

PRODGE 7 Trial

Phase III PRODIGE 7 trial - ASCO, 2018

265 patients who had stage IV colorectal cancer with isolated PC:

- 17 centers, between Feb 2008 and Jan 2014
- CRS w/HIPEC (oxaliplatin heated to 43°C) vs CRS alone
- RCT for additive benefit of HIPEC over that of CRS only

Characteristic	HIPEC (<i>n</i> = 113)	No HIPEC (<i>n</i> = 132)
PC involvement		
<11	56.4%	58.3%
11–15	13.5%	21.2%
16–24	30.1%	20.5%
Synchronous PC	38.6%	40.9%
Surgery outcomes		
Complete macroscopic cytoreduction (R0/R1)	89.5%	91.7%
Residual disease <1 mm (R2)	10.5%	8.3%

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Endpoint	HIPEC (<i>n</i> = 113)	No HIPEC (<i>n</i> = 132)	<i>p</i> Value
Overall survival (OS)			
Median OS	41.7 months	41.2 months	.995
1-year OS	86.9%	88.3%	
5-year OS	39.4%	36.7%	
Recurrence-free survival (RFS)			
Median RFS	13.1 months	11.1 months	.486
1-year RFS	59.0%	46.1%	
5-year RFS	14.8%	13.1%	
Morbidity at 60 days			
All grade 3–5 complications	24.1%	13.6%	.030
Intra-abdominal complications	6.0%	3.0%	.377
Extra-abdominal complications	20.3%	12.1%	.071
Mean hospital stay	18.0 days	13.0 days	<.001

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- “The addition of HIPEC with oxaliplatin does not influence the survival results”
- By 60 days, complication rates were almost twice as high for patients who had undergone HIPEC (24% vs 13.6%; $P = .03$).
- “The survival rate of the surgery alone group was unexpectedly high, which means every colorectal cancer patient with an isolated peritoneal carcinomatosis should be considered for surgery.”

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In a subgroup analysis:

- Survival benefit with HIPEC specifically among patients with a medium amount of disease in the peritoneal cavity (PCI between 11 - 15)

	HIPEC	Surgery alone	
Median OS (ms)	41.6	32.7	p= .0209

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- Heated abdominal chemotherapy does not improve survival in patients with metastatic colorectal cancer who undergo abdominal cytoreductive surgery for isolated peritoneal carcinomatosis, and in fact was associated with a higher rate of late side effects in these patients, according to findings from the phase III PRODIGE-7 clinical trial.
- However, patients with more peritoneal disease might benefit from hyperthermic intraperitoneal chemotherapy (HIPEC), a subgroup analysis suggested.
- "HIPEC with oxaliplatin may be beneficial for patients with a medium amount of disease in the peritoneal cavity."