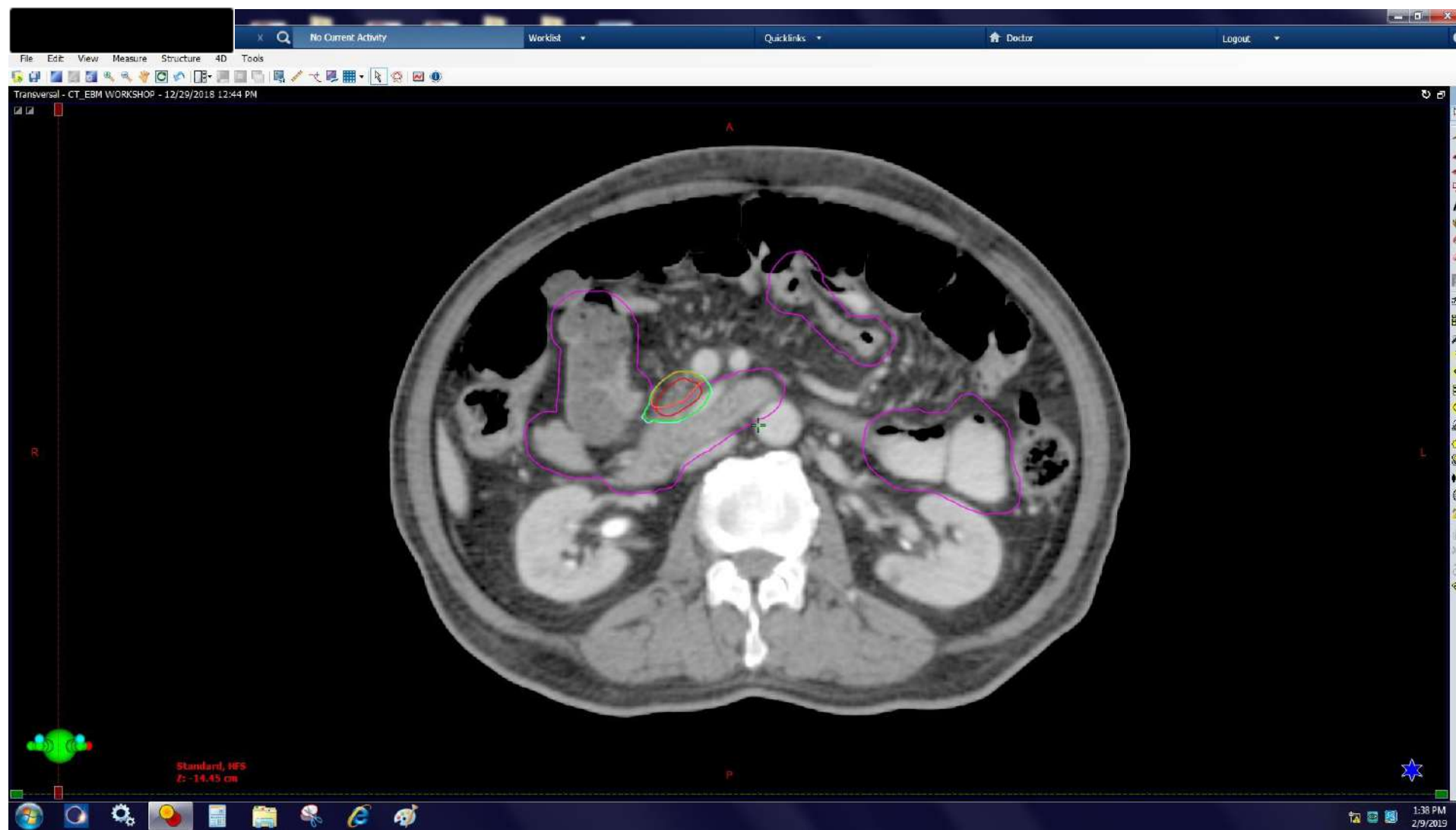
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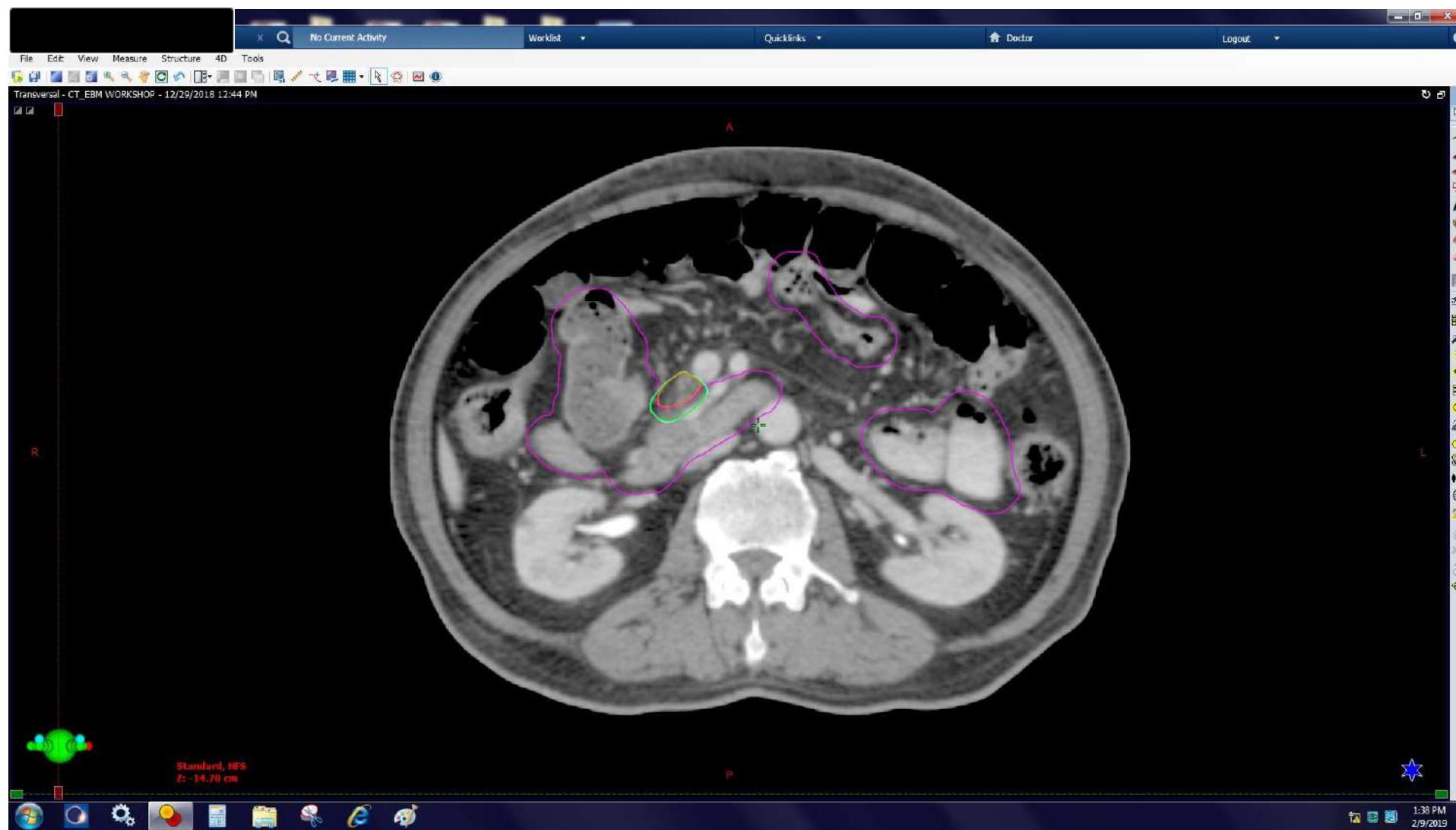
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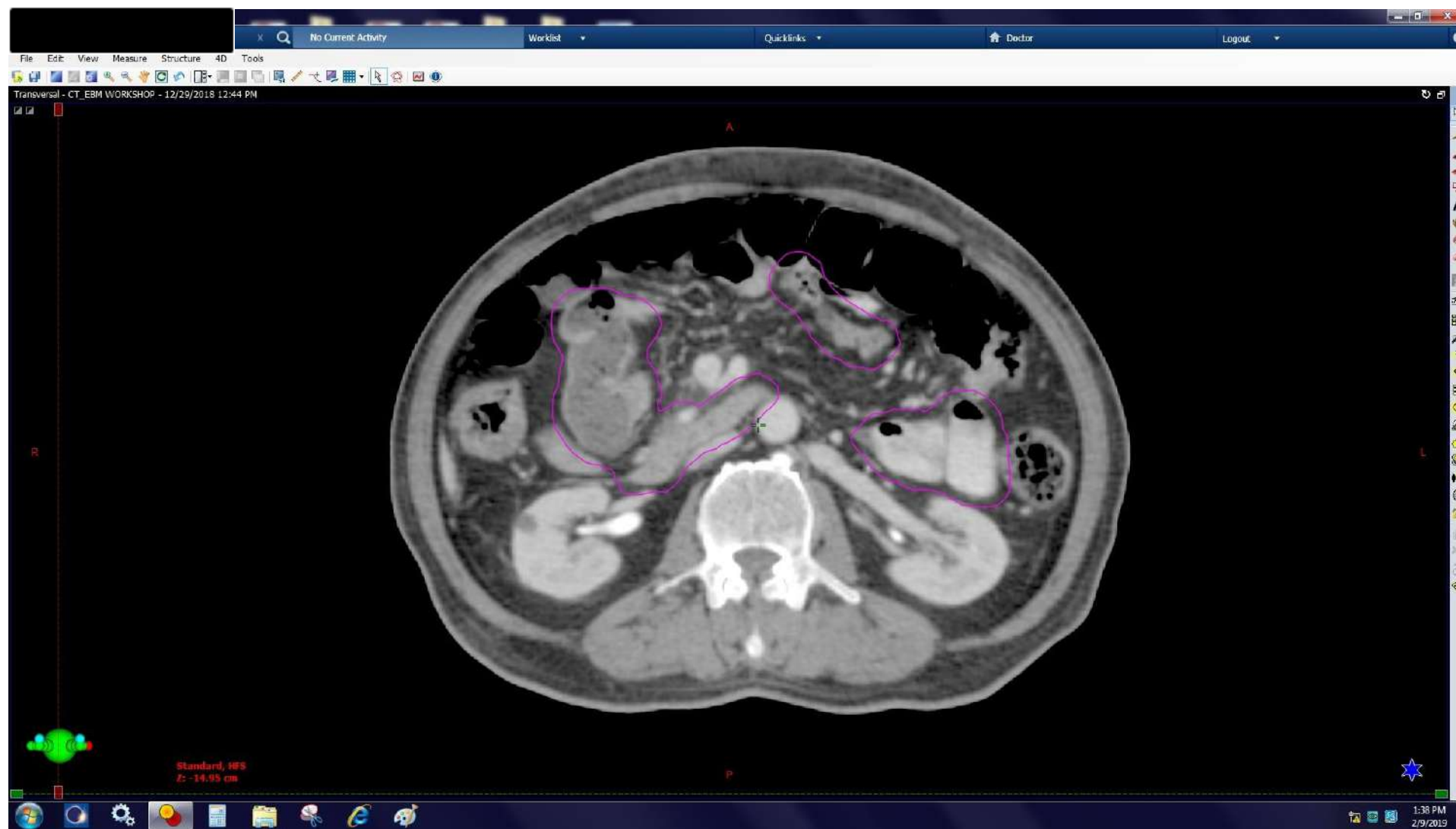
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International Journal of Radiation Oncology • Biology • Physics
Pattern of Local Failure in a Phase II Trial of Neoadjuvant Chemotherapy and
Stereotactic Body Radiation Therapy for Resectable and Borderline Resectable
Pancreas Cancer

