

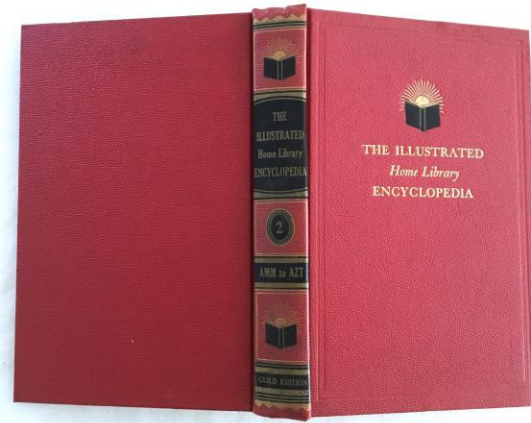
Perioperative enfortumab vedotin and pembrolizumab should replace cisplatin in muscle- invasive bladder cancer



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Dr. Ciuro has an impossible task today



FDA approves pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph each with enfortumab vedotin-ejfv for muscle invasive bladder cancer

On **July 10, 2026**, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex, Merck) each in combination with enfortumab vedotin-ejfv (Padcev, Astellas Pharma) as neoadjuvant treatment (before surgery) followed by adjuvant treatment after cystectomy (surgery to remove the bladder) for adults with muscle invasive bladder cancer (MIBC). This extends the prior approval for the regimen in this setting from patients who are cisplatin-ineligible to all patients with MIBC who are candidates for cystectomy.

KEYNOTE-B15/EV-304

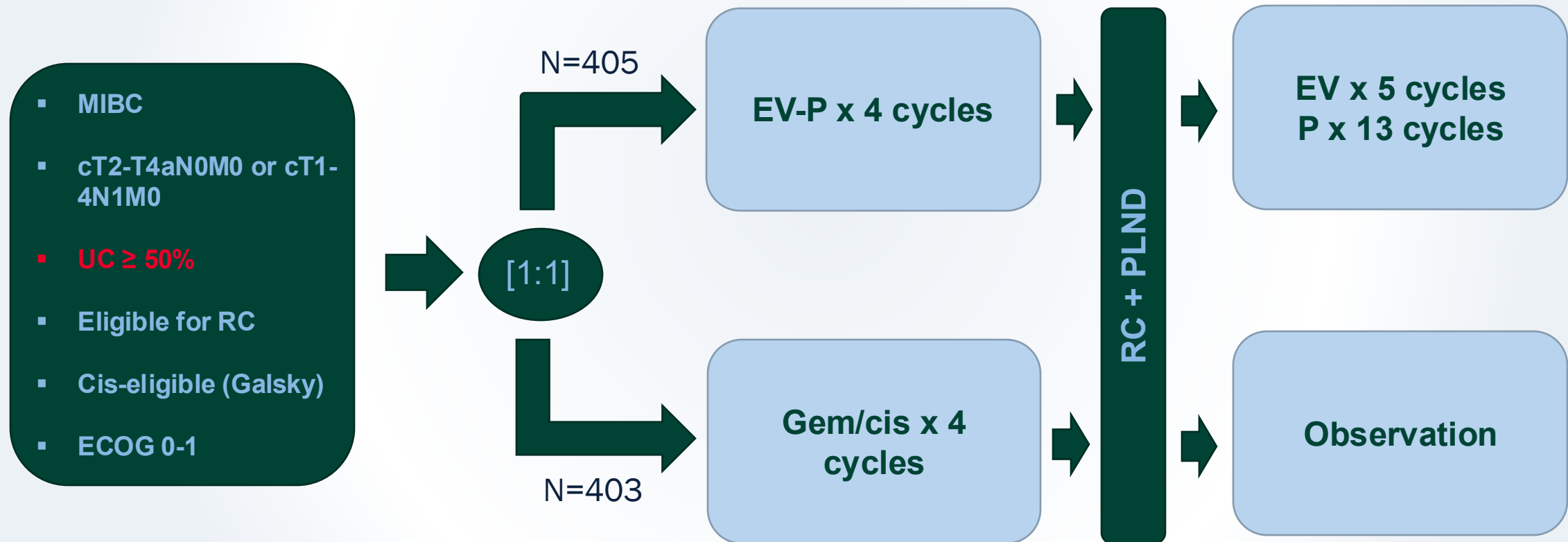
Perioperative EV-P vs neoadjuvant gem/cis in cis-eligible MIBC

Primary endpoint:

