Treatment Naïve and Treatment Experienced

Ombitasvir + Paritaprevir + Ritonavir +/- Ribavirin in HCV GT4

PEARL-I

Hézode C, et al. Lancet. 2015;385:2502-9.

Ombitasvir + Paritaprevir + Ritonavir +/- RBV in HCV GT4
PEARL-I: Study Design

PEARL-I: Features

- **Design**: Phase 2b, randomized, open-label trial evaluating safety and efficacy of ombitasvir-paritaprevir-ritonavir, with or without ribavirin, for 12 weeks in non-cirrhotic treatment-naive and treatment-experienced patients with chronic HCV GT 4
- **Setting**: Multicenter trial performed at international sites
- **Entry Criteria**
  - Chronic HCV infection with genotype 4
  - Treatment naïve or prior treatment with peginterferon plus ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Absence of cirrhosis
  - Absence of coinfection with HBV or HIV
- **Primary End-Point**: SVR12

Source: Hézode C, et al. Lancet. 2015;385:2502-9.

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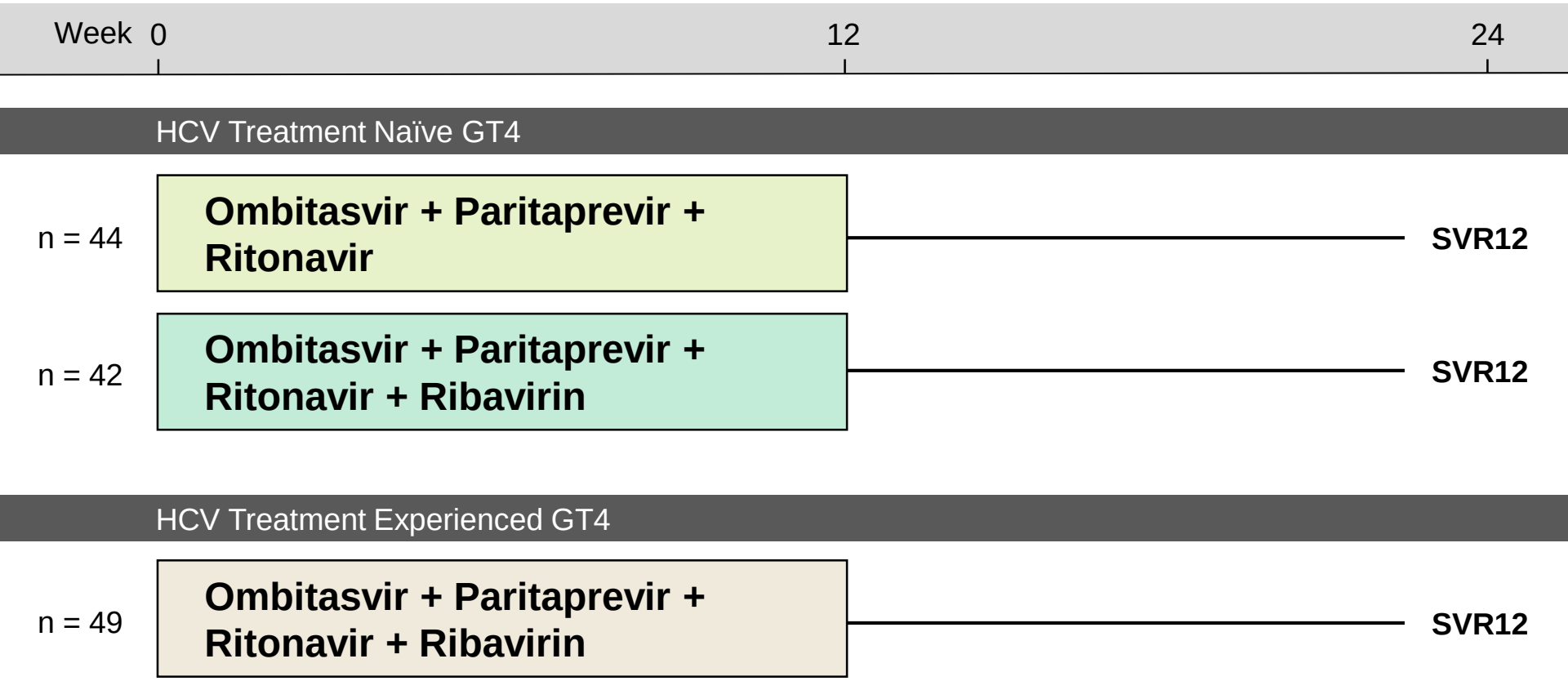
PEARL-I: Regimens



