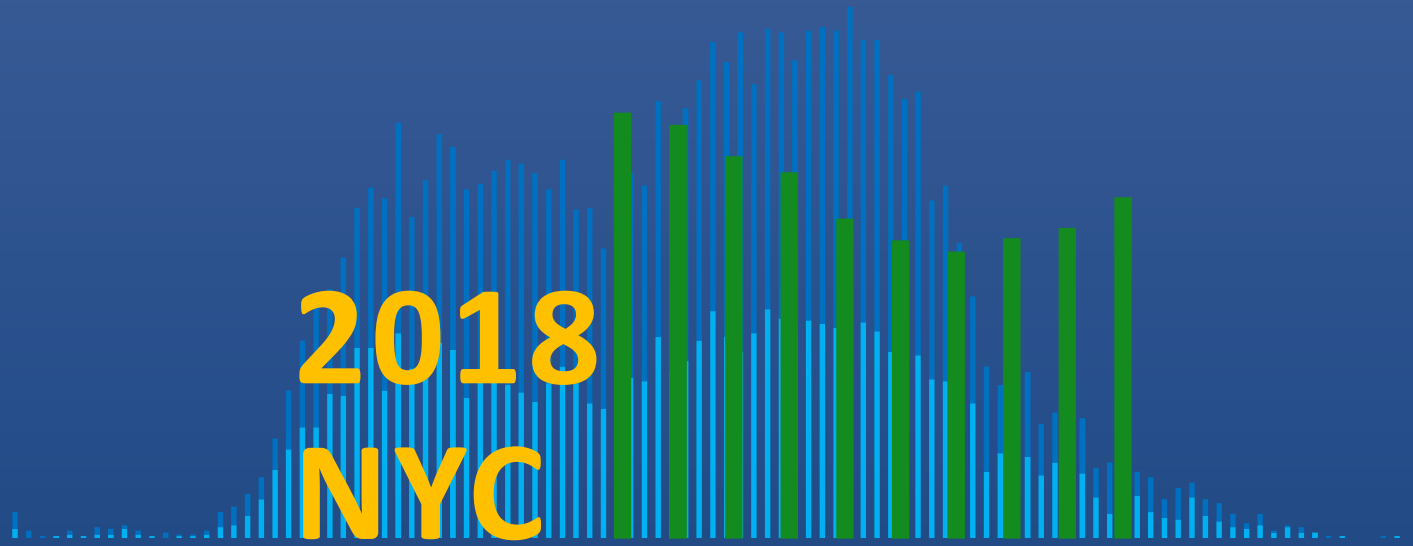

Viral Hepatitis Research Symposium

Effect of Direct Acting Antivirals on Health-Related Quality of Life in People who Inject Drugs

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Disclosure

- No disclosures to report

Background

- Rapid advancements in the field of hepatitis C virus (HCV) infection have made this once chronic disease now curable.
- Prior therapies for HCV centered on pegylated-interferon (PEG-IFN) bringing with them often debilitating side effects.
- In the modern era direct-acting antivirals (DAA) have become standard of care offering sustained virologic response (SVR) rates of greater than 90 percent.

HCV and Health-Related Quality of Life

- HCV itself carries with it a host of consequences—physically, mentally, financially and socially—that have a direct impact on health-related quality of life (HRQL).
- Prior studies have examined the positive effect of PEG-IFN-based regimens on HRQL particularly in people who inject drugs (PWID).

Our Aim

- To demonstrate the positive effects of HCV treatment on HRQL in PWID in the DAA era
- Evaluate and contrast the effectiveness of various modes of delivering HCV treatment among PWID

Location

- Patients were recruited and enrolled at outpatient primary care clinic sites belonging to Montefiore Medical Center located throughout the Bronx.

Study Methods

- Randomized controlled trial with enrolled patients randomized to 3 models of HCV care:
  - Directly Observed Therapy (DOT)
  - Group Therapy (GT)
  - Self-Administered Individual Treatment (SIT)
- At each study visit patients completed two HRQL questionnaires: EQ-5D-3L and HQLQ.

Timeline

- DAA treatment regimens consisted of 12 weeks of daily medication administration.
- Patients were all seen at baseline (BL) with initial administration of EQ-5D-3L and HQLQ questionnaires then at treatment weeks (TW) and follow-up weeks (FW).