- 18 patients from 11/2014-6/2017.
- Following 3 # CT,
- SBRT - to the tumor and abutting vessel and a 3 mm PTV margin to 33 Gy (6.6 Gy x 5)
- The cumulative incidence of Local failure (LF) at 12 months from resection was 50% (95% CI: 20-80). All LF were outside to the PTV33.

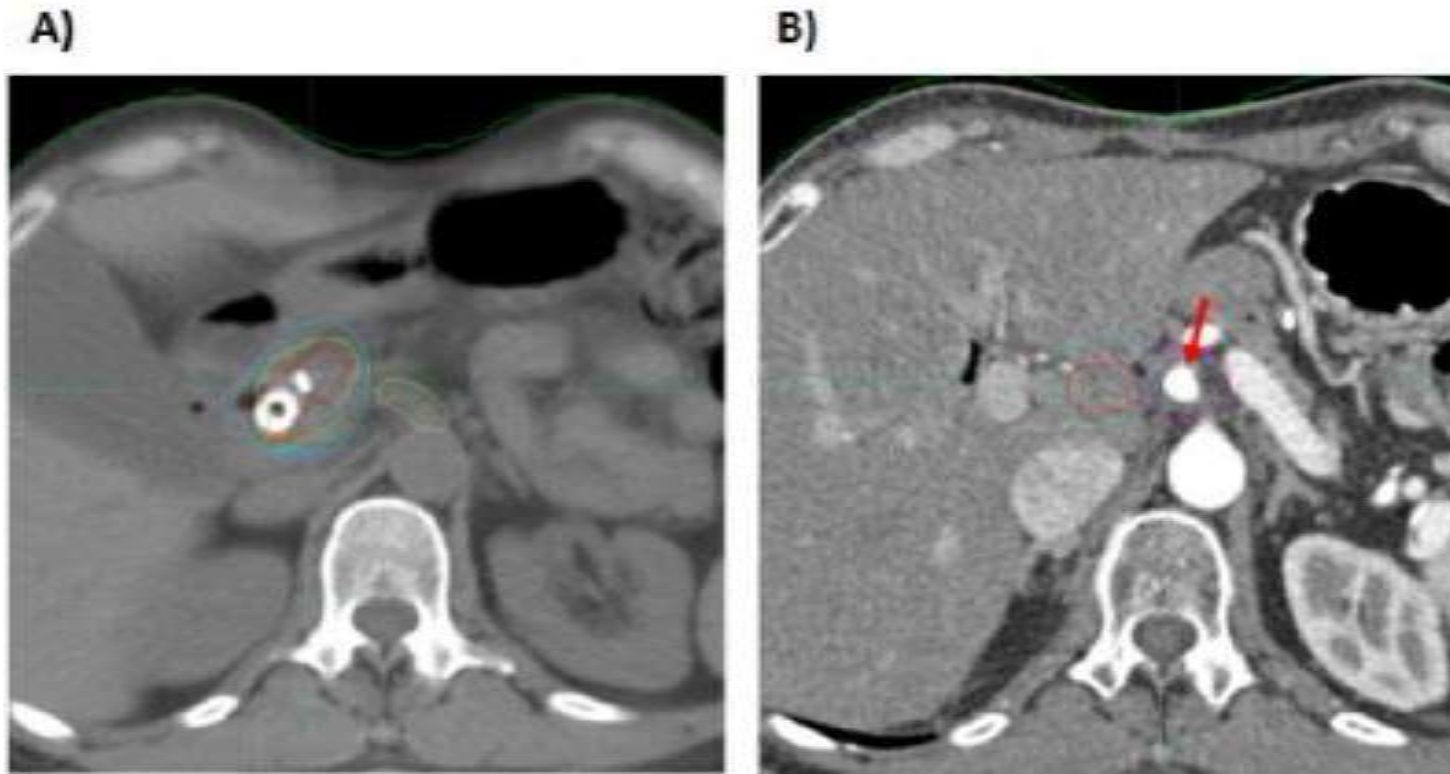


Figure 1. (A) Patient with borderline resectable tumor due to **SMV encasement** treated to the primary tumor alone. A **local-only recurrence** occurred at the **SMA** 7 months from surgery as the first site of failure. (B) CT at time of recurrence fused to planning CT revealing the recurrence volume marginal to the original PTV (arrow).

