

2848; LBA28

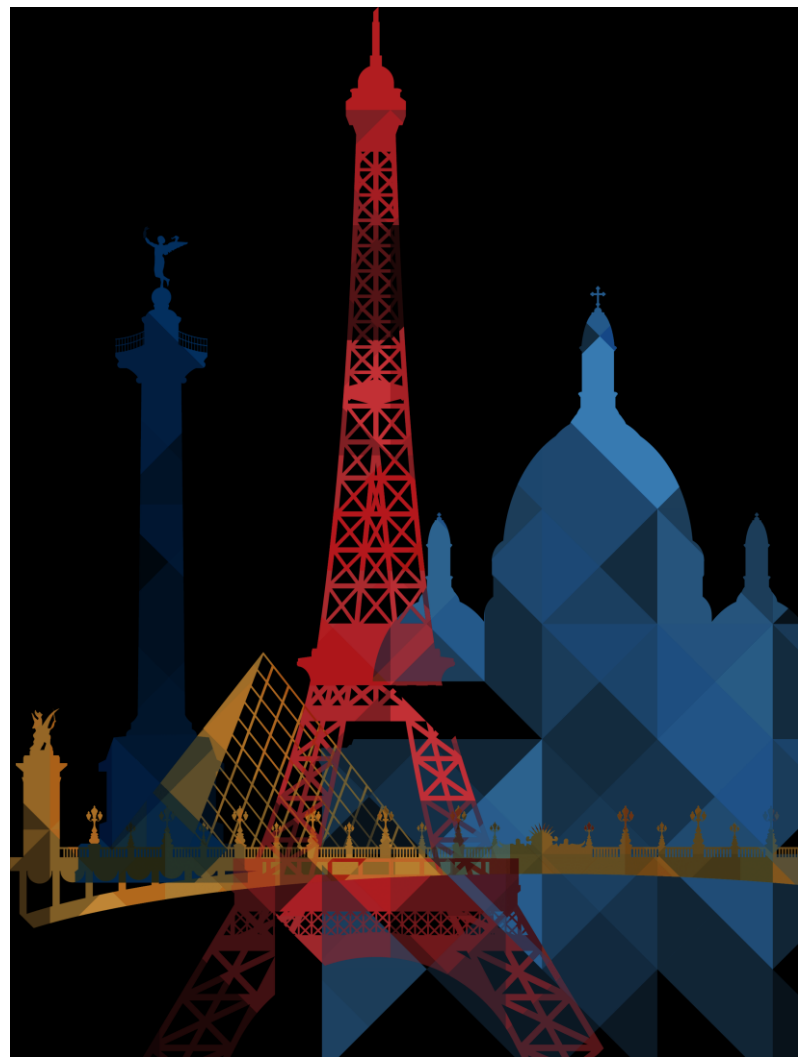
PRODIGE 13 : Prognostic effect of imaging and CEA follow-up in resected colorectal cancer

