



ADVANCES IN CHRONIC HEPATITIS C: MANAGEMENT AND TREATMENT

INDEPENDENT REPORTING ON AASLD 2015

COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

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Failure with All-oral DAA Regimens: Real-world experience from the TRIO Network

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Abstract LB-17

TRIO: Data Elements Collected

Patient Demographics

Age
Gender
Ethnicity
BMI

Clinical Demographics

Q80K (<5%)
IL-28
Baseline Labs
ALT / AST, Hemoglobin, Platelets,
Serum Creatinine, Viral Load
Co-infection
HIV, HBV
Co-morbid
Anxiety, Depression, Diabetes
Genotype / Subtype
Cirrhosis / Fibrosis Score

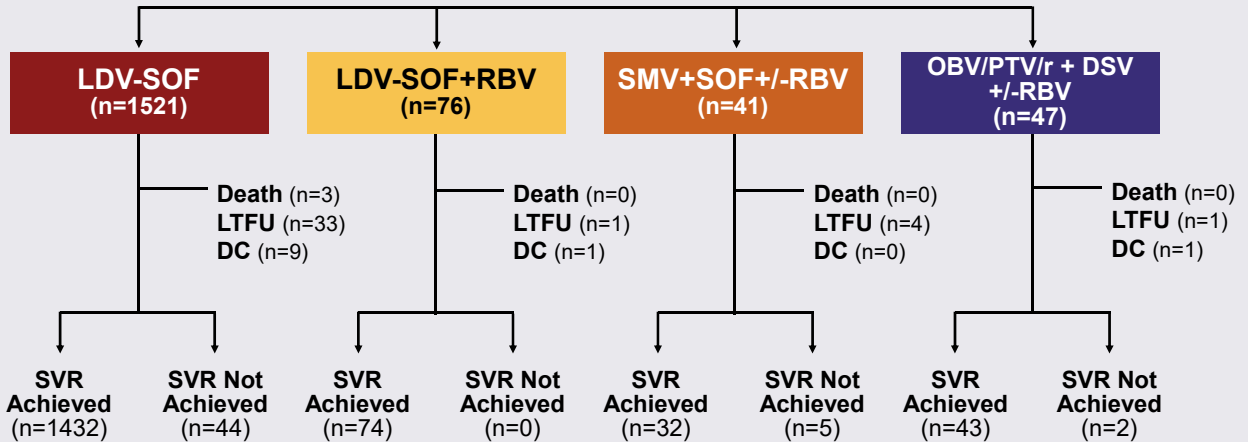
Treatment Specifications

Prior Transplant
Prior Treatment Status
Naïve, Experienced
Prior Treatment Response
Partial Responder, Responder Relapse,
Null Responder
Prior Treatment Regimen
Current Treatment Regimen
Intended Regimen / Duration, Dispensed
Regimen / Duration
Drug Dispense Information
NDC, Date, Dose, Days Supplied, Units
Treatment Outcomes
Discontinuation, EOT, SVR4, SVR12

TRIO: Patient Disposition

Treated with 12 Weeks of Therapy

(n=1685)



