Treatment-Naïve

Daclatasvir + Peg/RBV in Treatment-Naïve Genotype 4

COMMAND-4 Study

Hézode C, et. al. Antivir Ther. 2015;21:195-205.

Daclatasvir + Peginterferon/RBV for HCV GT 4
COMMAND-4 Trial: Study Features

Daclatasvir + PR Trial: Features

- **Design**: Phase 3 randomized, placebo-controlled trial of daclatasvir (DCV) with peginterferon alfa-2a and ribavirin in treatment-naïve patients with chronic HCV genotype 4
- **Setting**: United States and Europe
- **Entry Criteria**
  - Chronic HCV Genotype 4
  - Treatment-naïve
  - HCV RNA >10,000 IU/ml
  - Compensated cirrhosis allowed
- **Treatment Arm**
  - Daclatasvir with peginterferon alfa-2a and ribavirin (weight-based dosing) x 24 weeks with response-guided treatment: if extended rapid virologic response (eRVR), then treatment stopped, if no eRVR, then followed by 24-week PR tail.
- **End-Points**: Primary=SVR12

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

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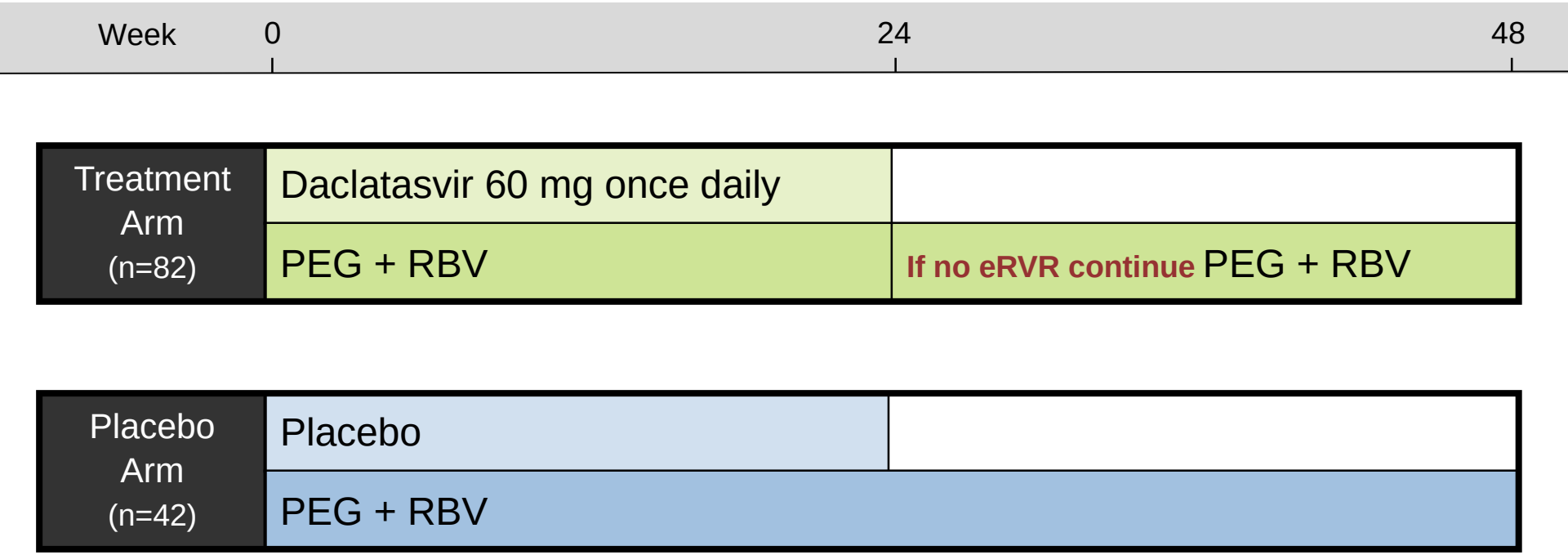
COMMAND-4 Trial: Design