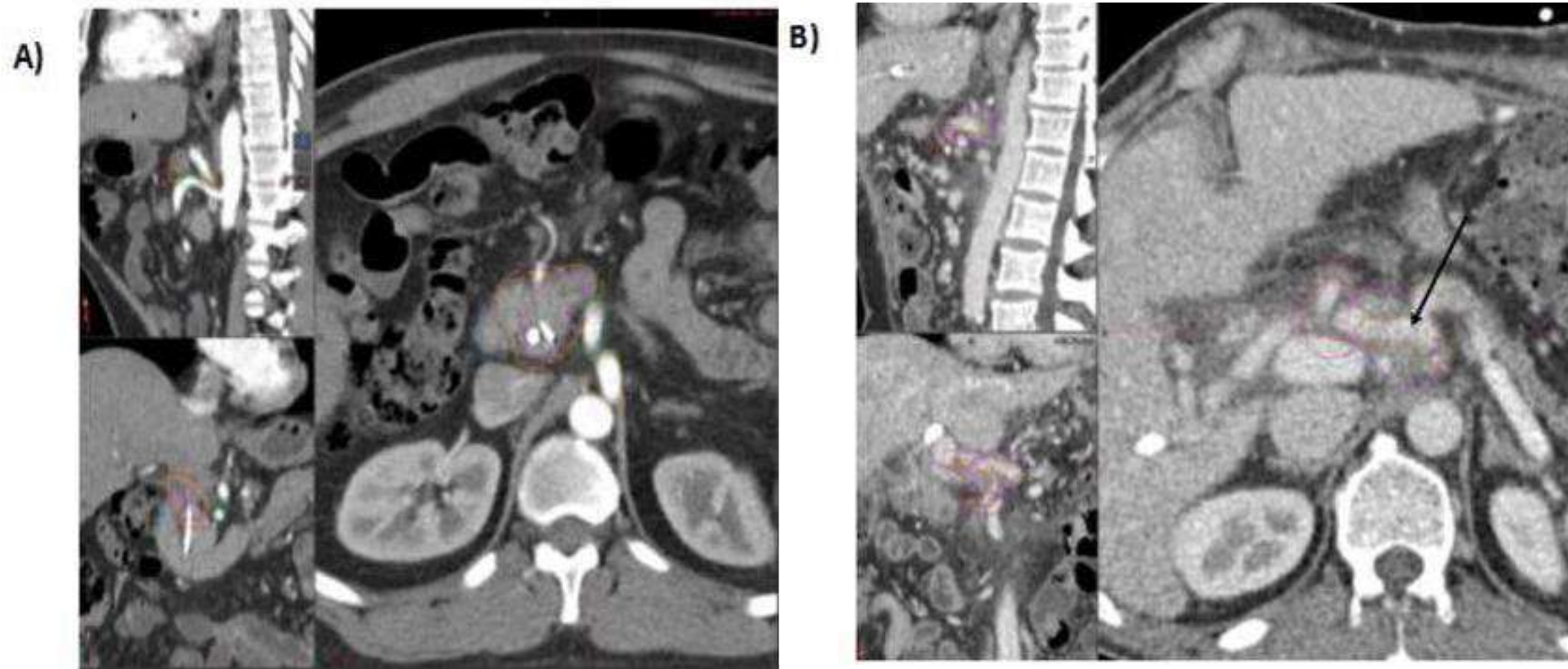


Figure 2. (A) Patient with borderline resectable tumor due to common hepatic artery abutment treated to the primary tumor alone. A local only recurrence occurred 12 months following surgery at the celiac artery as the first site of failure. (B) CT at time of recurrence fused to planning CT revealing the recurrence volume marginal to the original PTV (arrow)

Optional elective PTV to 25 Gy (5 Gy x 5)
customized to the nodal space and
mesenteric vessels

Table 2 Suggested dose constraints for pancreas SBRT

Organ	Standardized name	Parameter	Constraint		
		Constraint	Per protocol, Gy	Minor variation, Gy	Major variation, Gy
Duodenum	Duodenum	Dmax (0.5 cm ³)	<33	≤35	>35
		V30	<5*	5-10*	>10*
Stomach	Stomach	Dmax (0.5 cm ³)	<33	≤35	>35
		V30	<5*	5-10*	>10*
Small bowel	SmallBowel	Dmax (0.5 cm ³)	<33	≤35	>35
		V30	<5*	5-10*	>10*
Large bowel	LargeBowel	Dmax (0.5 cm ³)	≤35 Gy	35-38 Gy	>38
Duodenum PRV [†]	Duodenum_PRV	Dmax (0.5 cm ³)	<38 Gy	38-40 Gy	>40
Small bowel PRV [†]	SmallBowel_PRV	Dmax (0.5 cm ³)	<38 Gy	38-40 Gy	>40
Large bowel PRV [†]	LargeBowel_PRV	Dmax (0.5 cm ³)	<38 Gy	38-40 Gy	>40
Stomach PRV [†]	Stomach_PRV	Dmax (0.5 cm ³)	<38 Gy	38-40 Gy	>40
Spinal cord PRV	SpinalCord_05	Dmax (0.5 cm ³)	<20 Gy	≤25 Gy	>25
Combined kidneys	Kidneys_Comb	V12 [‡]	<25 [§]	25-30 [§]	>30 [§]
Single kidney	Kidney_L	V10 [‡]	<10 [§]	10-25 [§]	>25 [§]
	Kidney_R				
Liver	Liver	V12 [‡]	<40 [§]	≤50 [§]	>50 [§]