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TRIO: Baseline Demographics

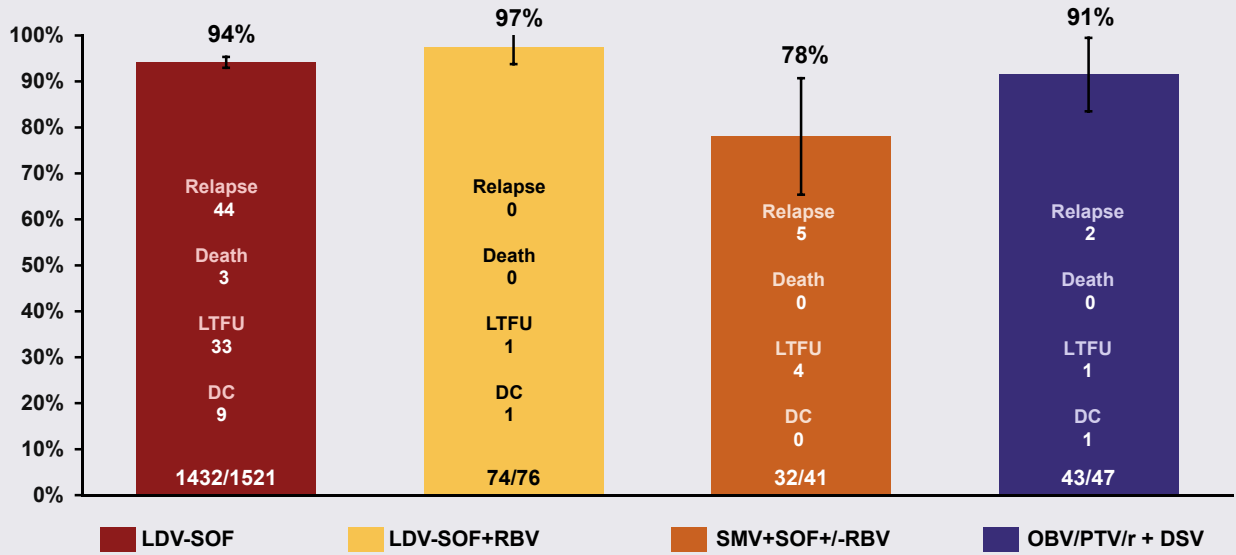
Patients on a 12 week regimen, n = 1685

Patient Demographics and Clinical Characteristics at Baseline

Group - no. (%)	LDV-SOF 12 Week n= 1521	LDV-SOF + RBV 12 Week n= 76	SMV + SOF +/- RBV 12 Week n= 41	OBV/PTV/r + DSV +/- RBV 12 Week n=47
Academic Practice - no. (%)	611 (40%)	65 (86%)	23 (56%)	19 (40%)
Age - mean (range)	60 (19-89)	59 (40-73)	60 (38-80)	58 (32-80)
Male - no. (%)	868 (57%)	56 (74%)	23 (56%)	28 (60%)
Patient Ethnicity - no. (%)				
Asian	53 (3%)	1 (1%)	0 (0%)	1 (2%)
Black	234 (15%)	11 (14%)	5 (12%)	9 (19%)
Hispanic/Latin	100 (7%)	5 (7%)	2 (5%)	4 (9%)
Pacific Islander	8 (1%)	0 (0%)	0 (0%)	0 (0%)
White	742 (49%)	52 (68%)	16 (39%)	23 (49%)
Other	12 (1%)	0 (0%)	0 (0%)	0 (0%)
Unknown	372 (24%)	7 (9%)	18 (44%)	10 (21%)
Baseline Labs				
ALT - mean (s.d.)	69 (59), n=1391	82 (53), n=74	66 (79), n=33	83 (108), n=45
AST - mean (s.d.)	62 (45), n=1382	78 (48), n=74	60 (50), n=32	64 (44), n=45
Hb - mean (s.d.)	14 (7), n=1464	14 (2), n=73	14 (1), n=34	15 (2), n=45
Platelets <100 K/ml - no. (%)	142 (11%)	15 (21%)	7 (21%)	6 (14%)
Platelets >=100 K/ml - no. (%)	1197 (89%)	58 (79%)	27 (79%)	38 (86%)
Genotype - no. (%)				
1a	1017 (67%)	57 (75%)	28 (68%)	26 (55%)
1b	433 (28%)	16 (21%)	13 (32%)	21 (45%)
1Mixed	7 (0%)	0 (0%)	0 (0%)	0 (0%)
1Unknown	64 (4%)	3 (4%)	0 (0%)	0 (0%)

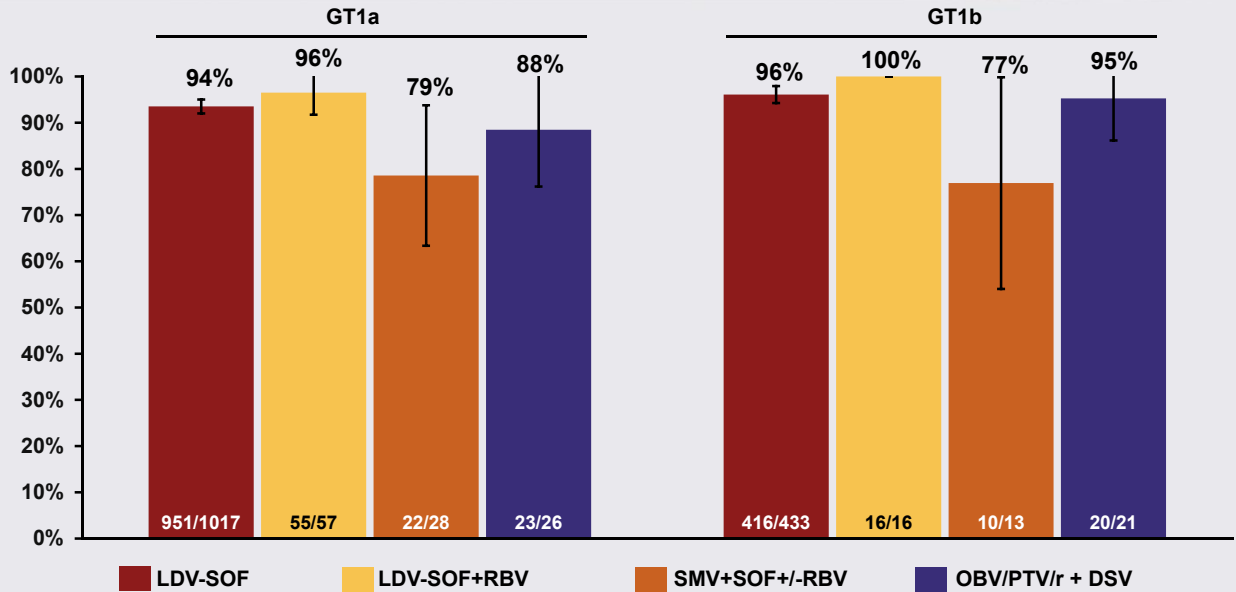
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TRIO: SVR12 Rates by Regimen