Drug Dosing

Ombitasvir (25 mg once daily), Paritaprevir (150 mg once daily), Ritonavir (100 mg once daily)
Ribavirin (RBV): weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

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PEARL-I: Baseline Characteristics

Baseline Characteristic	Treatment Naive		Treatment Experienced
	OBV/PTV/r (n=44)	OBV/PTV/r + RBV (n=42)	OBV/PTV/r + RBV (n=49)
Age, years	49	44	51
BMI kg/m^2	25	25	27
IL28B			
CC	27%	26%	12%
CT	55%	62%	65%
TT	18%	12%	22%
HCV RNA $\log_{10}$ IU/ml	6.1	6.1	6.3
HCV RNA ≥ 800,000 IU/ml	61%	71%	76%
Fibrosis Stage			
F0-F1	86%	79%	67%
F2	9%	14%	22%
F3	15%	7%	10%

OBV/PTRV/r = Ombitasvir-Paritaprevir-Ritonavir; **RBV** = Ribavirin

Source: Hézode C, et al. Lancet. 2015;385:2502-9.

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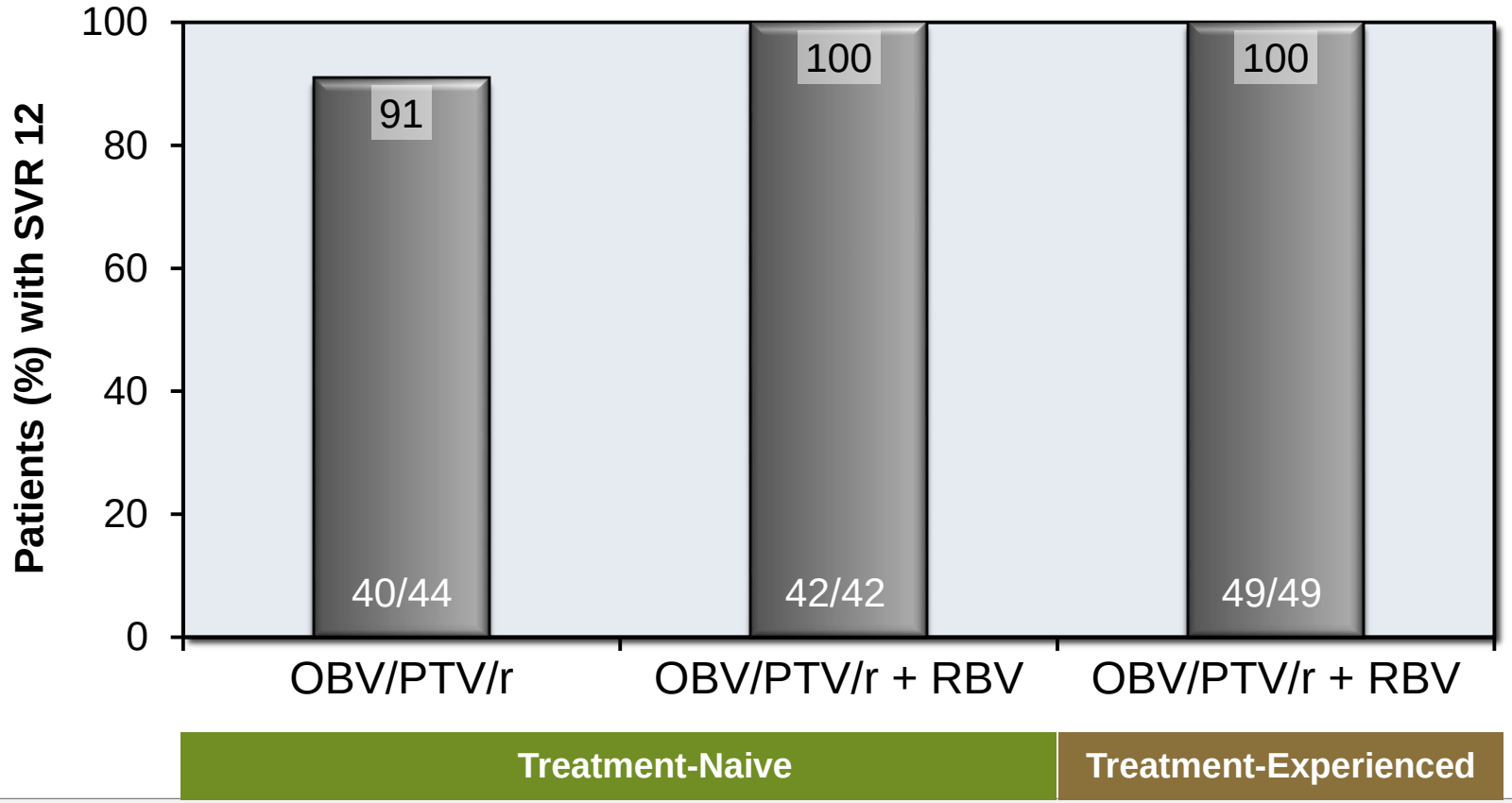
PEARL-I: Results