Statistical Methods

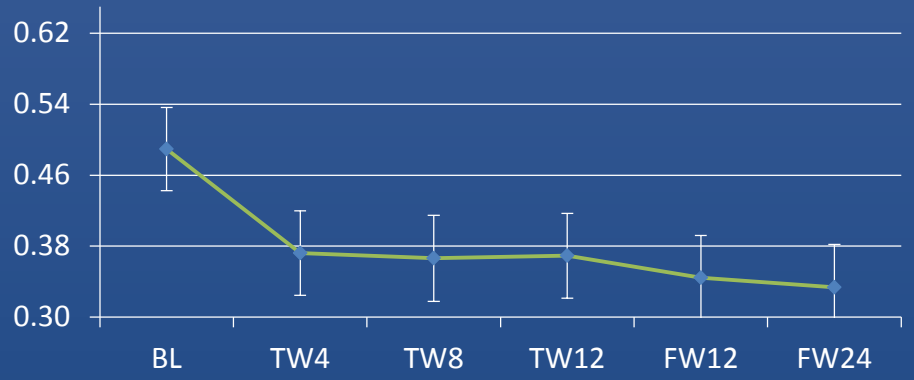
- We compared results from the EQ-5D-3L and HQLQ between BL and later time points and between treatment arms.
- We applied mixed-effect linear models with first order autoregressive correlation structure to account for temporal correlations among the repeated HRQL measures.
- 141 patients were included in our analysis, all of whom achieved SVR.

EQ-5D-3L Results

- Improvements were found in the following domains, all sustained through FW24:
  - Daily Activities
  - Pain/Discomfort
  - Anxiety/Depression
- Data also demonstrated an overall improvement in composite mean scores sustained through FW24.