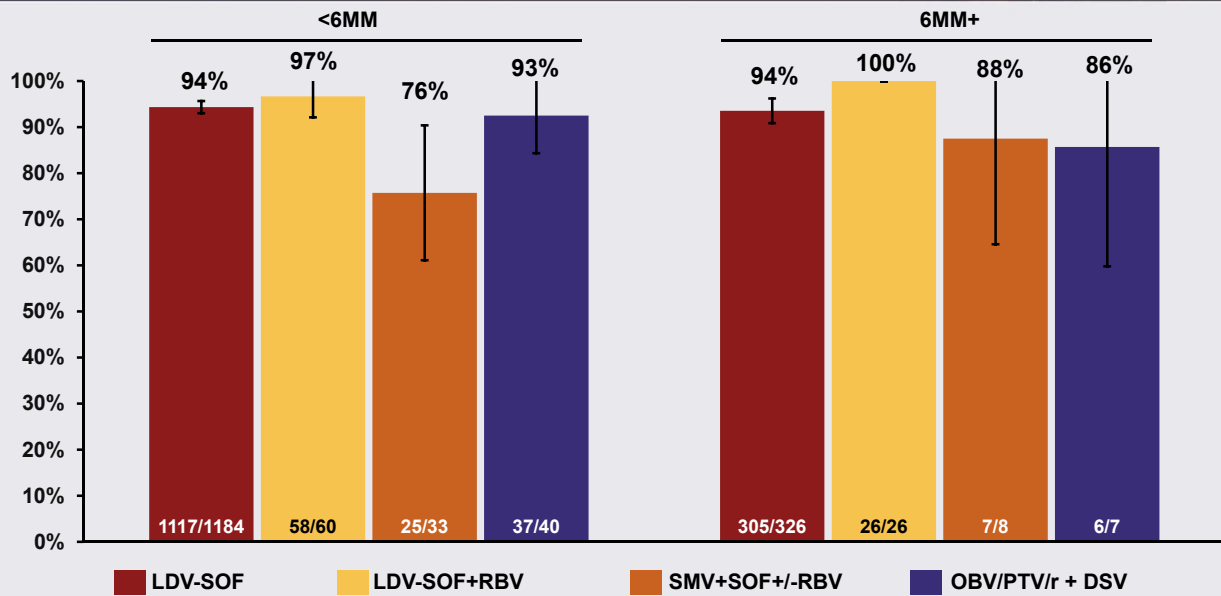
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TRIO: SVR12 Rates by Genotype



