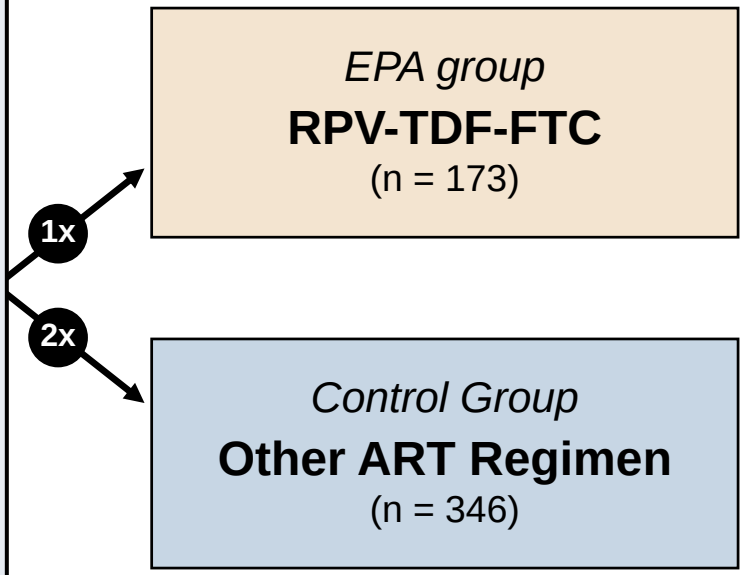
Rilpivirine-TDF-FTC in HIV-HCV Coinfected Patients

hEPAtic Study

Rilpivirine-TDF-FTC in HIV-HCV Coinfected Patients
hEPAtic: Design

Study Design: hEPAtic STUDY

- **Background**: Retrospective, case-control study to evaluate the hepatic safety (as measured by frequency of transaminase and total bilirubin elevations) of rilpivirine-tenofovir DF-emtricitabine once daily in HIV-HCV-coinfected patients.
- **Inclusion Criteria (n = 519)**
  - Age >18 years
  - Chronic HCV (detectable HCV RNA)
  - Starting new antiretroviral (ART) regimen
- **Treatment Arms**
  - EPA Group: Rilpivirine-tenofovir DF-emtricitabine
  - Control Group: Other new antiretroviral regimen



EPA = rilpivirine-tenofovir DF-emtricitabine (*Complera*)

Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

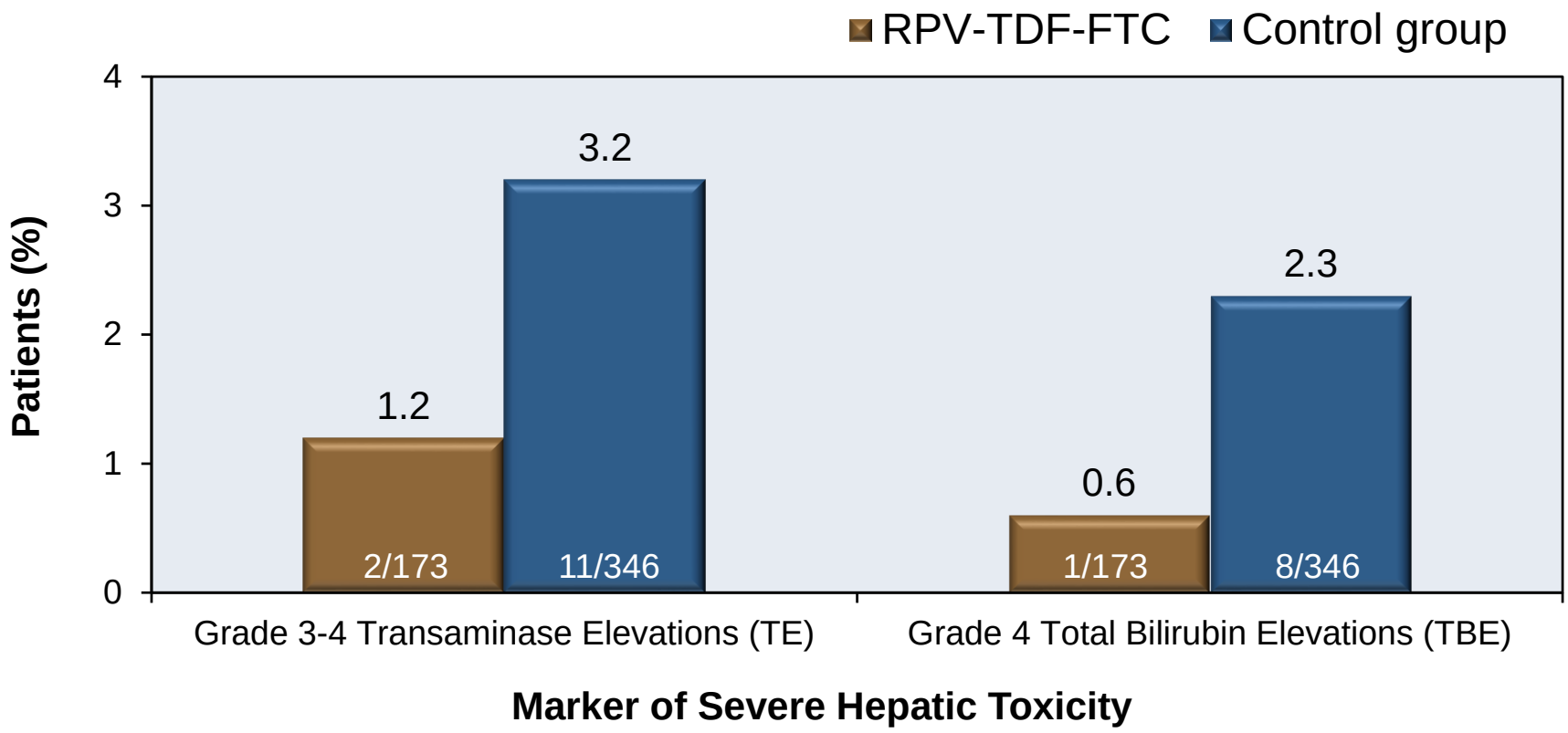
Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients
hEPAtic: Patient characteristics

Newly introduced antiretroviral therapy (ART) in the control group (n=346)			
Antiretroviral Drug	**Initiated ART (%)**	**Antiretroviral Drug**	**Initiated ART (%)**
Tenofovir DF-emtricitabine	21.7	Efavirenz	9.5
Abacavir-lamivudine	12.4	Nevirapine	2.9
Other NRTI combinations	11	Etravirine	8.7
Lopinavir/ritonavir	4.3	Raltegravir	13
Atazanavir/ritonavir	13.9	Maraviroc	6.9
Darunavir/ritonavir	32.9		

Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients
hEPAtic: Result

Frequency of Severe Hepatic Toxicity

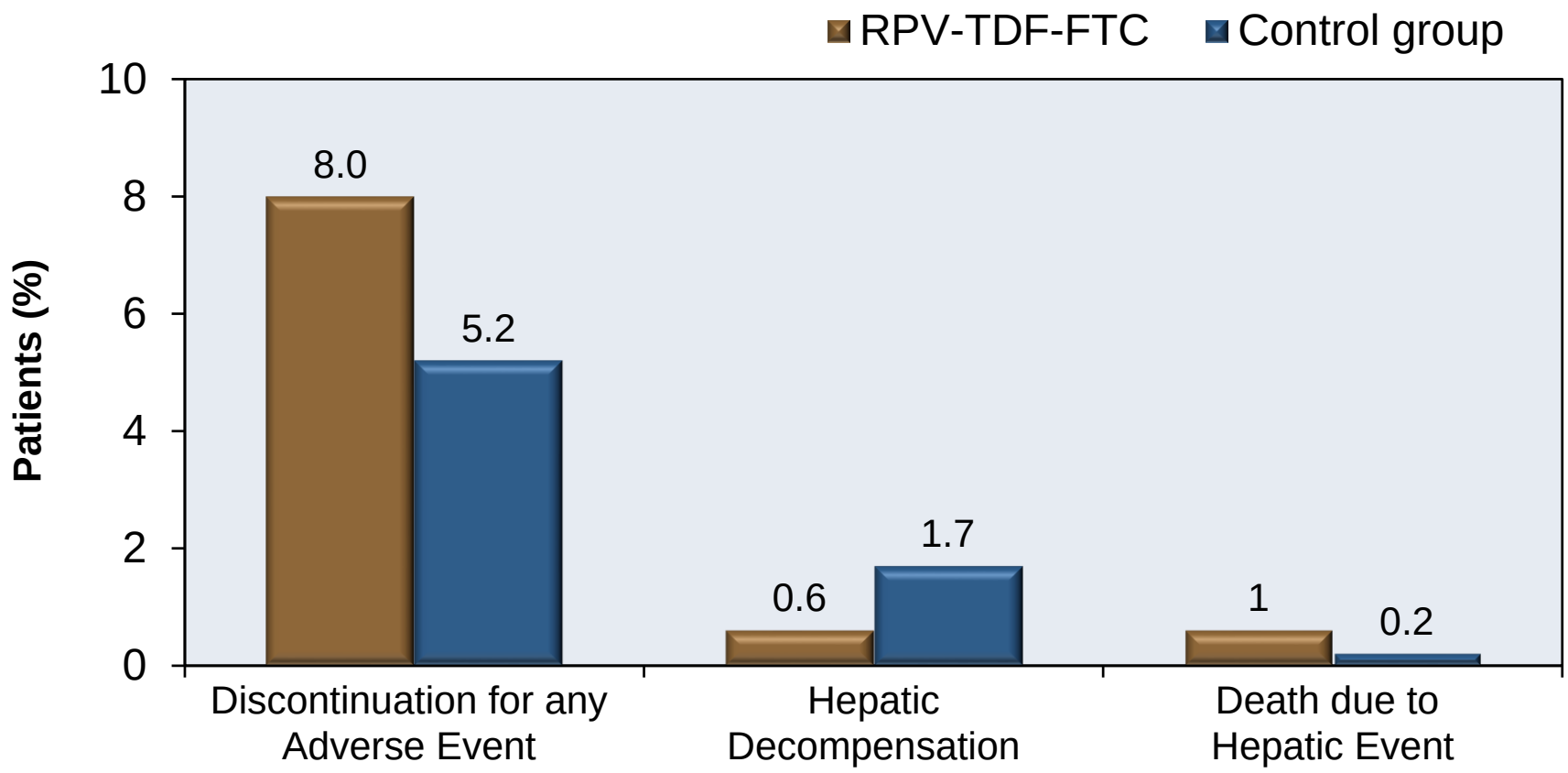


Grade 3 TE = ALT or AST 5-10x ULN; Grade 4 TE = ALT or AST > 10x ULN; Grade 4 TBE: total bilirubin ≥ 5 mg/dL

Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients
hEPAtic: Result

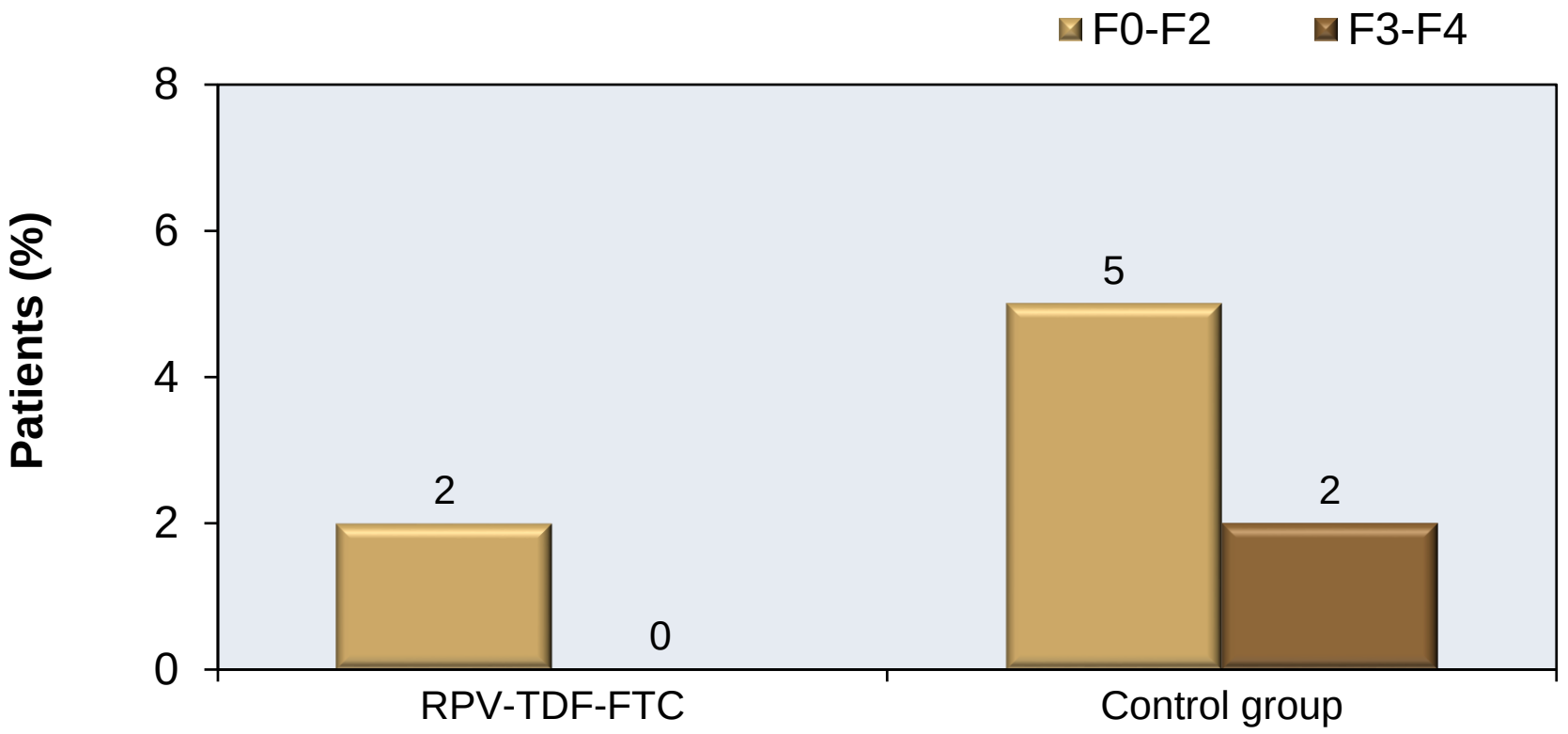
Discontinuation, Decompensation, and Death



Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients
hEPAtic: Result

Grade 3-4 Transaminase Elevation, by Degree of Hepatic Fibrosis



Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

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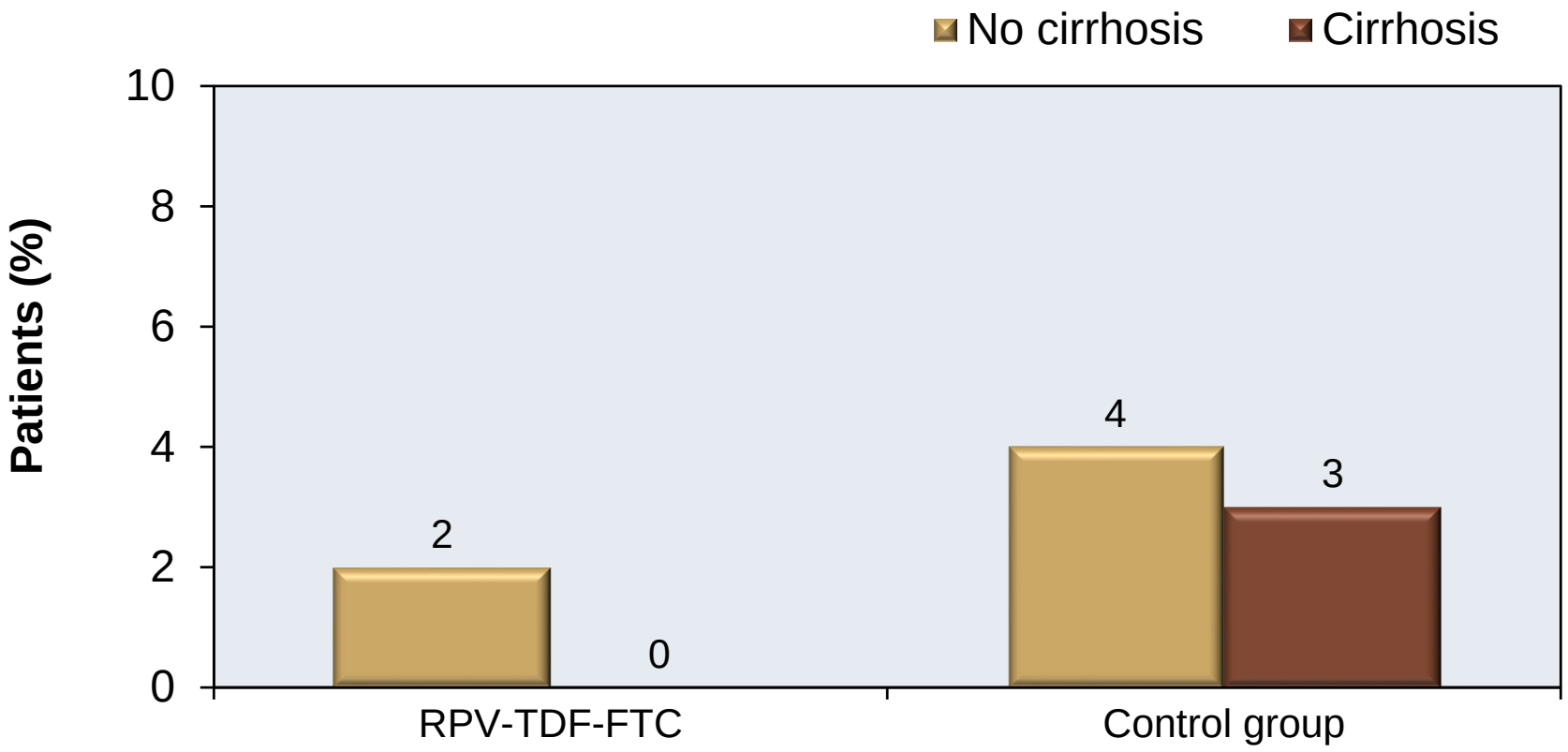
Rilpivirine-FTC-TDF in HIV-HCV Coinfected Patients
hEPAtic: Result

Grade 3-4 Transaminase Elevation, by Presence of Cirrhosis



Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

Rilpivirine-FTC-TDF in HIV-HCV Coinfected Patients
hEPAtic: Conclusions

Conclusion: “The frequency of severe liver toxicity in HIV/HCV-coinfected subjects receiving EPA under real-life conditions is very low, TE were generally mild and did not lead to drug discontinuation. All these data suggest that EPA can be safely used in this particular subpopulation.”

Source: Neukam K, et al. PLoS One. 2016;11:e0155842.

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