Evaluation of Newer Drug Therapies for **Hepatitis C** at a Specialty Pharmacy

Objective

- When patient's taking a tyrosine kinase inhibitor (TKI) oral therapy, Determine if clinical trial differs from real world experience by comparing sustained virologic response at week 12 post-treatment (SVR12) rates of newer Hepatitis C (HCV) therapies, approved between November 2013 and December 2014, between Avella Specialty Pharmacy and published literature.
- Determine if a sub-analysis of SVR12 rates in specific patient populations based on genotype (GT), fibrosis score, and treatment-experience differ to SVR12 rates of specific patient populations in published literature.
- Examine insurance coverage rates for newer HCV therapies.

Methods

Study Design:

- A retrospective chart review (retrospective cohort design)

Eligibility Criteria:

- Eligible participants were ≥18 years of age with a diagnosis of HCV, and received Harvoni, Olysio + Sovaldi ± ribavirin (RBV), Viekira Pak ± RBV, or Sovaldi + RBV.
- Therapy had to be completed between May 2014 and June 2015, with final SVR12 results collected by the prescribers by June 30th, 2015.
- Patients received standard Avella HCV services: assistance with insurance and financial assistance coverage; free shipping; a counsel call; mid-therapy wellness call and refill call each month; and follow-up SVR call 12 weeks post therapy completion. If pt was not available, a call to physician for SVR
- For insurance coverage rates, data included any patients with Harvoni, Olysio + Sovaldi ± RBV, Viekira Pak ± RBV, or Sovaldi + RBV therapy completed between May 2014 and June 2015.

Data Collection:

- The primary dependent variable was the SVR12 rate for each therapy.
- A complete data collection form in excel included all SVR12 rates by therapy, and demographic and descriptive variables.
- A separate data collection form in excel included SVR12 rates by therapy, and demographic and descriptive variables for published literature.
- Insurance coverage was collected through an electronic report.
- Demographic variables included gender and medical insurance.
- Descriptive variables included HCV GT, fibrosis score, treatment-experienced, treatment-naive, and adverse drug events (ADEs).

Analysis:

- SVR12 rates from Avella Specialty Pharmacy were compared to SVR12 rates from published literature using a Chi-squared test.
- SVR12 rates achieved by specific patient populations, namely treatment-experienced, treatment-naïve, cirrhosis, and GT were compared to the mean SVR12 rates in specific patient populations from published literature using a Chi-squared test.
- A percentage rate was calculated for insurance coverage (Medicare, Medicaid, Commercial insurances and Other) and Adverse Effects.
- The a priori alpha level was 0.05.

Results

Table 1: Demographic Data

		Total
Total number of patients, n(%)		578
Gender, n(%)	Males	345 (60%)
	Females	233 (40%)
Age (years)	Mean	59
	Range	21-86
GT, n(%)	1A	291 (50%)
	1B	108 (19%)
	1A or 1B	37 (6%)
	2	59 (10%)
	3	53 (9%)
	Unknown	27 (5%)
Treatment History, n(%)	Treatment-naïve	346 (60%)
	Treatment-experienced	166 (29%)
	Prior re-lapse	64 (11%)
	Prior null response	76 (13%)
	Prior partial response	31 (5%)
	Unknown prior response	73 (13%)
	Unknown treatment history	66 (11%)
Fibrosis Score, n(%)	Cirrhosis (F4)	106 (18%)
	Non-cirrhosis	377 (65%)

Table 2: SVR12[a] Rate Results

		Harvoni	Sovaldi+RBV	Olysio +Sovaldi	Olysio+ Sovaldi+RBV	TOTAL
Total SVR Rate	Avella	96% (178/185)	89% (173/194)	86% (115/134)	100% (13/13)	91% (479/526)
	Literature Avg	97%	78%	94%	90%	91%
	p-value	0.68	**< 0.05**	**< 0.05**	0.24	0.75
Cirrhotic Patients	Avella	100% (28/28)	89% (16/18)	86% (38/44)	N/A	91% (82/90)
	Literature Avg	97%	64%	93%	92%	84%
	p-value	0.33	**< 0.05**	0.08	100%	0.05
Treatment Naïve Patients	Avella	94% (109/116)	91% (104/114)	94% (74/79)	(7/7) 94%	93% (294/316)
	Literature Avg	96%	89%	94%	0.49	94%
	p-value	0.17	0.45	1.00	100%	0.54
Treatment Experienced Patients	Avella	100% (39/39)	87% (53/61)	74% (34/46)	(6/6) 97%	87% (132/152)
	Literature Avg	97%	74%	96%	89%	89%
	p-value	0.27	**< 0.05**	**< 0.05**	0.39	0.40