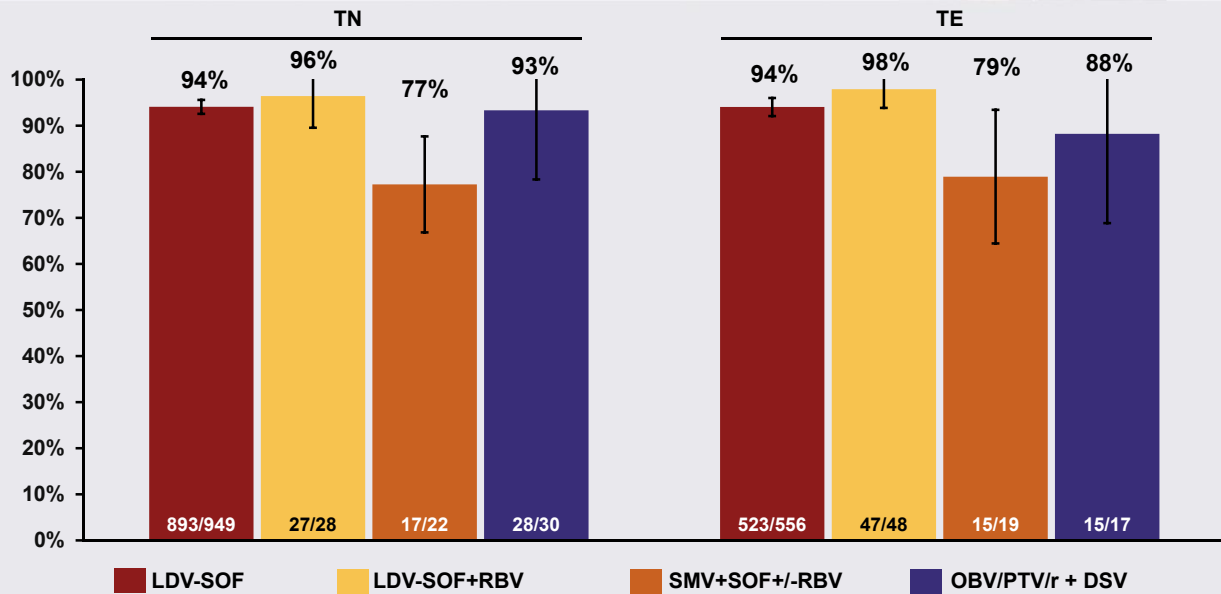
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TRIO: SVR12 Rates by Baseline Viral Load



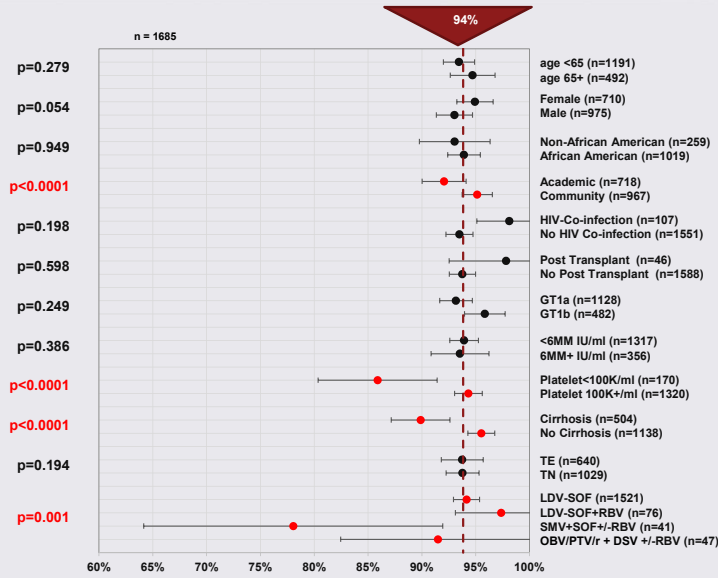
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TRIO: SVR12 Rates by Treatment Status



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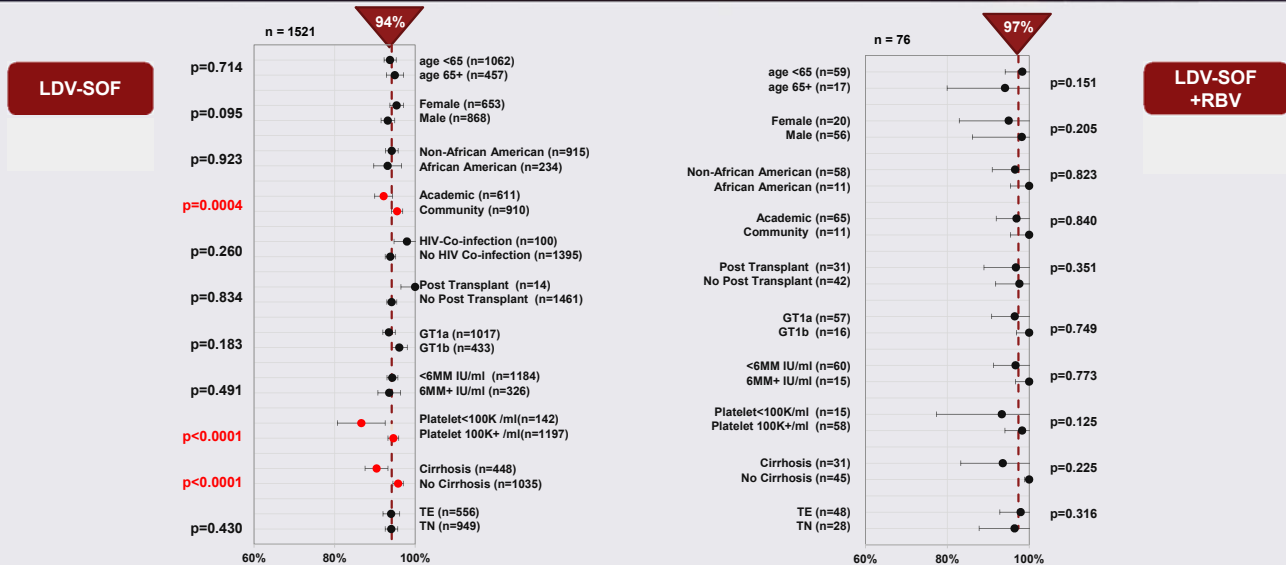
TRIO: Predictors of Response All Treatment Regimens