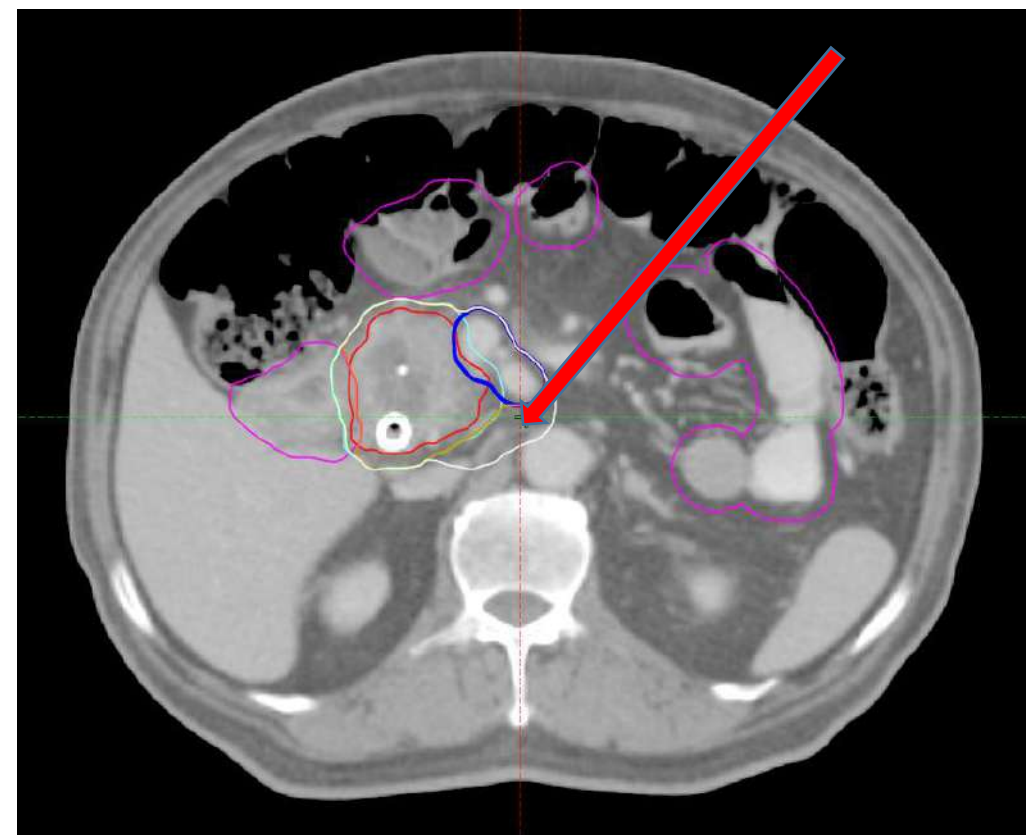
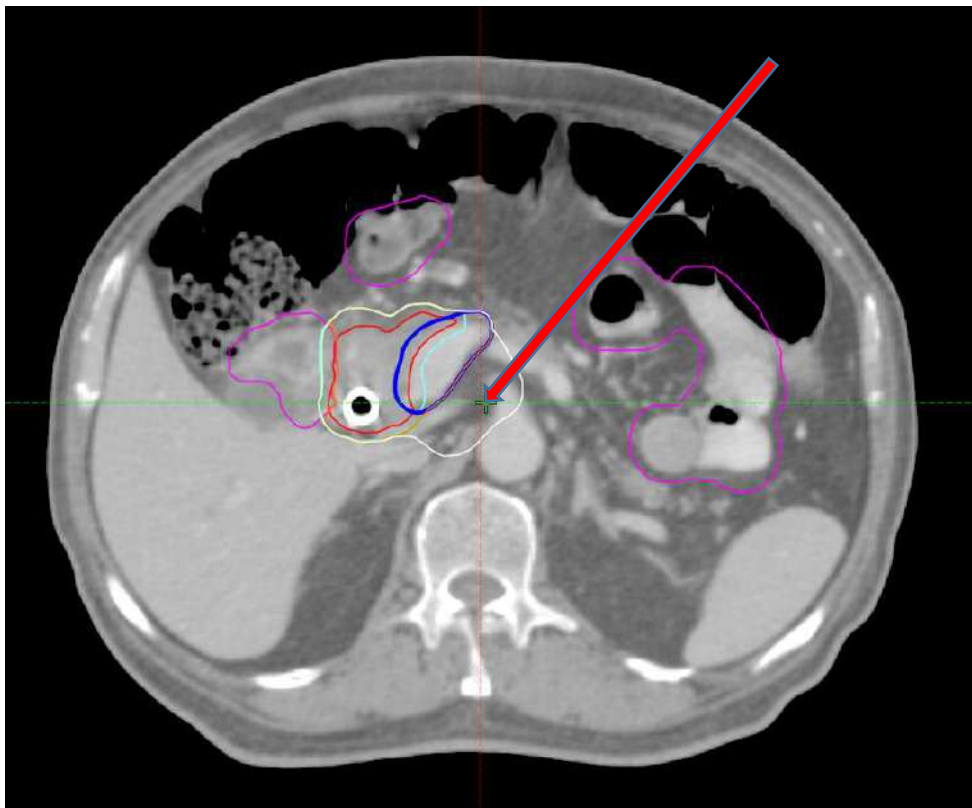
Abbreviations: Dmax = maximum dose; PRV = planning organ-at-risk volume; SBRT = stereotactic body radiation therapy.

* Unit is cm³.

† Minimum PRV expansion should be 3 mm; however, larger expansions should be considered in a setting of increased organ movement or uncertainty.

‡ Unit is Gy.

§ Unit is percent.