- EFS

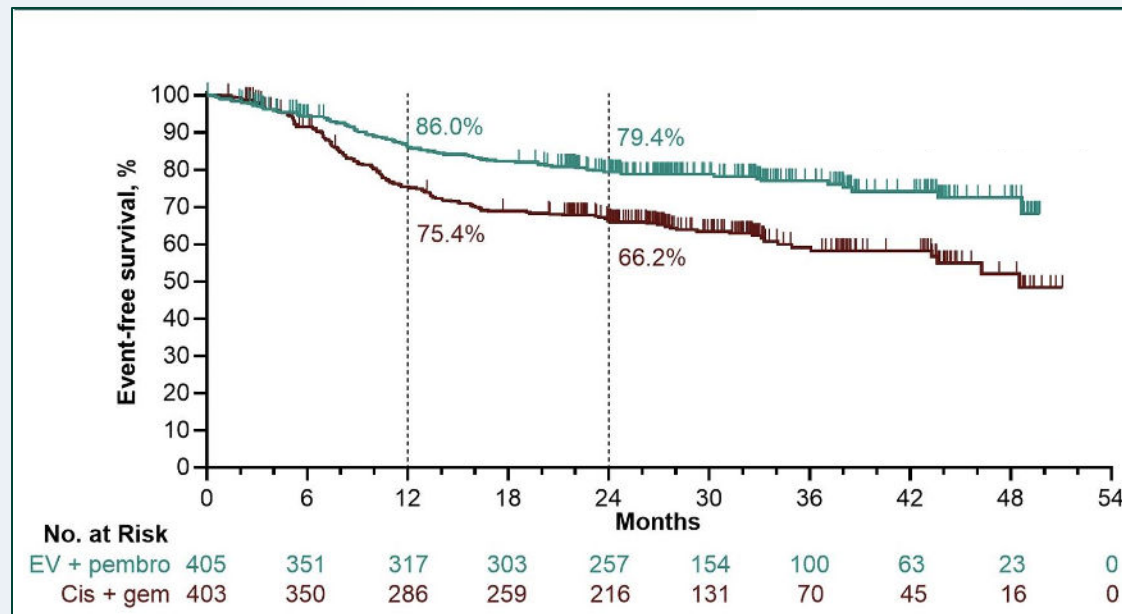
Key secondary endpoints:

- OS, pCR



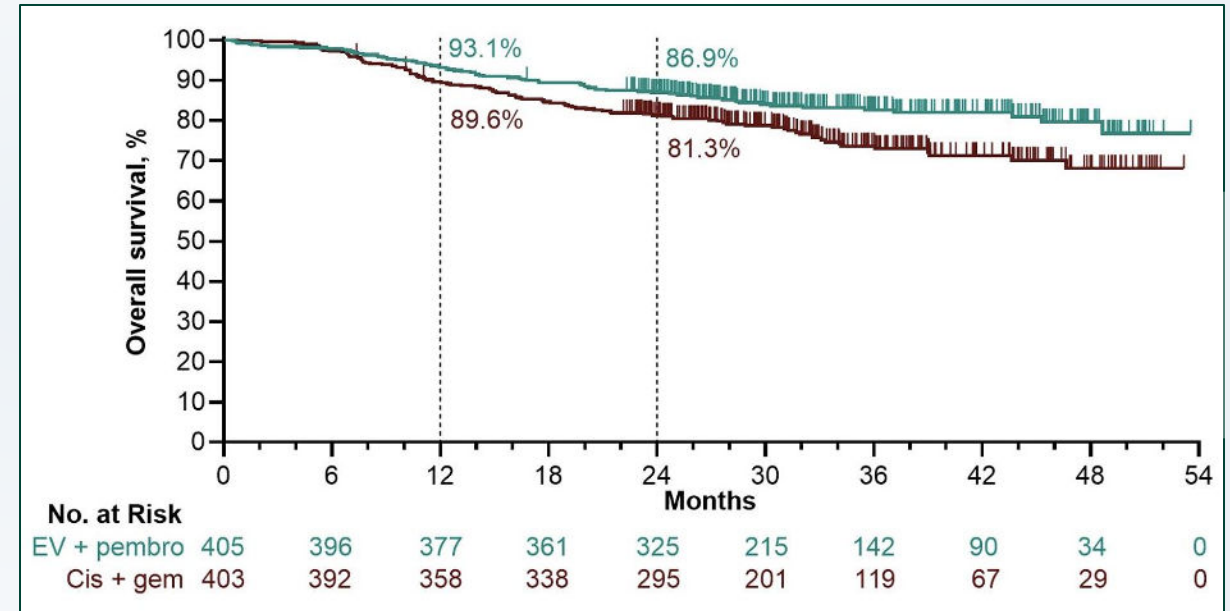
EV-P improves survival over neoadjuvant GC, period