*Closed circles = proportions; whiskers = 95% confidence interval; dotted lines = overall SVR12; 2-side asympt. p-value via Pearson c2.

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TRIO: Predictors of Response LDV-SOF+/-RBV

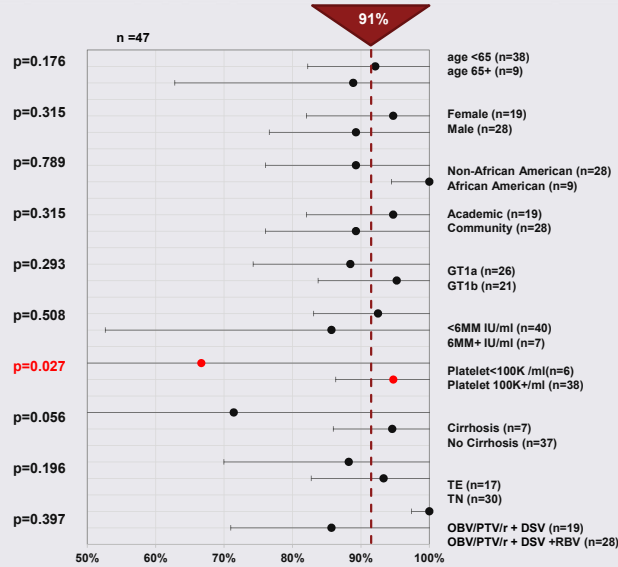


*HIV excluded due to n<5 in HIV population on LDV-SOF+RBV

*Closed circles= proportions; whiskers = 95% confidence interval; dotted lines = overall SVR12; 2-side asympt. p-value via Pearson c2.

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TRIO: Predictors of Response OBV/PTV/r + DSV +/-RBV



*HIV excluded due to n<5 in HIV population. Post Transplant excluded due to n<5 in Post-Transplant population
 *Closed circles= proportions; whiskers = 95% confidence interval; dotted lines = overall SVR12; 2-side asympt. p-value via Pearson c2.
 Afzal N, et al. 66th AASLD; San Francisco, CA; November 13-17, 2015; Abst. LB-17.

TRIO: Predictors of Response

Variable	Full Population Distribution % (n)	Treatment Failure Distribution % (n)	p-value
Platelets <100k/ml Platelets 100l+/ml	11% (170) 89% (1320)	40% (19) 60% (29)	<0.001
Cirrhosis No Cirrhosis	31% (504) 69% (1138)	70% (35) 30% (15)	<0.001
Outside FDA Guidelines Inside FDA Guidelines	10% (149) 90% (1536)	33% (17) 37% (34)	<0.001
Male Female	58% (975) 42% (710)	76% (39) 24% (12)	0.008

*Patients outside of guidelines: GT1a on VKP without RBV, tx failure cirrhotic patients on 12 weeks of VKP+/-RBV, LDV-SOF without RBV, or SMV+SOF+/-RBV
 *2-side asympt. p-value via Pearson c2.

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TRIO: Conclusions

- Overall SVR in real world Genotype 1 HCV patients is 94% across all DAA therapies
- 149 patients were treated outside of FDA guidelines and saw a significantly lower SVR rate (84% SVR outside vs. 95% SVR inside)
- Platelets <100k/ml, cirrhosis, prescribing outside of FDA guidelines, and males all had a positive association with treatment failures
- Practice type, ethnicity, genotype subtype, baseline viral load, post transplant, age, treatment status, and HIV had no clear association with treatment failures
- Overall discontinuation rate was <1% (12/1685)