eRVR = HCV RNA < 25 IU/mL at weeks 4 and 12
PEG = peginterferon; RBV = ribavirin

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

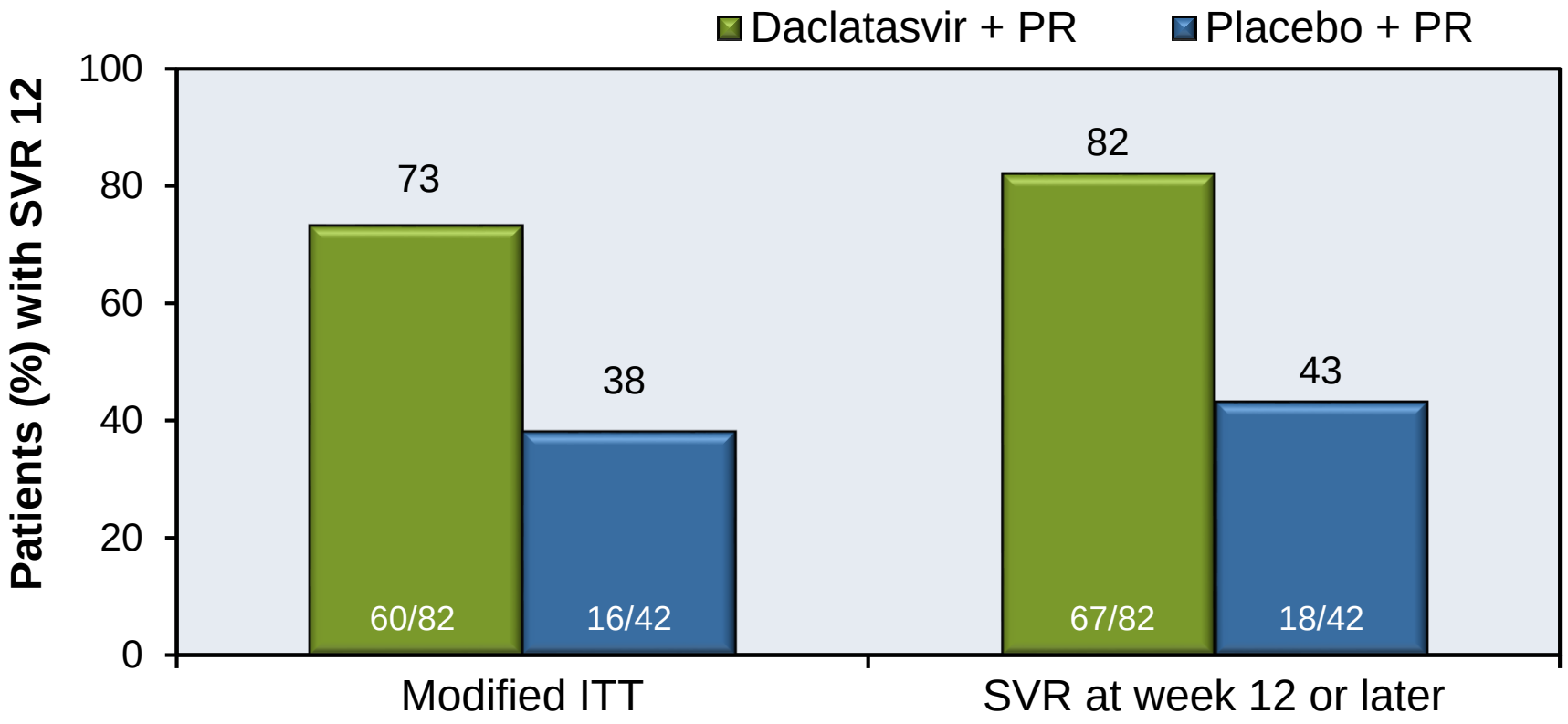
Daclatasvir + Peginterferon/RBV for HCV GT 4
COMMAND-4 Trial: Patient Characteristics

Characteristic	DCV + Peg/RBV (n=82)	Placebo + Peg/RBV (n=42)
Male	61 (74%)	29 (69%)
Median age, years	49 (20-71)	50 (32-61)
Race White Black Other	 60 (73%) 18 (22%) 4 (5%)	 36 (86%) 5 (12%) 1 (2%)
HCV genotype 4 unspecified 4a, 4c, or 4d	 26 (32%) 46 (56%)	 16 (38%) 24 (57%)
HCV RNA ≥800,000 IU/ml	39 (48%)	16 (38%)
Cirrhosis	9 (11%)	4 (9.5%)
IL28B non-CC genotype	60 (73%)	33 (79%)