EFS



HR 0.53 (0.41-0.70), $P < 0.0001$
2 year EFS: 79% vs 66%

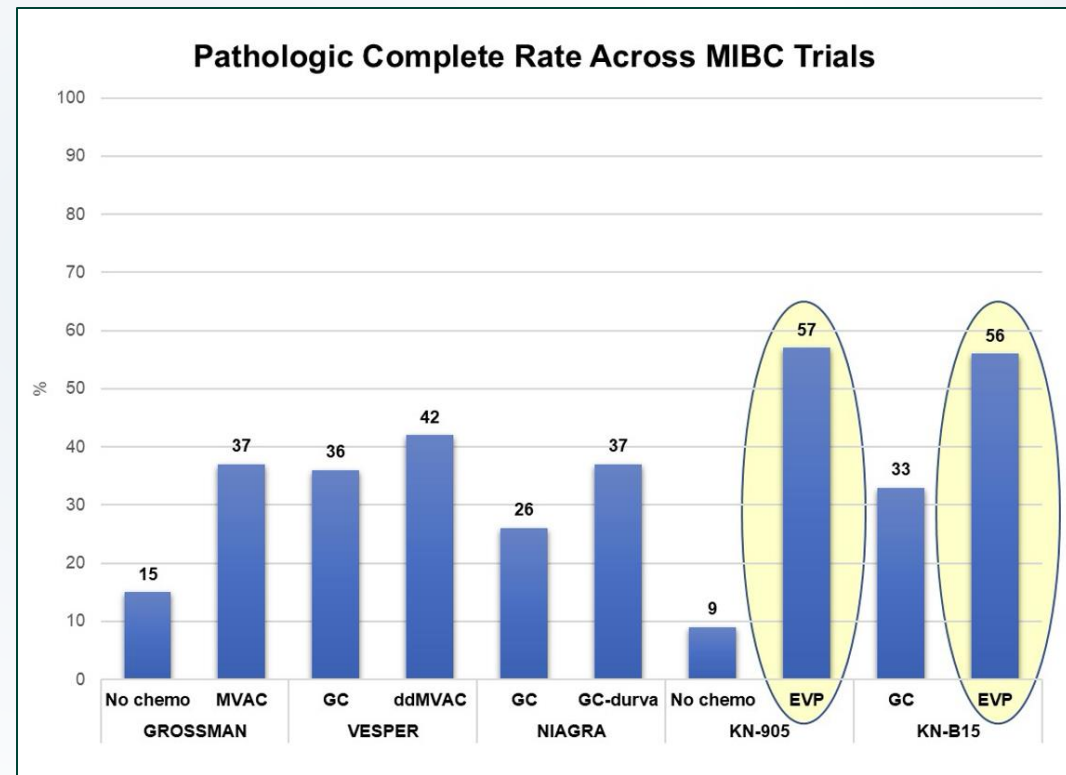
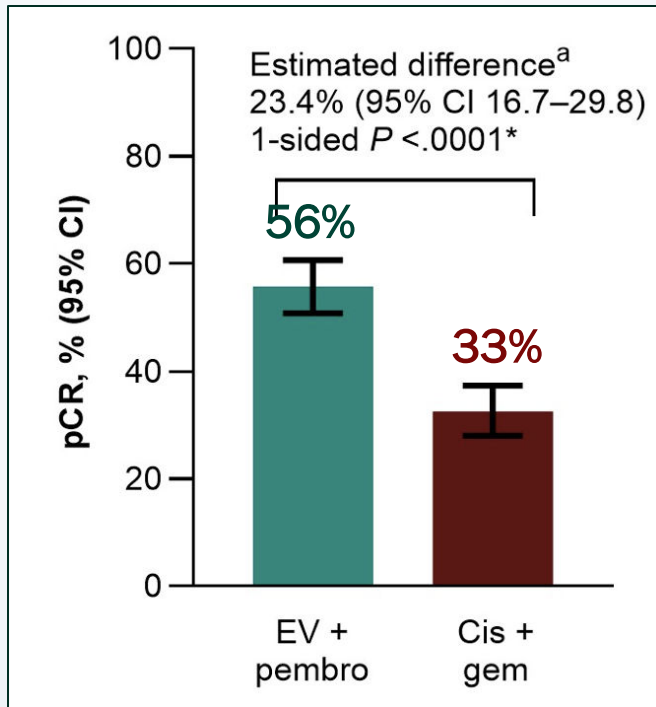
OS