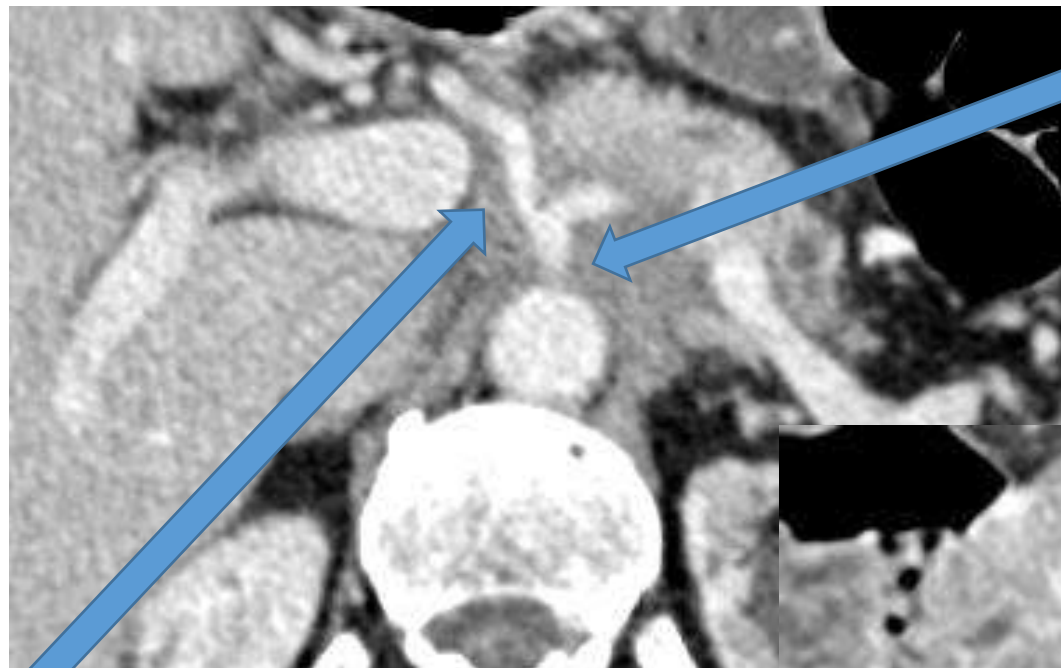


Summary

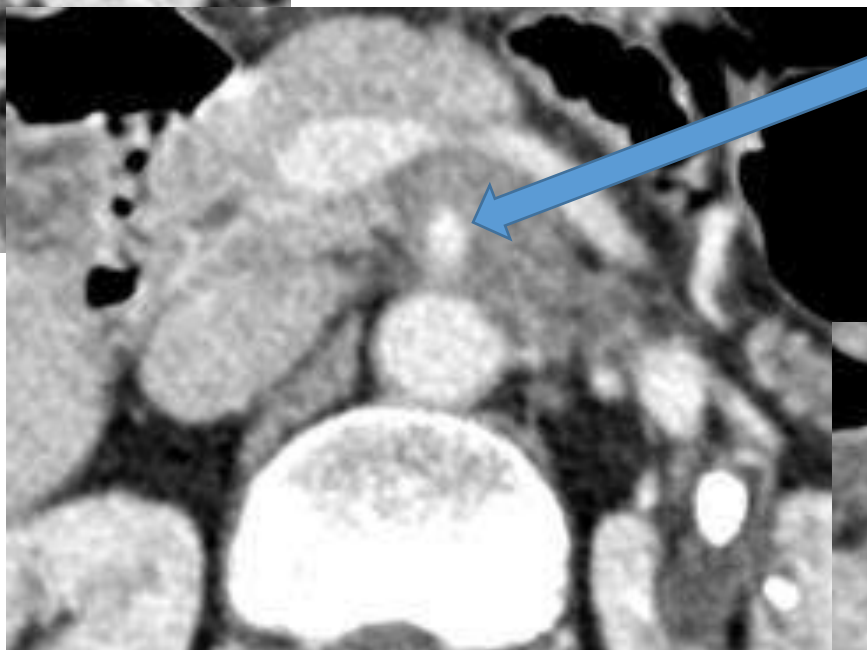
- SBRT is feasible for all intact pancreatic cancers
- Better integrated with Chemotherapy regimens

History

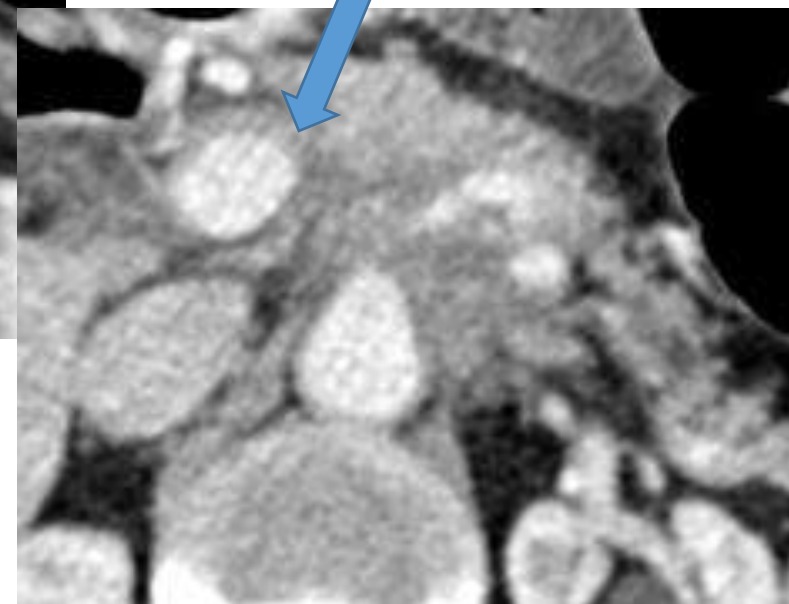
- 58 y/o gentleman
- P/W Pain in epigastric region, significant weight loss
- Investigations
 - Triphasic CECT TAP: Hypoattenuating lesion involving head and body of pancreas
 - CT guided biopsy of pancreatic mass: MDAC
 - CA 19.9: 16.46



