

# Efficacy evaluation of 24 week SOF + RBV in a heterogeneous, real-world population of Genotype 3 HCV; data from the TRIO network



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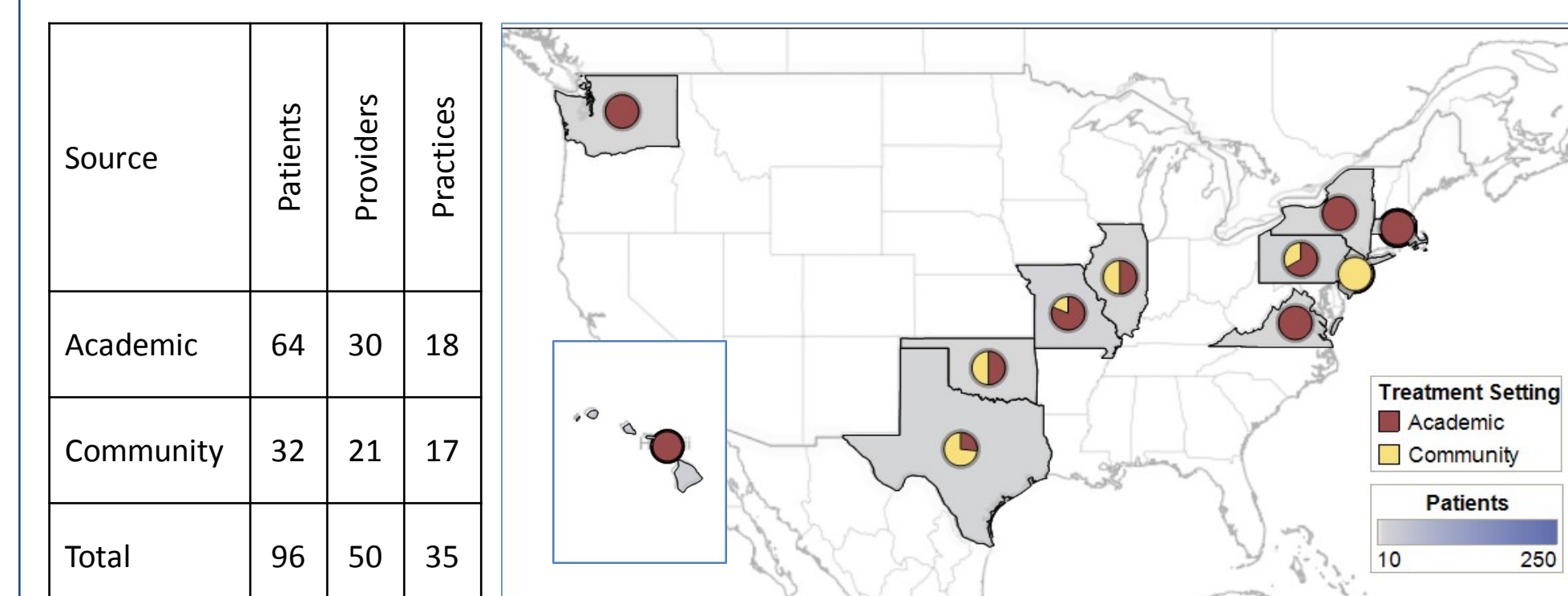
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## 1. BACKGROUND AND AIM