EQ-5D-3L Results

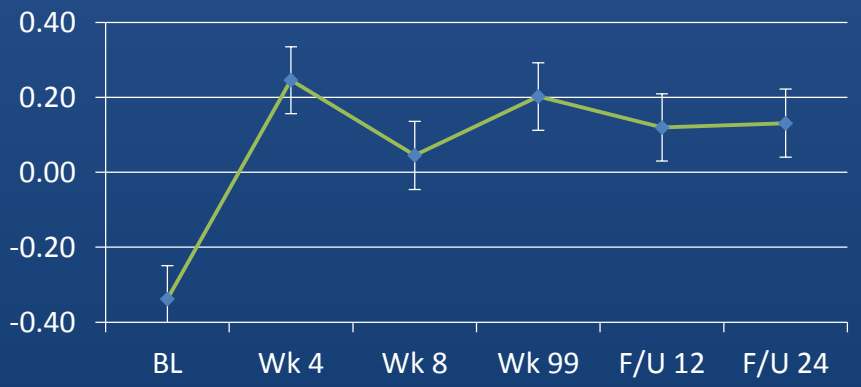
Ability to Perform Daily Activities*



Pain and Discomfort*

Anxiety and Depression*

Composite*

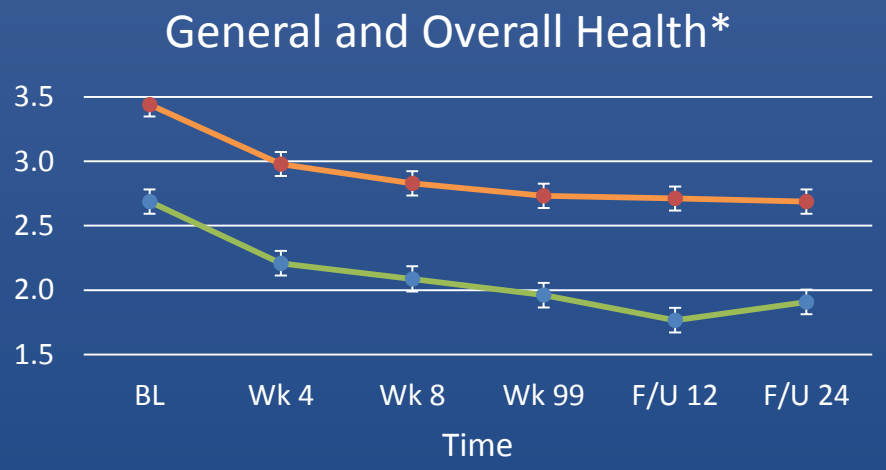


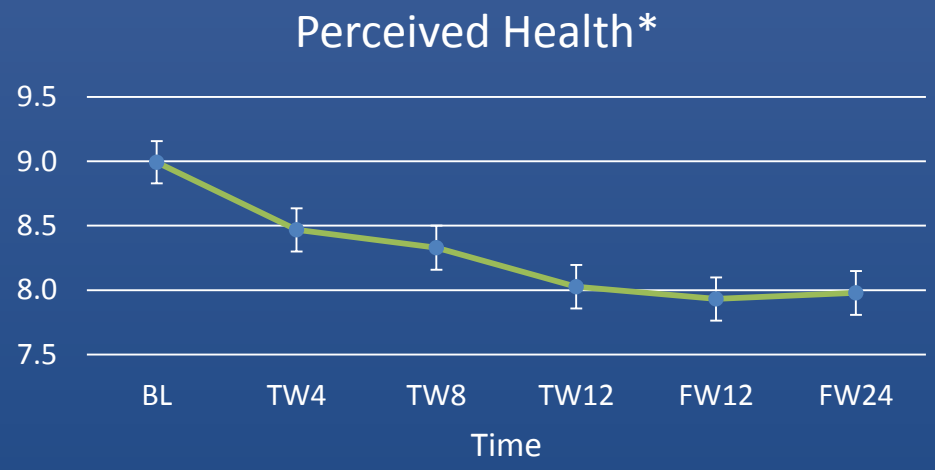
*All statistically significant; $p<0.05$

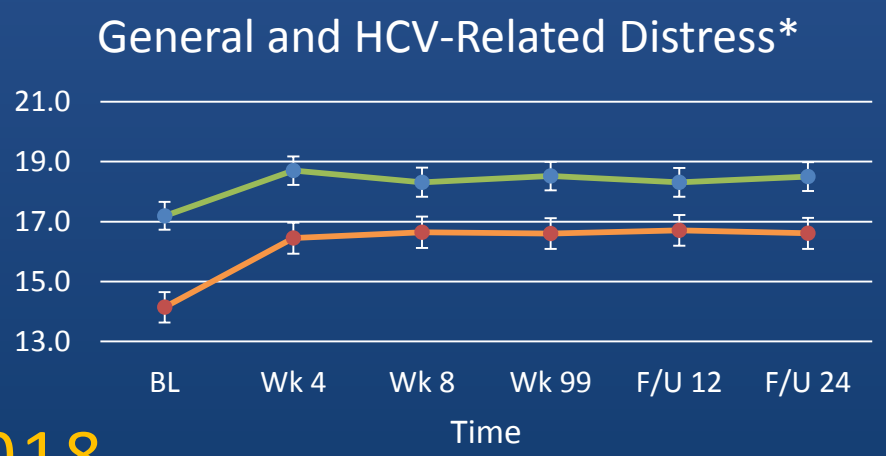
HQLQ Results

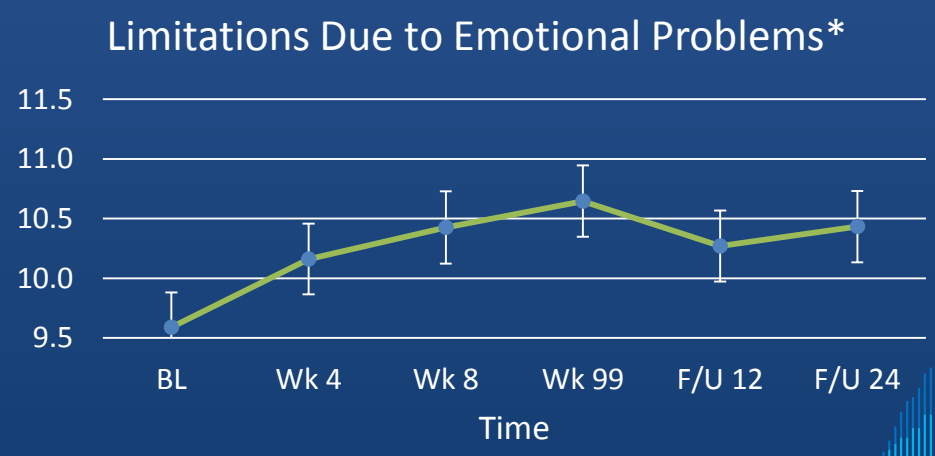
- Improvements were seen in the following domains all sustained, at minimum, through FW12:
  - General Health, Limitations Due to Emotional Problems, Perceived Overall Health, General Distress, and HCV-Related Distress