Final results and relapse free survival

NCT00995202

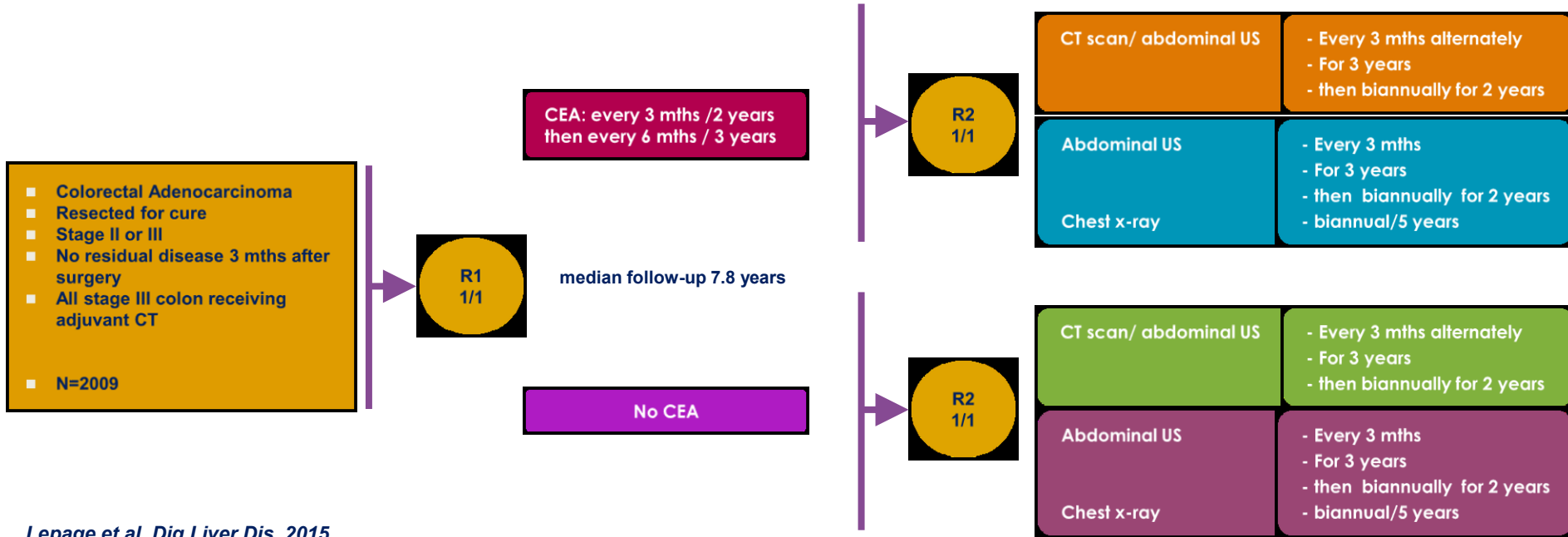
C LEPAGE Dijon, France

Phelip J-M, Cany L, Barbier E, Manfredi S, Deguiral P, Faroux R, Baconnier M, Pezet D, Terrebonne E, A. Adenis, Ben Abdelghani M, Ain J-F, G. Breysacher, Boillot-Benedetto I., Pelaquier A, A. Lièvre, Laurent-Puig P, Bibeau F, Bouché O.



Prodige 13 : Trial design

Rational: no consensual recommendations for CRC surveillance after resection for cure



Lepage et al. Dig Liver Dis. 2015

Prodige 13 : Patients' Characteristics (%)

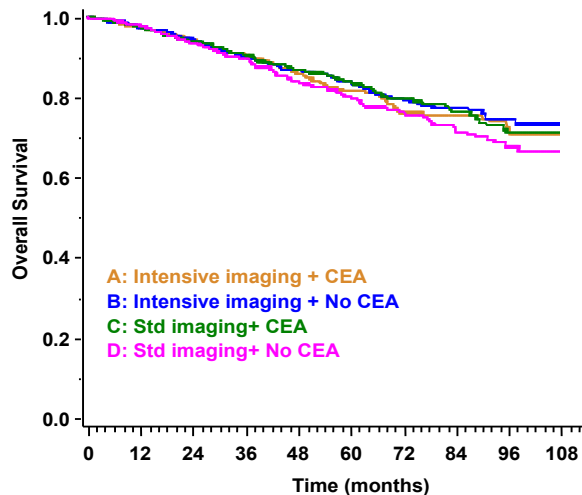
		CT scan + CEA	CT scan	Standard + CEA	Standard	p
n= 1995*		n=501	n=497	n=498	n=499	
Age	≤ 75 years	78.3	77.7	77.9	75.7	0.6
Gender	Women	39.7	44.3	40.6	39.7	0.4
Localisation	Right	36.8	38.4	42.0	41.8	0.8
	Left	45.5	44.2	42.2	41.4	
	Rectum	17.3	15.7	15.4	16.7	
Presentation	Emergency	14.4	14.5	14.7	15.9	0.9
Stage III	Global	49.6	45.9	44.5	53.2	0.04
	pT4 &/or N2	14,1	12.2	17.3	21.1	0,04
Stage II	Global	50.4	54.1	55.5	46.8	0.04
	With adjuvant ct	13.5	15.1	14.7	14.1	0,6
	High risk**	54.6	51.4	53.0	59.0	0,5