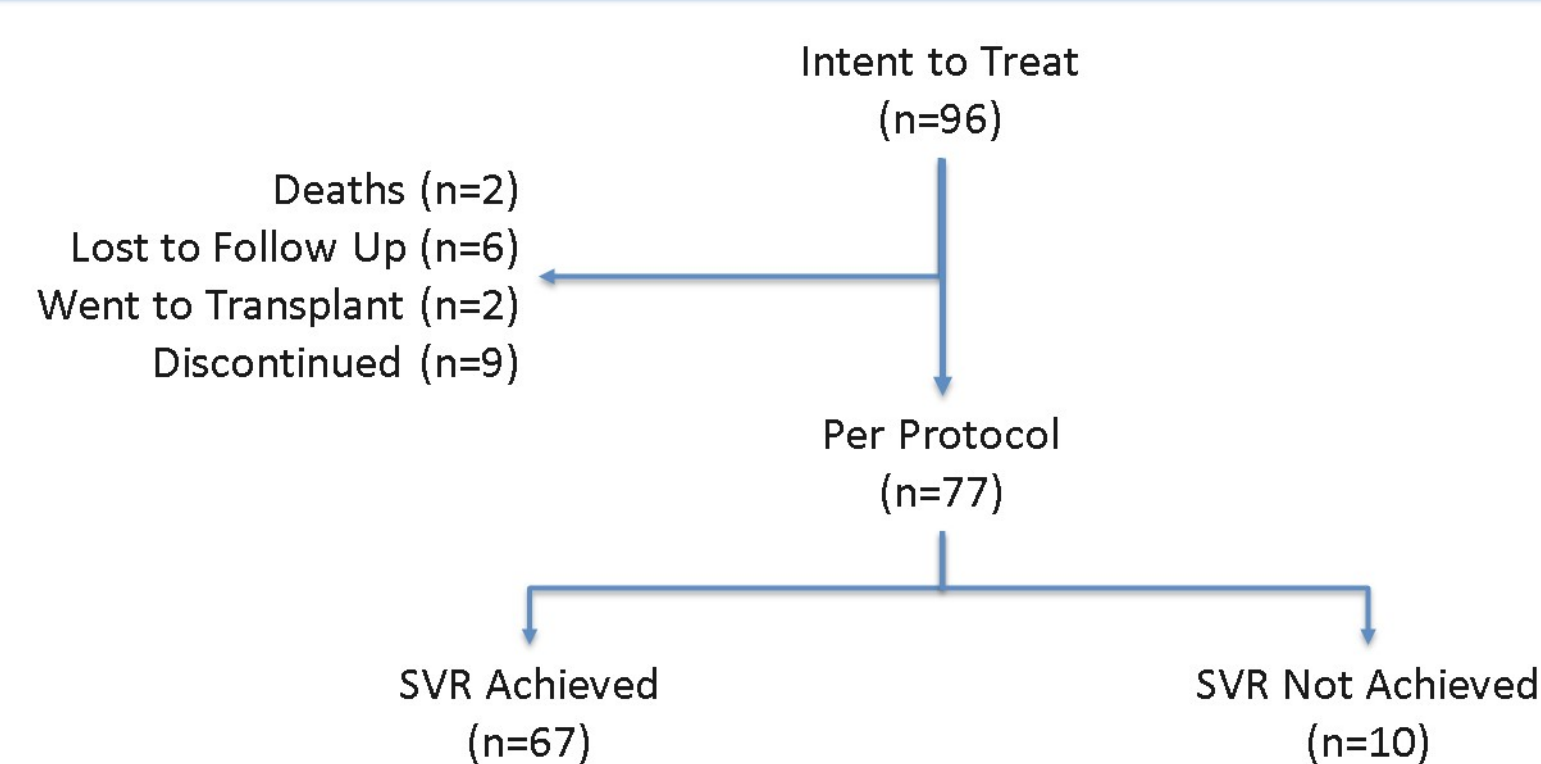
HCV genotype 3 has proven difficult to treat in clinical trials. Understanding outcomes in a heterogeneous real-world population is important for patients and physicians. Data obtained through the Trio Health program were used to evaluate 24 week sofosbuvir plus ribavirin (SOF + RBV) for HCV genotype 3 patients.

## 2. METHODS

Trio Health is a disease management company that works in partnership with academic medical centers, community physicians and specialty pharmacies to optimize care for Hepatitis C. Data were collected from Rx records through the Trio Platform in partnership with AcariaHealth, AllCare Plus Pharmacy, Aureus Health Services and other specialty pharmacies. Analyses were limited to 96 patients who initiated a 24 week course of SOF + RBV between Dec 2013 and Mar 2014. These 96 patients were treated in 35 practices, 17 of which were community based and 18 that were academic.



## 3. PATIENT DISPOSITION



## 4. BASELINE CHARACTERISTICS

Regimen - no.	24 Week RBV + SOF
	96
<b>Age - mean (range)</b>	54 (27-72)
<b>Male - no. (%)</b>	54 (56%)
<b>Ethnicity - no. (%)</b>	
AFRICAN AMERICAN	3 (3%)
ASIAN	7 (7%)
CAUCASIAN	65 (68%)
LATIN / HISPANIC	7 (7%)
OTHER	14 (15%)
<b>Baseline - mean (range)</b>	
AST (n=300)	89 (23-456)
ALT (n=300)	97 (11-790)
Hb (n=297)	14.2 (8.6-17.6)
Platelets (n=296)	158 (38-429)
<b>Initial Viral Load - no. (%)</b>	
<800K IU/ml	39 (41%)
800K<2MM IU/ml	17 (18%)
2MM<=6MM IU/ml	25 (26%)
>6MM IU/ml	14 (15%)
Unknown	1 (1%)
<b>Cirrhosis - no. (%)</b>	29 (30%)
<b>Treatment Experienced - no. (%)</b>	37 (39%)
Null Responder	15 (41%)
Responder Relapse	22 (59%)
<b>Prior Treatment</b>	
PEG + RBV	24 (65%)
PEG + RBV + PI	1 (3%)
Other/Unknown	12 (32%)

## 5. DISCONTINUED PATIENTS

9 (9%) of 96 patients discontinued treatment. 4 (4%) patients were non-compliant with treatment, 3 (3%) patients stated intolerance to treatment, 2 (2%) patients stopped due to clinical reasons unrelated to treatment. No additional information on discontinuation reasons was provided or is available.