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

Daclatasvir + Peginterferon/RBV for HCV GT 4
COMMAND-4 Trial: Results

COMMAND-4: SVR12 by Analysis

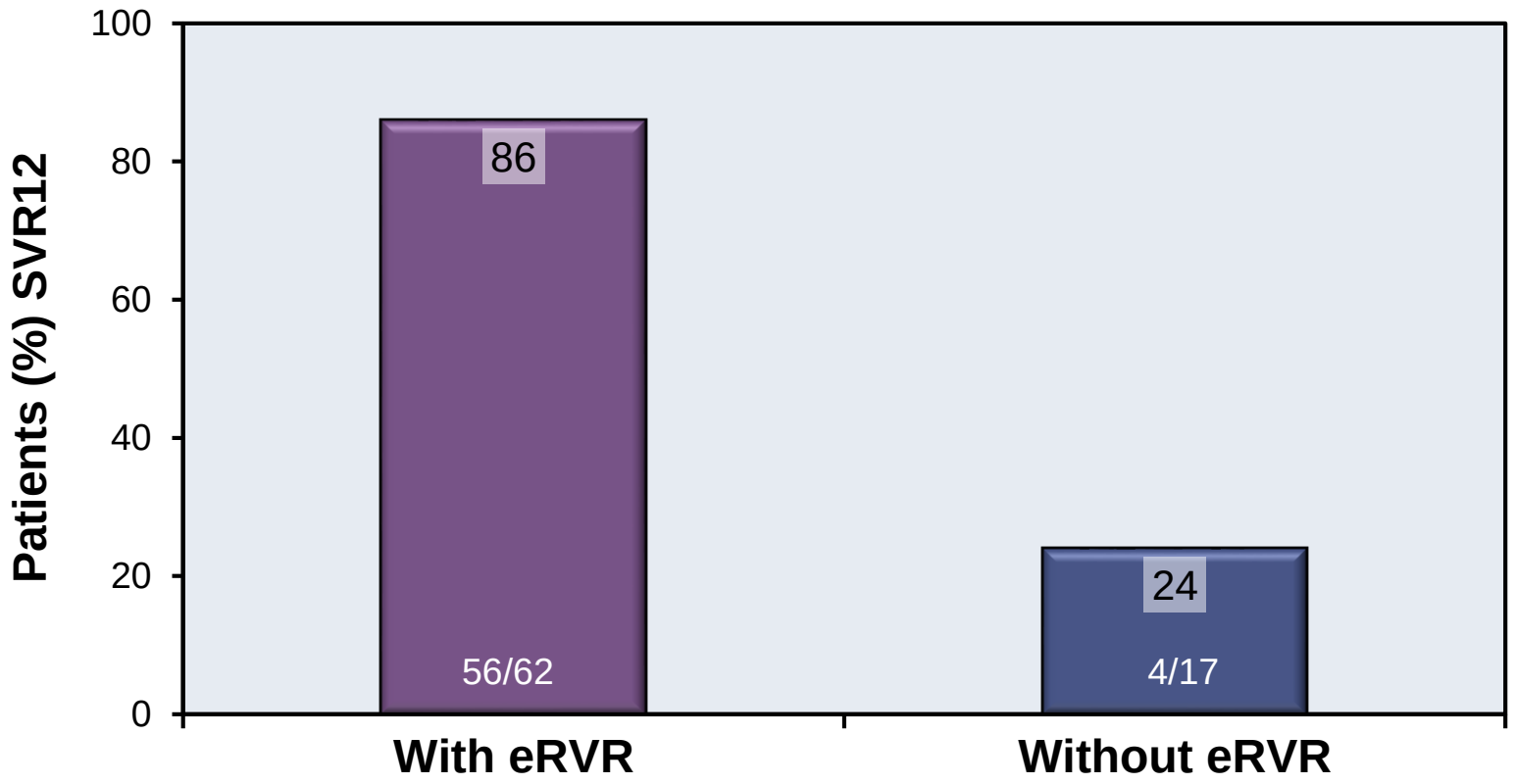


Modified ITT, intent-to-treat: patients with missing data at post-treatment week 12 were considered treatment failures.

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

Daclatasvir + Peginterferon/RBV for HCV GT 4
COMMAND-4: Results in Daclatasvir Arm

COMMAND-4: SVR12 by eRVR in Patients Receiving DCV



In DCV group, most (79%) patients achieved an eRVR and were eligible for shortened (24 week) duration

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

Hepatitis web study

Daclatasvir + Peginterferon/RBV for HCV GT 4
COMMAND-4: Conclusions

Conclusions: “In treatment-naive patients with HCV GT4 infection, daclatasvir plus peginterferon/ribavirin achieved higher SVR12 rates than peginterferon/ribavirin alone. These data support daclatasvir-based regimens for treatment of HCV GT4 infection, including all-oral combinations with other direct-acting antivirals.”

Source: Hézode C, et. al. Antivir Ther. 2015;21:195-205.

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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Hepatitis
web study