HR 0.63 (0.48-0.89), $P = 0.0029$
2 year OS: 87% vs 81%

pCR of 64% - the highest ever reported in MIBC

pCR in those who underwent surgery: 64% vs 36%

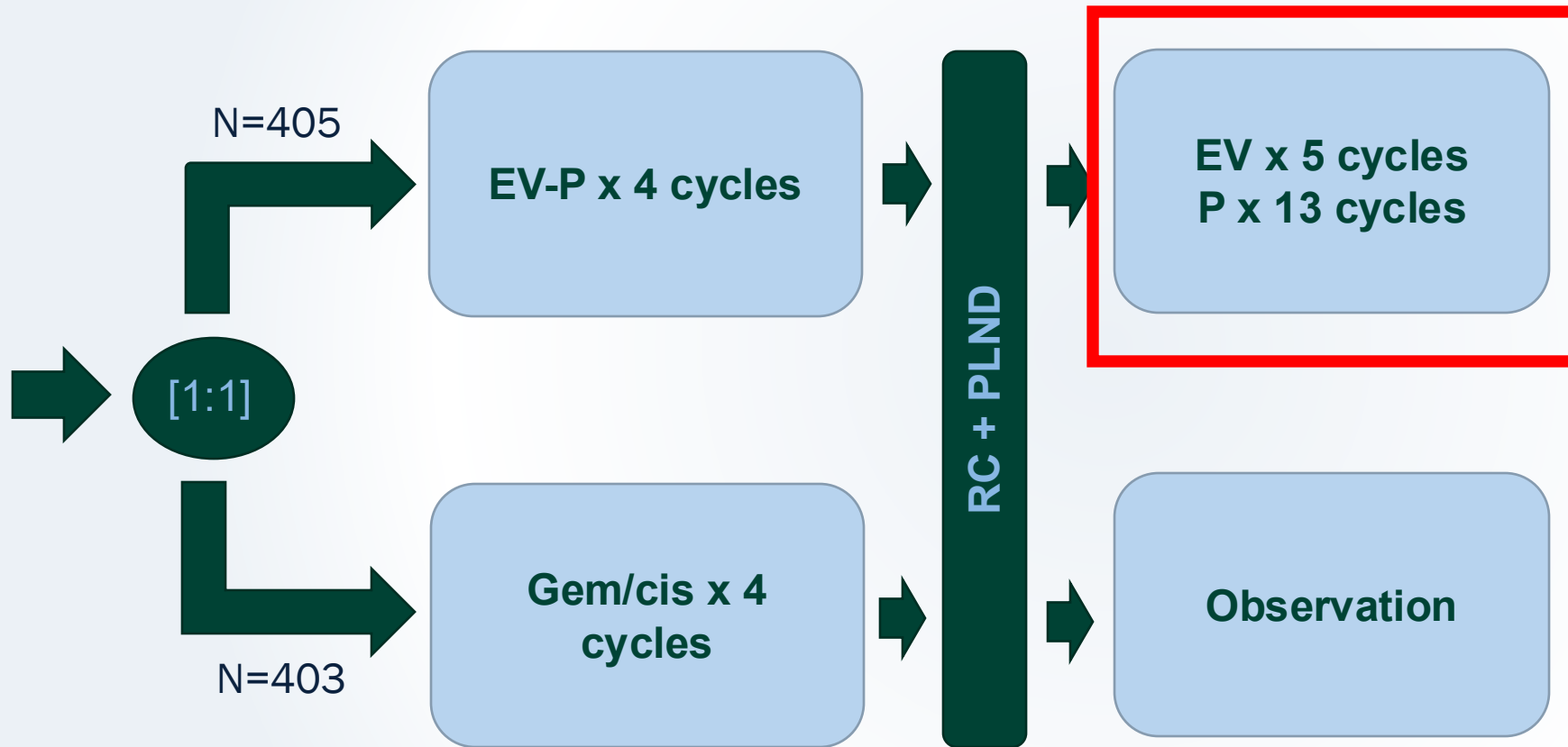


Want to talk about the control arm? Let's talk about it.