PEARL-I: SVR 12 Rates (HCV RNA <25 IU/mL)



OBV/PTV/r = Ombitasvir-Paritaprevir-Ritonavir; **RBV** = ribavirin

Source: Hézode C, et al. Lancet. 2015;385:2502-9.

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PEARL-I: Adverse Events

Baseline Characteristic	Treatment Naive		Treatment Experienced
	OBV/PTV/r (n=44)	OBV/PTV/r + RBV (n=42)	OBV/PTV/r + RBV (n=49)
Any adverse event	34 (77%)	37 (88%)	43 (88%)
Any serious adverse event	1 (2%)	0	0
Adverse event causing drug D/C	0	0	0
Asthenia	11 (25%)	10 (24%)	16 (33%)
Diarrhea	2 (5%)	6 (14%)	3 (6%)
Fatigue	3 (7%)	5 (12%)	9 (18%)
Headache	13 (30%)	14 (33%)	14 (29%)
Insomnia	2 (5%)	4 (10%)	8 (16%)
Irritability	3 (7%)	6 (14%)	2 (4%)
Myalgias	0	0	5 (10%)
Nasopharyngitis	2 (5%)	2 (5%)	6 (12%)
Nausea	4 (9%)	7 (17%)	6 (12%)
Pruritis	2 (5%)	1 (2%)	5 (10%)

OBV/PTV/r = Ombitasvir-Paritaprevir-Ritonavir; **RBV** = Ribavirin; D/C = discontinuation

Source: Hézode C, et al. Lancet. 2015;385:2502-9.

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PEARL-I: Interpretation

Interpretation: “An interferon-free regimen of ombitasvir plus paritaprevir plus ritonavir with or without ribavirin achieved high sustained virological response rates at 12 weeks after the end of treatment and was generally well tolerated, with low rates of anaemia and treatment discontinuation in non-cirrhotic previously untreated and previously treated patients with HCV genotype 4 infection.”

Source: Hézode C, et al. Lancet. 2015;385:2502-9.

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

http://depts.washington.edu/hepstudy/

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