[a]SVR12 : A sustained virologic response achieved at week 12 of treatment

Table 3: SVR12 Rate Results

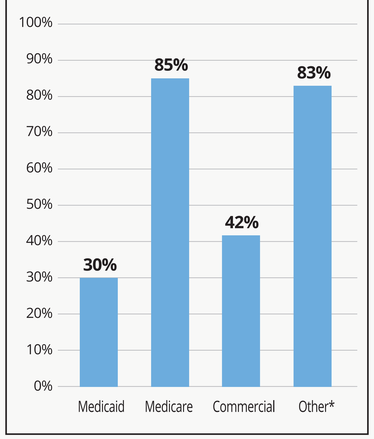
SVR12 Rate		Total (All Therapies)	
Males	Avella	91%	(281 / 310)
	Literature Average	86%	
	p-value	**< 0.05**	
Females	Avella	92%	(198 / 216)
	Literature Average	93%	
	p-value	0.33	
GT 1A	Avella	91%	(246 / 270)
	Literature Average	97%	
	p-value	**< 0.05**	
GT 1B	Avella	90%	(86 / 96)
	Literature Average	97%	
	p-value	**< 0.05**	
GT 2	Avella	89%	(47 / 53)
	Literature Average	93%	
	p-value	.17	
GT 3	Avella	96%	(47 / 49)
	Literature Average	76%	
	p-value	**< 0.05**	

Table 4: ADE Results

	Harvoni (N=201)	Sovaldi+RBV (N=212)	Olysio +Sovaldi (N=150)	Olysio +Sovaldi +RBV (N=15)	TOTAL (N=578)
Patients who reported any ADE–n(%)	18 (9.0)	11 (5.2)	7 (4.7)	0 (0)	36 (6.2)
ADES reported –n					
Headache	9	2	0	0	11
Fatigue	3	2	2	0	7
Nausea	4	2	0	0	6
Diarrhea	4	1	0	0	5
Rash	1	0	1	0	2
Insomnia	1	0	0	0	1
Depression	1	0	0	0	1
Pruritus	0	0	1	0	1
Other[a]	4	7	4	0	15

[a] Other: Harvoni: hot flashes, low platelet count, & pain; Olysio + Sovaldi: cold symptoms (sore throat, cough, runny nose), severe sickness, alopecia, & weight gain; Sovaldi + RBV: thromboembolic event, dizziness, breathing issues, achiness, vomiting & pancytopenia

Figure 1: Insurance Coverage Rates of all pts May 2014–June 2015



Key Findings

- The overall SVR12 rate of patients from Avella Specialty Pharmacy was not significantly different from published literature (91% vs 91%, p = 0.75).
- Patients with cirrhosis at Avella Specialty Pharmacy achieved an overall higher SVR12 rate compared to published literature (p < 0.05).
- Males achieved a higher SVR12 rate at Avella Specialty Pharmacy compared to published literature (p < 0.05).
- Patients with genotype 1a, 1b, at Avella Specialty pharmacy achieved a significantly lower SVR12 rate compared to published literature (p < 0.05). Although a small n
- The therapy with the highest percentage of ADEs was Harvoni (9%). Headache was the most common adverse effect (31%) while insomnia, depression and pruritus were the least common (3%).
- Medicare had the highest coverage rate (85%) while Medicaid had the lowest (30%).

Limitations

- Data included many unknowns such as SVR12 (loss of follow up), fibrosis score, and treatment-experience.
- Patients who received newer therapies approved/started after 2014 were excluded since therapy and follow-up results were not completed within the study period.
- Location of SVR data: patient vs. provider reported.

Conclusion

- Overall SVR12 rate for published controlled studies compared to patients from a specialty pharmacy solidifies the effectiveness of newer, direct-acting viral HCV therapies with combination of services received from a specialty pharmacy. Validation of therapy efficacy would be collecting SVR results at a retail site with no pharmacy clinician intervention.
- Patients experienced minimal adverse effects compared to older therapies.
- Medicaid had the lowest insurance coverage rate which is most likely attributable to managing costs associated with treating large volumes of patients.
- Males and patients with cirrhosis in a real world setting were more successful with newer HCV therapies.
- Differences observed with GT may be influenced by excluding patients with genotypes 1a and 1b in the Sovaldi + RBV studies, thus increasing the likelihood of a difference in our comparison.
- Since a cure is viable with newer therapies with limited ADE, this can encourage insurance payer types to provide coverage, without any stipulations. Additionally, the continued use of these newer therapies from a specialty pharmacy may lead to an overall goal for the eradication of HCV.

Disclosures

Authors of this presentation have the following to disclose: Michelle Garfunkel, David Hoehn, Kayleen Thompson, Kelly Mathews, Sarjit Patel: Nothing to Disclose