*14 patients withdrew their consent

**pT4 tumours, <12 lymph nodes examined, Occlusion or Perforation, high-grade tumour, perineural or lymphovascular invasion

Prodige 13 : Primary end-point (Overall Survival (OS))

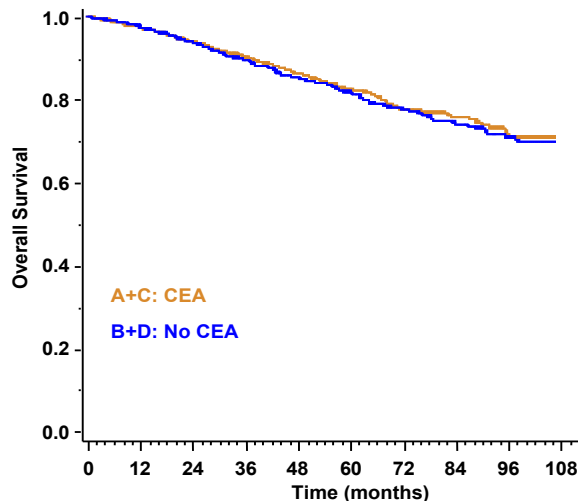
OS by randomisation arm



501	487	471	449	408	310	216	145	75	11
497	482	467	446	411	316	242	152	70	10
498	484	465	448	415	315	235	143	66	7
499	487	466	447	396	311	227	139	65	10