Celiac Axis: $>180^\circ$ encasement
Aorta: $<180^\circ$ encasement

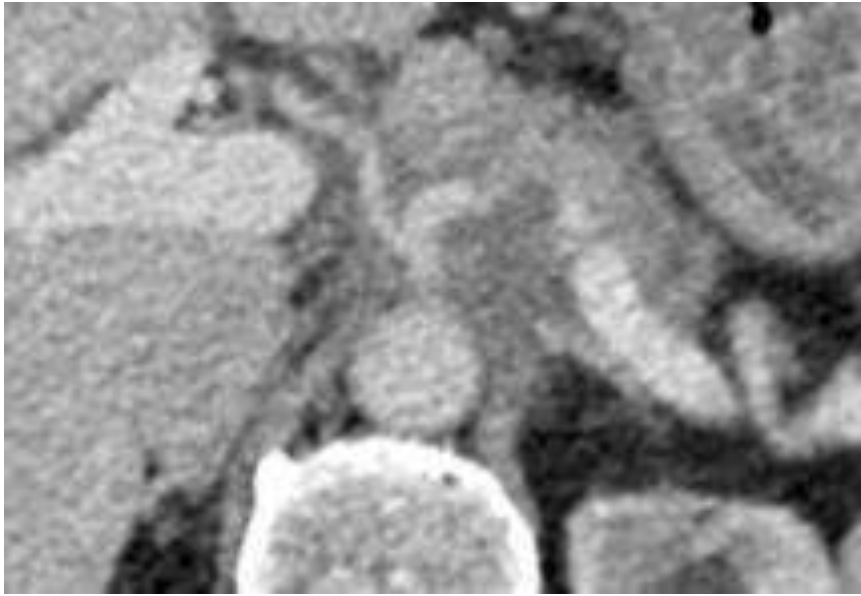


SMA: $>180^\circ$ encasement
PV: $<180^\circ$ encasement



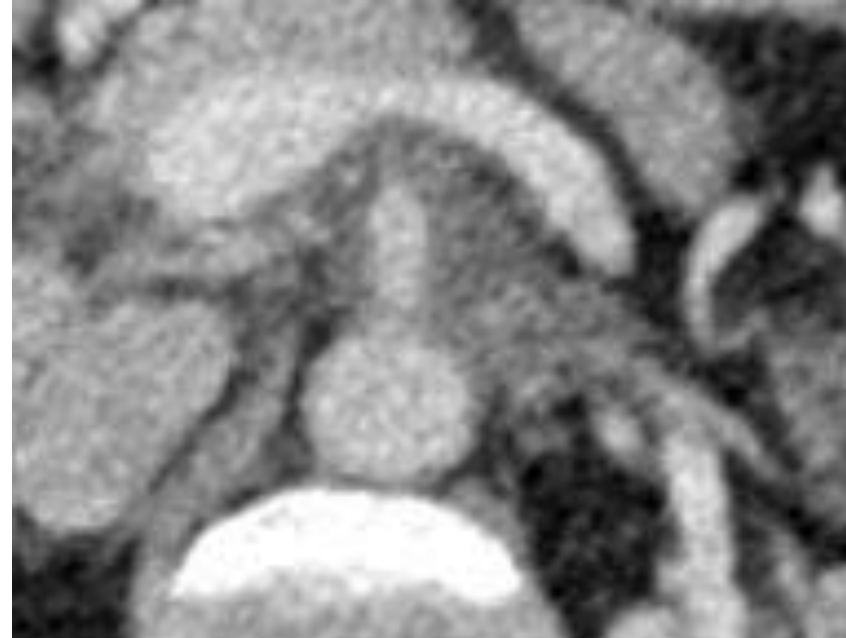
CHA: $>180^\circ$ encasement

LAPC, unlikely to come up for Surgery

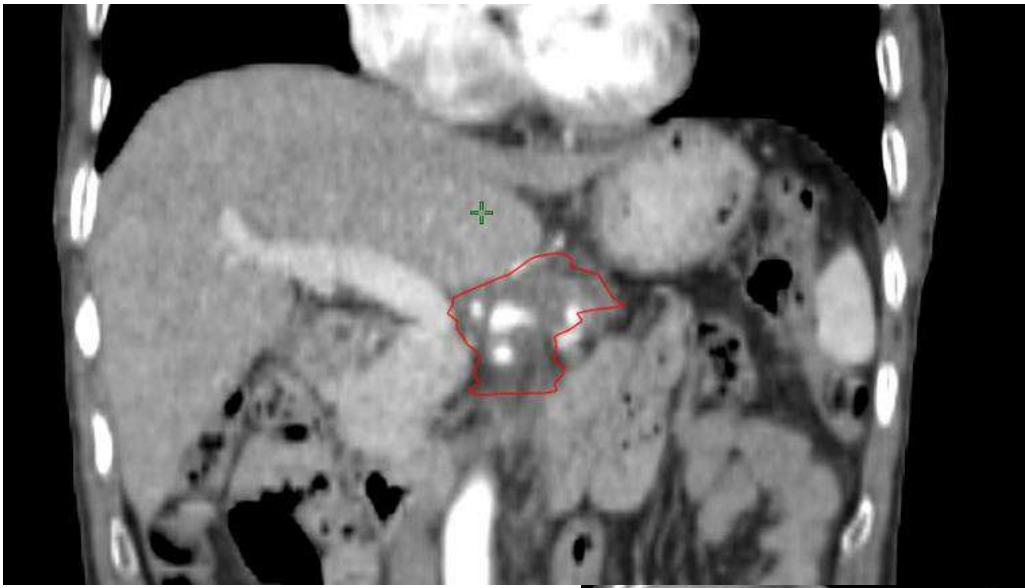


Post 6# m FOLFIRINOX

- Decrease in disease volume
- Persistent encasement of CA, CHA, SMA
- Unresectable
- Clinical improvement- Pain relief +, Wt gain+

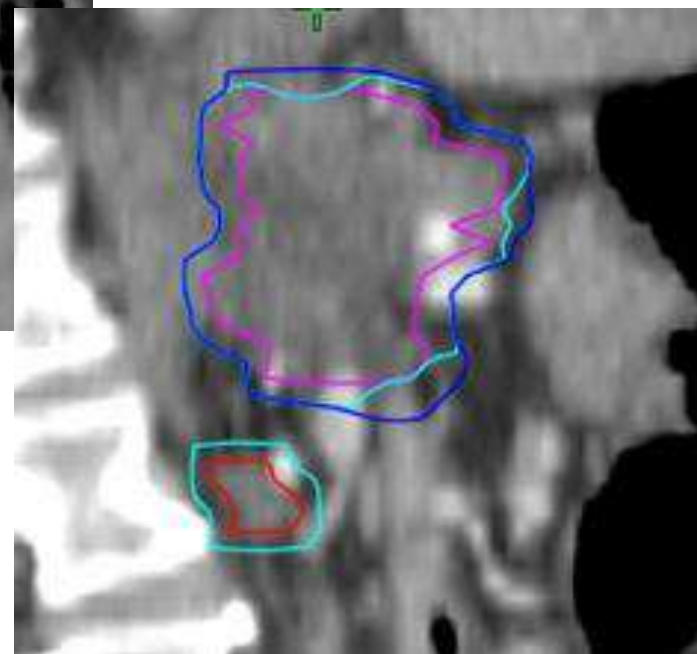
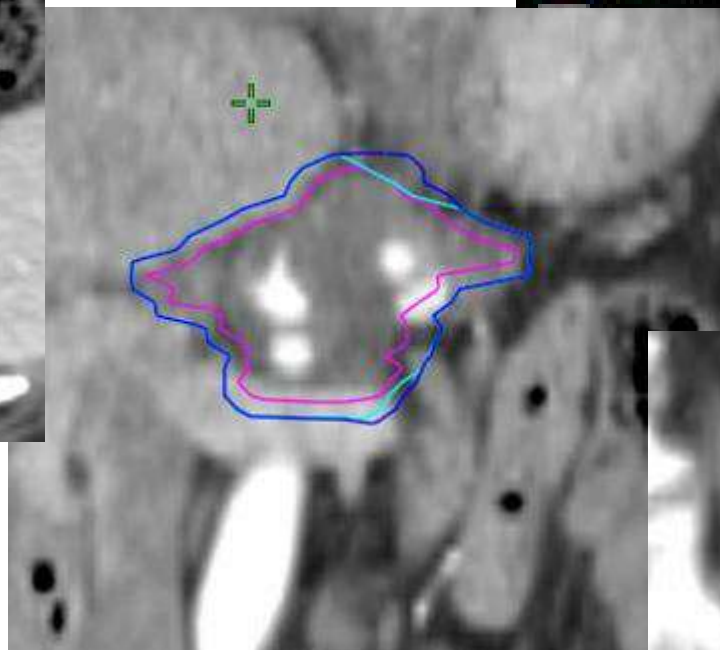