## 6. DEATHS

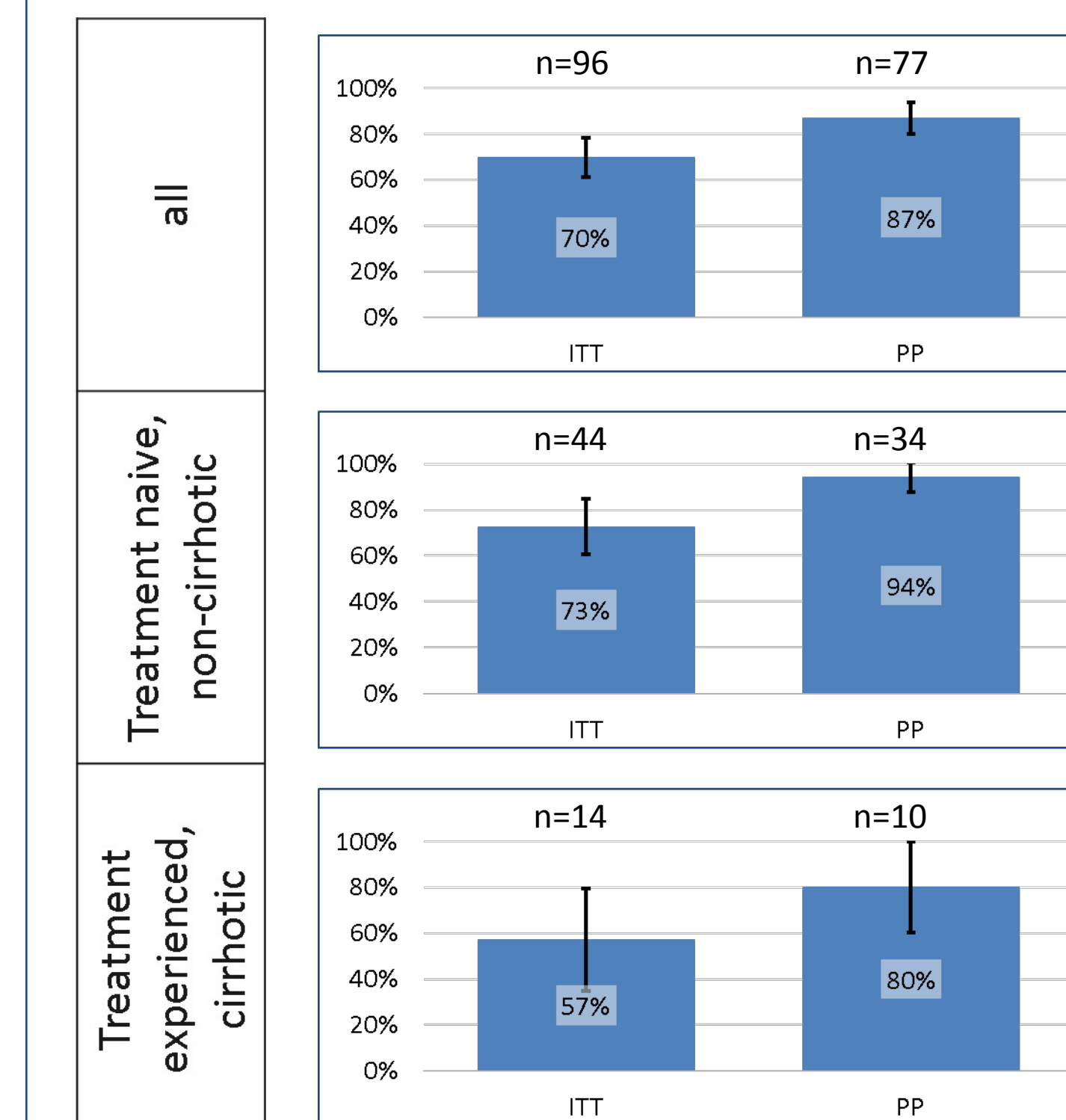
2 (2%) of 96 patients died due to causes unrelated to treatment. No additional information on reasons for death was provided or is available.

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## 7. SVR12 RATES

SVR12 for GT3 patients treated with 24 week SOF + RBV. Numerator = SVR Achieved; Denominator = Intent to Treat (ITT) or Per Protocol (PP) Population. Whiskers = 95% confidence intervals.



## 9. SUMMARY

From an initial data collection of 1,211 patients that initiated treatment for HCV between Dec 2013 and Mar 2014, 96 patients were identified as receiving 24 week SOF+RBV for genotype 3. Of the 96 patients, 54/96 (56%) were male, 14 /96 (15%) had an initial viral load >6MM IU/ml, 29/96 (30%) had cirrhosis, and 37/96 (39%) were previously treated.

Overall SVR12 for the Intent to Treat (ITT) group was 70% (67/96) with 9% (9/96) of patients who discontinued treatment and 2% (2/96) of patients who expired. Overall SVR12 for the Per Protocol (PP) group was 87% (67/77). SVR12 rates in subgroups indicated a significant difference in the PP group when stratified by prior treatment status; treatment experienced patients achieved an SVR12 rate of 74% (23/31) compared to 96% (44/46) SVR12 in treatment naive patients. Other stratifications, including cirrhotic status, revealed differences that did not reach significance.

## 8. PREDICTORS OF RESPONSE

Circles indicate SVR12, whiskers = 95% confidence intervals. Rates that are significantly different are indicated by filled circles.