Critics say	I say
"it wasn't ddMVAC"	Thank goodness
"There was no adjuvant immunotherapy"	28 of 403 in the GC arm received IO Doesn't change the pCR rate

If we rejected every new study because the control arm didn't reflect the future standard-of-care – **we would never make progress.**

GU medical oncologists are VERY nervous about the toxicity of the sandwich approach



Community oncologists are not

ORIGINAL ARTICLE

Trastuzumab Emtansine for Residual Invasive HER2-Positive Breast Cancer

Authors: Gunter von Minckwitz, M.D., Chiun-Sheng Huang, M.D., Ph.D., Max S. Mano, M.D., Ph.D., Sibylle Loibl, M.D., Eleftherios P. Mamounas, M.D., Michael Untch, M.D., Ph.D., Norman Wolmark, M.D., [+22](#), for the KATHERINE Investigators* [Author Info & Affiliations](#)

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ORIGINAL ARTICLE

Perioperative Chemotherapy or Preoperative Chemoradiotherapy in Esophageal Cancer

Authors: Jens Hoenpner, M.D. [ID](#), Thomas Brunner, M.D. [ID](#), Claudia Schmoor, Ph.D. [ID](#), Peter Bronsert, M.D. [ID](#), Birte Kulemann, M.D., Rainer Claus, M.D. [ID](#), Stefan Utzolino, M.D., [+24](#), and Florian Lordick, M.D. [Author Info & Affiliations](#)

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ORIGINAL ARTICLE

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Trastuzumab Deruxtecan in Residual HER2-Positive Early Breast Cancer

[i](#) This article has been corrected. [VIEW THE CORRECTION](#)

Authors: Sibylle Loibl, M.D., Yeon Hee Park, M.D., Ph.D. [ID](#), Zhiming Shao, M.D., Chiun-Sheng Huang, M.D., Ph.D., M.P.H., Carlos Barrios, M.D., Jame Abraham, M.D., Aleix Prat, M.D., Ph.D., [+23](#), for the DESTINY-Breast05 Trial Investigators* [Author Info & Affiliations](#)

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ORIGINAL ARTICLE

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Adjuvant Capecitabine for Breast Cancer after Preoperative Chemotherapy

Masuda, M.D., Ph.D., Soo-Jung Lee, M.D., Ph.D., Shoichiro Ohtani, M.D., Ph.D., Young-Hyuck Im, M.D., Ph.D., Isao Yokota, Ph.D., Katsumasa Kuroi, M.D., Ph.D., [+13](#), and Masakazu Toi, M.D. [Author Info & Affiliations](#)

2017 | N Engl J Med 2017;376:2147-2159 | DOI: 10.1056/NEJMoa1612645 | [VOL. 376 NO. 22](#)

More than 3-4 cycles is often needed in the metastatic setting to achieve best response...

	EV+P All CR (n=133)	EV+P CR after PR (n=88)
Median time to CR (IQR), months	4.3 (2.2-8.4)	6.6 (4.3-12.1)
Time to PR	–	2.1 (1.9-2.2)
Time from PR to CR	–	4.5 (2.2-10.1)
Median EV cycles prior to CR (IQR), n	6.0 (3.0-9.0)	8.0 (6.0-11.5)
EV cycles prior to PR	–	3.0 (3.0-3.0)
EV cycles from PR to CR	–	5.0 (3.0-8.0)
Median P cycles prior to CR (IQR), n	6.0 (3.0-10.0)	9.0 (6.0-12.0)
P cycles prior to PR	–	3.0 (3.0-3.0)
P cycles from PR to CR	–	6.0 (3.0-9.0)
Median total EV cycles (IQR), n	13.0 (8.0-28.0)	15.0 (9.0-30.0)
Median total P cycles (IQR), n	28.0 (10.0-35.0)	31.0 (12.5-35.0)

- Median 5 cycles of EV to convert a patient from PR to CR
- Median 8 cycles EV total to CR in mUC
- Compare THIS to 9 cycles perioperative EV-P in MIBC

*So yes – there’s an adjuvant component.
And yes, some patients absolutely need it.*

Let's go back to ESMO 2023 when EV-P in mUC got a standing ovation

- A few of my patients come to mind:
 - 71 year old woman with a durable complete response cried last visit because she is allowing herself to think about her grandchildren getting older now
 - 63 year old male with a durable CR for last 3 years who celebrates only having to drive through Atlanta traffic every 3 months for scans now

Some drugs just work better.

Are you *really* going to ignore the patients you are curing with metastatic disease with EV-P when meeting a new patient with MIBC?

3 reasons EV-P is the new standard of care in MIBC

- **The Data:** Category 1, RCT evidence showing superior OS and EFS with EV-P over cisplatin in MIBC
- **The Experience:** Medical oncologists have enough real-world EV-P experience from the metastatic setting to safely and confidently use it perioperatively.
- **The Goal:** I am not sequencing treatments in preparation for future metastatic disease. **I am focused on curing patients now.**