p (Logrank)=0.340

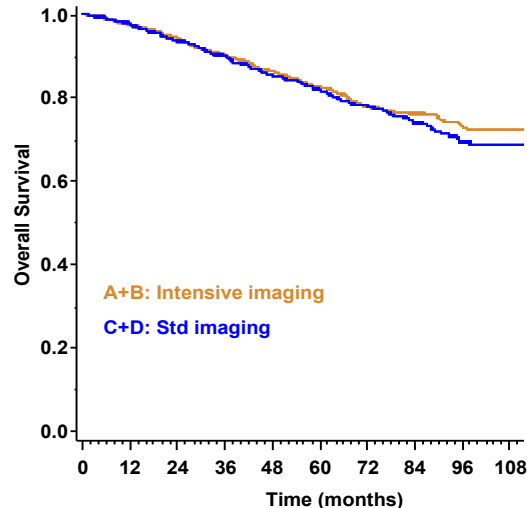
OS : CEA surveillance vs. Not



999	971	936	897	823	625	451	288	141	18
996	969	933	893	807	627	469	291	135	20

p (Logrank)=0.540

OS : CT scan surveillance vs. Not



998	969	938	895	819	626	458	297	145	21
997	971	931	895	811	626	462	282	131	17

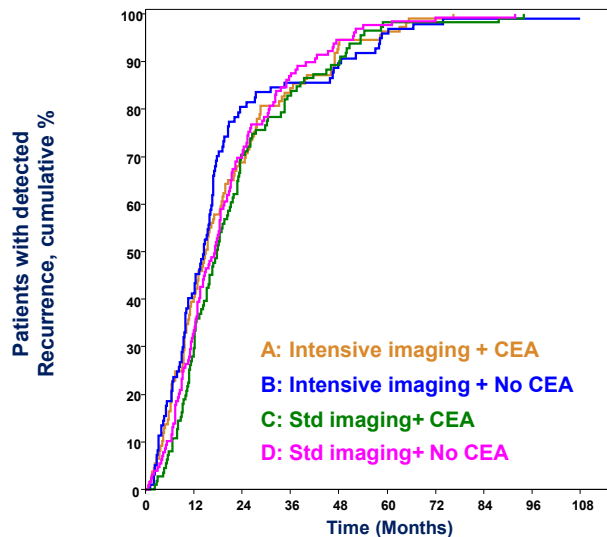
p (Logrank)=0.390

Recurrence & treatment by Arm

n= 1995*		CT scan + CEA n=501	CT scan n=497	Standard + CEA n=498	Standard n=499	p
Recurrence	(n=446)	n=109	n=97	n=111	n=129	
	Total	21.8	19.5	22.3	25.9	
	Locoregional	2,2	1,4	2,2	3,6	0.584
	Metastatic	15,4	14,5	16,3	19,0	
	Both	4,2	3,6	3,8	3,2	
Treatments :						
n= 422		n=104	n=91	n=110	n=117	
Surgery	R0	39.4	36.3	49.1	32.5	0.012
	Non R0 resection	21.2	19.7	16.4	15.4	
	No surgery	39.4	44.0	34.5	52.1	
Chemotherapy	After R0 resection	22.1	26.4	32.7	17.1	0.120
	Palliative CT	52,9	57,1	50,9	61,5	
	Other palliative treat.	25.0	16.5	16.4	21.4	

Time to relapse (TTR) among patients with recurrence (ITT)

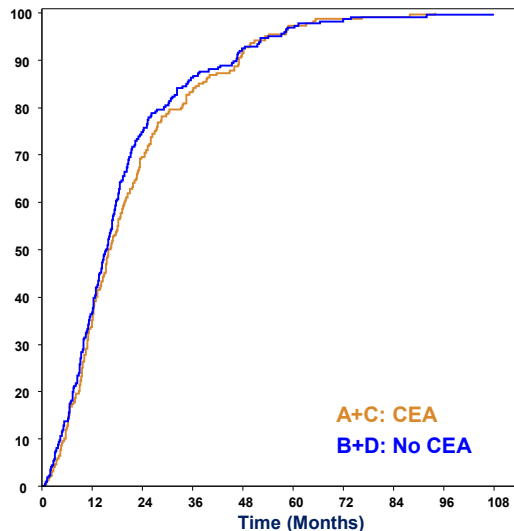
TTR by randomisation arm



N at risk	0	12	24	36	48	60	72	84	96	108
A:	109	65	34	18	7	4	1	0		
B:	97	57	19	14	10	4	2	1	1	1
C:	111	79	33	19	12	2	2	2	0	
D:	129	87	38	17	7	3	1	1	0	

p (Logrank)= 0.644

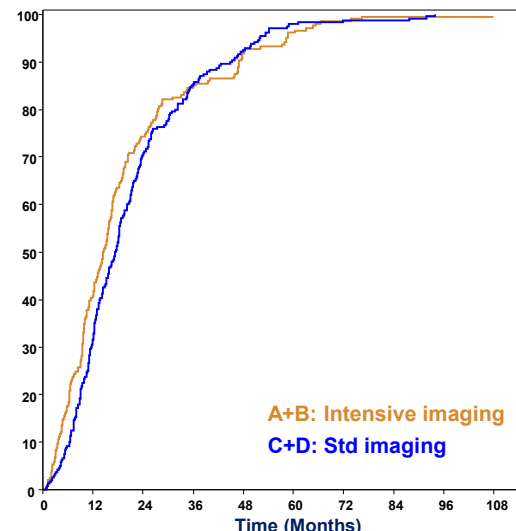
TTR: CEA surveillance vs. Not



N at risk	0	12	24	36	48	60	72	84	96	108
A+C:	220	144	67	37	19	6	3	2	0	1
B+D:	226	144	57	31	17	7	3	2	1	1