HQLQv2 Results







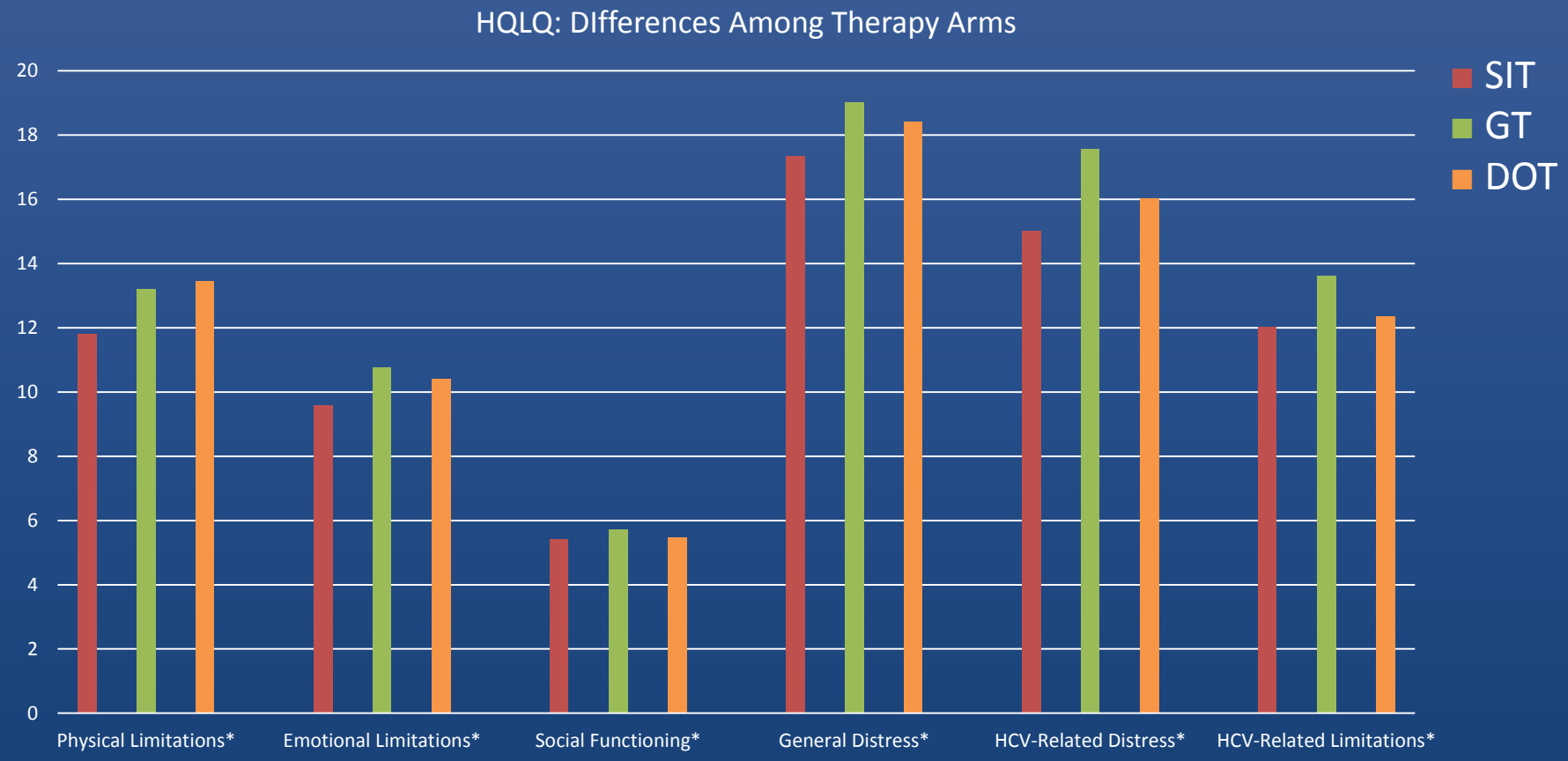


*All statistically significant; p<0.05

Therapy Arm Comparisons

- Data revealed improvements in multiple HQLQ domains when compared GT to both DOT and SIT
  - Limitations Due to Physical Problems, Social Functioning, General Distress, HCV-Related Distress, HCV-Related Limitations

Therapy Arms: Summary of Findings



*All statistically significant; p<0.001

Therapy Arms: Summary of Findings

Baseline Arm	Comparison Arm	HRQL Domain	Differences of Least Squares Means	p-value
SIT	GRP	Limitations Due to Emotional Problems	-1.397	p<0.05
SIT	DOT	Limitations Due to Emotional Problems	-1.648	p<0.05
SIT	GRP	Social Functioning	-0.305	p<0.05
SIT	GRP	General Distress	-1.6678	p<0.05
SIT	GRP	HCV-Related Distress	-2.565	p<0.05

Discussion and Conclusions

- Our study demonstrates improvements in HRQL in multiple tested domains with current use of DAAs in PWID as was seen in prior studies with use of PEG-IFN.
- Additionally, our study suggests the important role of group treatment in such a vulnerable population.

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Questions?