Evidence Table 11. Sustained virologic response and clinical outcomes summary results

| **Author, Year Country Quality** | **Study Type Number Analyzed Duration of Followup Proportion with Cirrhosis: SVR vs. no SVR** | **Hepatocellular Carcinoma: Adjusted Hazards Ratio (95% CI)** | **Liver-Related Mortality: Adjusted Hazard Ratio (95% CI)** | **All-Cause Mortality: Adjusted Hazard Ratio (95% CI)** | **Other Clinical Outcomes: Adjusted Hazard Ratio (95% CI)** | **Results Adjusted for at Least Age, Sex, Viral Load, Genotype, and Fibrosis Stage, or no Association Found in Univariate Analyses** |
| --- | --- | --- | --- | --- | --- | --- |
| ***Studies of general populations of treated patients with HCV infection*** |  |  |  |  |  |  |
| Arase, 200763 Japan  Overall Quality: Fair | Retrospective cohort n=500 Mean 7.4 years Cirrhosis: 9% vs. 16% | SVR vs. no SVR: 0.19 (0.08-0.45) | SVR vs. no SVR: 0.13 (0.03-0.59) | SVR vs. no SVR: 0.39 (0.16-0.93) | NR | Yes |
| Backus, 201164# USA  Overall Quality: Fair | Retrospective cohort n=16,864 Median 3.8 years Cirrhosis: 9-12% vs. 12-20% | NR | NR | SVR vs. no SVR (genotypes 1, 2, and 3, respectively): 0.71 (0.60-0.86), 0.62 (0.44-0.87), and 0.51 (0.35-0.75) | NR | Yes |
| Coverdale, 200467\* Australia  Overall Quality: Poor | Prospective cohort (some patients originally enrolled in randomized trials) n=343 Median 9 years Cirrhosis: Not reported, median fibrosis score F2 (Scheuer) | SVR vs. response-relapse vs. nonresponse Adjusted HR not reported (p>0.05) | SVR vs. response-relapse vs. nonresponse Liver transplant or liver-related death: Adjusted HR not reported (p=0.20) | NR | SVR vs. response-relapse vs. nonresponse Liver-related complications:\*\* Adjusted HR not reported (p=0.06) | Unclear |
| Imazeki, 200372 Japan  Overall Quality: Fair | Retrospective cohort n=459 Mean 8.2 years Cirrhosis: 13% overall | NR | SVR vs. no SVR: 0.11 (0.01-0.96)## | SVR vs. no SVR: 0.12 (0.01-1.3)## | NR | Yes |
| Innes, 201173  UK  Overall Quality: Fair | Retrospective cohort  n=1215  Mean 5.3 years  Cirrhosis: 10% vs. 18% | NR | SVR vs. no SVR: 0.22 (0.09-0.58) | NR | SVR vs. no SVR  Liver-related hospital episode: 0.22 (0.15-0.34) | Yes |
| Izumi, 200574  Japan  Overall Quality: Fair | Cohort study, appears retrospective n=495 Duration of followup: Not reported Cirrhosis: 5.1% overall | SVR vs. no SVR: 0.36 (0.04-0.83) | NR | NR | NR | Unclear |
| Kasahara, 200475 Japan  Overall Quality: Poor | Retrospective cohort n=2698 Mean 6 years Cirrhosis: 3.0% vs. 5.4% | NR | SVR vs. no SVR: 0.04 (0.005-0.30) | SVR vs. no SVR: 0.14 (0.06-0.35) | NR | No |
| Maruoka, 201276  Japan  Overall Quality: Fair | Retrospective cohort  n=577  Mean 9.9 years  Cirrhosis: 10% overall | SVR vs. no SVR: 0.12 (0.04-0.40)## | NR | SVR vs. no SVR: 0.20 (0.08-0.54)## | NR | Yes |
| Yoshida, 200280 Japan  Overall Quality: Poor | Retrospective cohort n=2889 Mean 5.4 years Cirrhosis: 6.5% vs. 11% | NR | SVR vs. no SVR: 0.13 (0.02-0.66)## | SVR vs. no SVR: 0.32 (0.12-0.86)## | NR | No |
| Yu, 200642 Taiwan  Overall Quality: Poor | Retrospective cohort n=1057 Mean 5.2 years Cirrhosis: 16% overall | S SVR vs. no SVR: 0.25 (0.13-0.54)## | NR | SVR vs. no SVR: 0.28 (0.08-1.0)## | NR | No |
| ***Studies of populations with advanced fibrosis and cirrhosis*** |  |  |  |  |  |  |
| Bruno, 200765 Italy  Overall Quality: Fair | Retrospective cohort study n=883 Mean 8 years Cirrhosis: All | SVR vs. no SVR: 0.39 (0.17-0.88) | SVR vs. no SVR: 0.14 (0.04-0.59) | NR | SVR vs. no SVR Ascites, encephalopathy, or gastrointestinal bleeding: Not calculated, 0 events/1061 person-years vs. 107 events/5703 person-years (1.88 events/100 person-years) | No |