p (Logrank)= 0.324

TTR: CT scan surveillance vs. Not

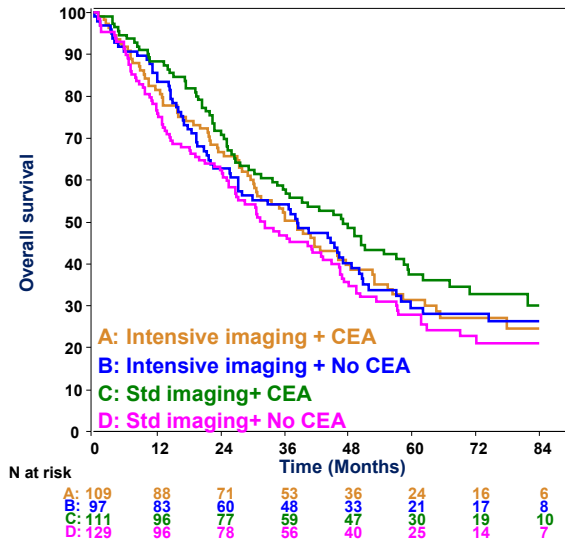


N at risk	0	12	24	36	48	60	72	84	96	108
A+B:	206	122	53	32	17	8	3	1	1	1
C+D:	240	166	71	36	19	5	3	3	0	1

p (Logrank)= 0.287

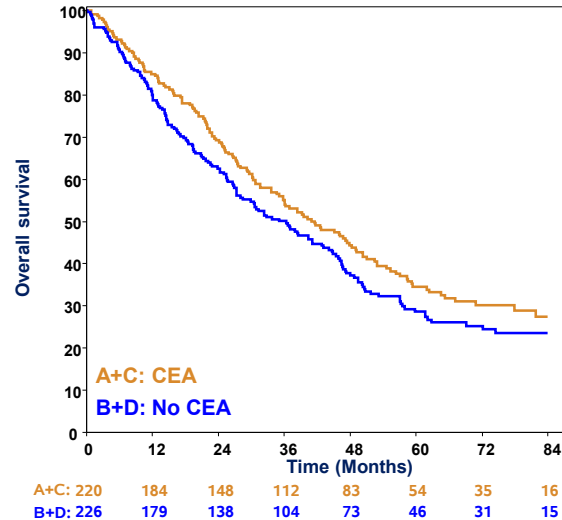
Overall Survival (OS) among patients with recurrence (ITT)

OS by randomisation arm



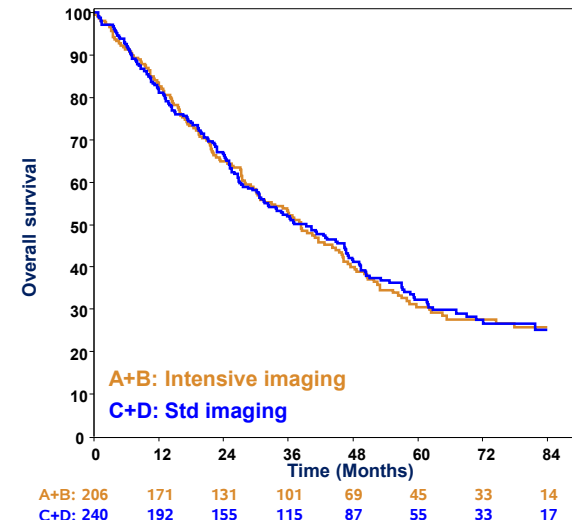
p (Logrank)=0.151

OS CEA surveillance vs. Not



p (Logrank)=0.088

OS CT scan surveillance vs. Not



p (Logrank)=0.952

Conclusion :

- **This study showed no difference in terms of OS for any of the surveillance arms**
- **Among patients who relapsed, no difference could be demonstrated concerning OS and TTR**
- **According to our results guidelines for CRC surveillance after curative resection should be amended and the new standard could be:**
 - **Regular semiological assessments of patients**
 - **with the help of ultrasound and chest X-ray**
- **CEA surveillance seems to be useless**
- **CT scans should be performed only in cases of suspected recurrence (clinical +/- imaging)**
- **Several ancillary studies are under way on: Molecular subtypes, ctDNA, Heat shock proteins, new anatomical pathology patterns, immune contexture ...**