GTV

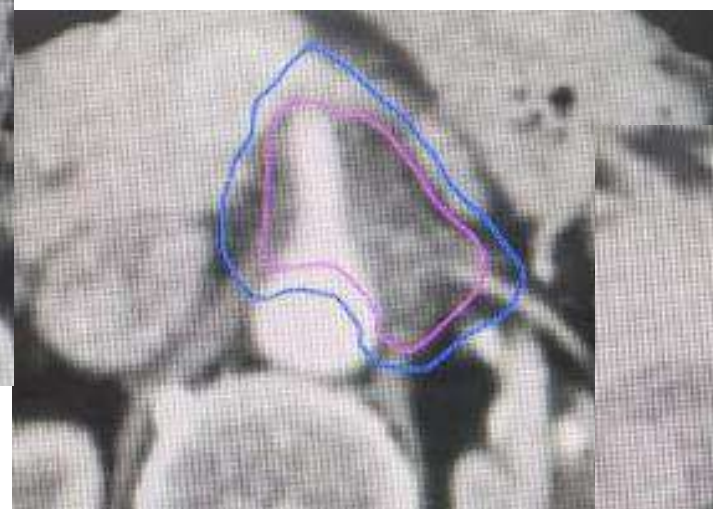
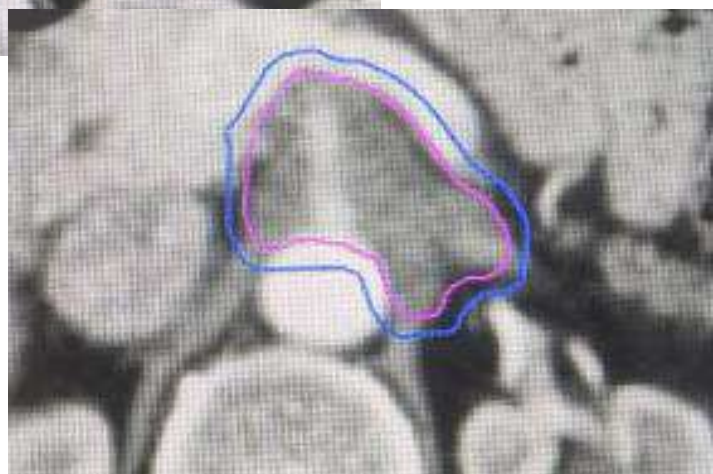
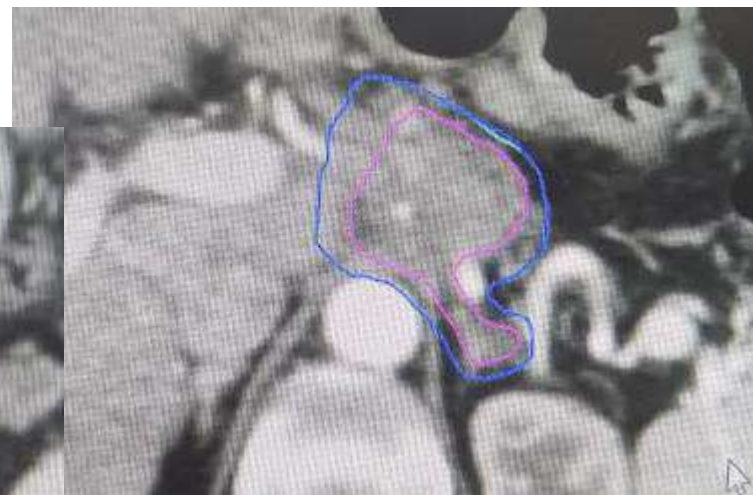
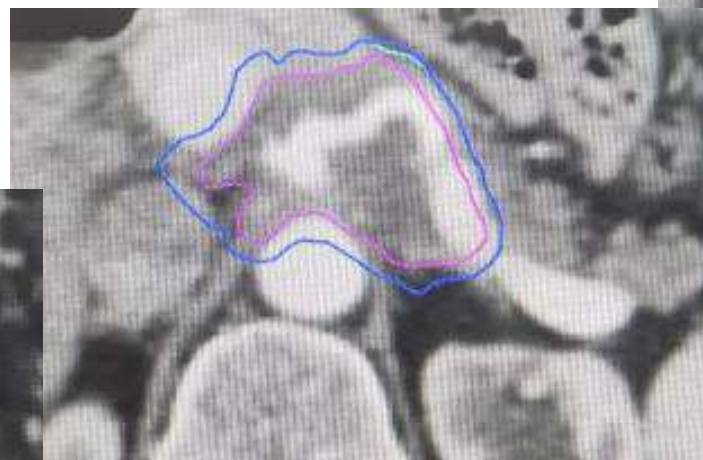
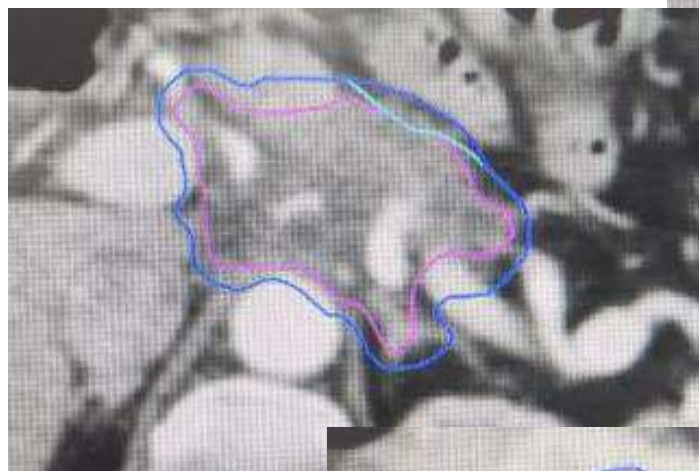




☒  PTV_35/5_RE
☒  PTV_45/5_RE
☒  PTV_50/5_RE



PTV_35/5: GTV+3mm
 PTV_45/5: GTV+3mm – PRV_GI
 PTV_50/5: GTV – PRV_GI



THANK YOU