| Cardoso, 201066 France  Overall Quality: Fair | Retrospective cohort study (of patients originally enrolled in clinical trials) n=307 Median 3.5 years Cirrhosis: 53% vs. 61% | SVR vs. no SVR: 0.33 (0.23-0.89) | SVR vs. no SVR: 0.27 (0.08-0.95) | NR | SVR vs. no SVR Ascites or variceal bleeding: 0.21 (0.05-0.92) | Yes |
| El Braks, 200768 France  Overall Quality: Poor | Retrospective cohort study n=113 Mean 7.7 years Cirrhosis: All | NR | NR | NR | SVR vs. no SVR Clinical events (hepatocellular cancer, ascites, hepatic encephalopathy, or death): 0.14 (0.04-0.45) | No |
| Fernandez-Rodriguez, 201069# Spain  Overall Quality: Poor | Retrospective cohort study n=509 Median 35 months Cirrhosis: All | NR | NR | NR | SVR vs. no SVR Combined clinical endpoint:\*\*\* 0.38 (0.18-0.76) | Unclear |
| Hasegawa, 200770^ Japan  Overall Quality: Fair | Retrospective cohort study n=105 Median 4.6 years Cirrhosis: All | SVR vs. no SVR: 0.18 (0.04-0.81) | NR | NR | NR | Yes |
| Hung, 200671 Taiwan  Overall Quality: Fair | Cohort study (unclear if retrospective or prospective) n=132 Median 37 months Cirrhosis: All | SVR vs. no SVR: 0.28 (0.09-0.92) | NR | NR | NR | Yes |
| Morgan, 201077# USA  Overall Quality: Fair | Prospective cohort study of patient enrolled in a randomized trial n=526 Median 79 to 86 months Cirrhosis: 21% vs. 43% | SVR vs. no SVR: 0.19 (0.04-0.80) | SVR vs. no SVR Liver-related mortality or liver transplantation: 0.12 (0.03-0.48) | SVR vs. no SVR All-cause mortality or liver transplantation: 0.17 (0.06-0.46) | SVR vs. no SVR Any liver-related outcome:^^ 0.15 (0.06-0.38) Decompensated liver disease: 0.13 (0.03-0.53) | Unclear |
| Shiratori, 200578 Japan  Overall Quality: Poor | Prospective cohort study of patients enrolled in randomized trials n=271 Median 6.8 years Cirrhosis: All | SVR vs. no SVR: 0.40 (0.18-0.89)## | NR | SVR vs. no SVR: 0.07(0.01-0.56)## | NR | No |
| Veldt, 200779 Europe and Canada  Overall Quality: Fair | Retrospective cohort n=479 Median 2.1 years Cirrhosis: 71% vs. 77% | SVR vs. no SVR: 0.46 (0.12-1.7) | SVR vs. no SVR: 0.19 (0.02-1.4) | SVR vs. no SVR: 0.31 (0.07-1.4) | SVR vs. no SVR Any event (death, liver failure, and hepatocellular cancer): 0.20 (0.07-0.58) | No |

Abbreviations: HCV, hepatitis C virus; NR, not reported; SVR, sustained virologic response.

Note: SVR defined in all studies as undetectable HCV RNA in serum 6 months after the end of antiviral therapy, except as noted.

\* SVR defined as undetectable HCV RNA on at least 2 occasions at least 2 years after completion of therapy.

^ Duration of undetectability to meet criteria for SVR not reported.

# Study primarily evaluated patients who received pegylated interferon plus ribavirin.

\*\* Hepatic decompensation, complications of portal hypertension, hepatocellular carcinoma, liver transplantation, and liver-related mortality.

\*\*\* Hepatic decompensation, upper gastrointestinal bleeding secondary to rupture of esophageal or gastric varices, hepatocellular carcinoma, liver transplantation, and liver-related or liver-unrelated mortality.

^^ Decompensated liver disease (ascites, variceal bleeding, hepatic encephalopathy, spontaneous bacterial peritonitis), hepatocellular carcinoma, liver transplantation, and liver-related mortality.

## Calculated from estimates for SVR vs. untreated and no SVR vs. untreated