P-001

# Real-world efficacy, safety and clinical outcomes of ombitasvir/ paritaprevir/ ritonavir ± dasabuvir ± ribavirin combination therapy in patients with hepatitis C virus genotype 1 or 4 infection: Turkey experience

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**INTRODUCTION:** Clinical trials and real-world experiences evaluating ombitasvir/paritaprevir/ritonavir (OMV/PTV/r) ± dasabuvir (DSV) ± ribavirin (RBV) combination therapy have shown excellent rates of sustained virological response (SVR) and good safety profiles in patients with chronic hepatitis C virus (HCV) genotype 1 or 4 infections. We aimed to investigate the effectiveness and safety of OMV/PTV/r ± DSV ± RBV combination regimen in a real-world clinical practice.

**METHODS:** Data from HCV genotype 1 and 4 patients treated with OMV/PTV/r ± DSV ± RBV (n=862) in 34 centers across Turkey between April 1, 2017 and August 31, 2018 were recorded in a large national database. Study patients were treatment-naïve or interferon plus RBV-experienced with or without compensated cirrhosis. Follow-up (FU) ranged from 24 to 36 weeks depending on-treatment duration. Demographic, clinical and virological data were analyzed. Details of clinical and laboratory adverse events (AEs) were recorded.

**RESULTS:** The mean age of the patients was 55.63 and 430 (49.9%) were male. The majority had HCV genotype 1b infection (77.3%), and 66.2% were treatment-naïve. Non-cirrhosis was present at baseline in 789 patients (91.5%). The HCV RNA level was below 800.000 IU/mL in 442 of the cases. Of all patients, 18 had hepatitis B virus (HBV) co-infection. Sixty-five percent of the patients had an underlying disease. Out of the 862 analysed patients, 57 patients did not return for viral load FU at 12 weeks, 6 patients stopped antiviral therapy because of AEs, 7 patients had virological failure and 1 patient died. Virological rates by per protocol analysis was calculated in the patients. SVR12 rate was 99.1% in all patients. No significant differences were observed in SVR12 according to HCV genotypes (p= 0.410). HCV RNA was undectable at treatment week 4 in 90.9%, at treatment week 8 in 98.5%, and at end of treatment (EOT) in 98.9%. No significant differences were observed in at treatment week 8 and EOT virological response according to HCV genotypes (p= 0.630, p= 0.785, respectively). Rates of rapid virological response (RVR) were significantly


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higher in the patients infected with HCV genotype 1a or 1b than in the patients infected with genotype 4 (p< 0.001). RVR and SVR12 ratios were significantly higher in non-cirrhotic patients compared to compensated cirrhotic patients (p= 0.004, p=0.016). There was not significant difference in on-treatment or EOT or FU12 weeks responses between treatment-naïve and treatment-experienced patients (p= 0.599, p= 0.166, p= 1000, p=0.431). Rates of AEs and AEs-associated treatment discontinuation were 59.7% and 0.7% in the patients, respectively. HBV reactivation occurred in 13.3% of the patients.

**CONCLUSION:** The present real-life data of Turkey for OBV/PTV/r ± DSV ± RBV treatment of patients with HCV genotype 1b, 1a or 4 infection from 862 patients demonstrated high efficacy and a safety profile.

**Keywords:** Chronic hepatitis C, HCV genotypes 1 and 4, ombitasvir, paritaprevir, dasabuvir, real-world effectiveness

Table 1. Baseline demographical and clinical characteristics

| **Patient characteristics** | **Genotype 1a (n= 141)** | **Genotype 1b (n= 666)** | **Genotype 4 (n= 55)** | **Total (n= 862)** |
|---|---|---|---|---|
| Gender (male), n (%) | 94 (66.7) | 307 (46.1) | 29 (52.7) | 430 (49.9) |
| Age (years) | 49.60 ± 15.61 | 56.94 ± 14.15 | 55.22 ± 14.93 | 55.63 ± 14.68 |
| | (19.00-85.00) | (18.00-87.00) | (23.00-85.00) | (18.00-87.00) |
| Treatment-naïve, n (%) | 94 (66.7) | 439 (65.9) | 38 (69.1) | 571 (66.2) |
| Non-cirrhotic | 88 (93.6 | 406 (92.5) | 29 (76.3) | 523 (91.6) |
| Compensated cirrhotic | 6 (6.4) | 33 (7.5) | 9 (23.7) | 48 (8.4) |
| Treatment-experienced, n (%) | 47 (33.3) | 227 (34.1) | 17 (30.9) | 291 (33.8) |
| Non-cirrhotic | 45 (95.7) | 205 (90.3) | 16 (94.1) | 266 (91.4) |
| Compensated cirrhotic | 2 (4.3) | 22 (9.7) | 1 (5.9) | 25 (8.6) |
| HCV RNA, log10 IU/mL | 5.88 ± 0.81 | 5.81 ± 0.86 | 6.09 ± 0.66 | 5.84 ± 0.84 |
| | (3.53-7.61) | (3.11-7.69) | (4.46-7.22) | (3.11-7.69) |
| ≥ 800.000, IU/L, n (%) | 71 (50.4) | 310 (46.5) | 39 (70.9) | 420 (48.7) |
| ALT, IU/L | 44.00 (30.00-68.00) | 41.00 (27.00-63.00) (nmd=3) | 32.00 (22.00-56.00) | 41.00 (27.00-63.00) |
| AST, IU/L | 36.00 (27.00-53.00) | 37.00 (26.00-54.00) (nmd=3) | 31.00 (21.00-53.00) | 36.00 (26.00-54.00) |
| Total bilirubin, mg/dL | 0.69 (0.51-0.97) (nmd=12) | 0.65 (0.49-0.83) (nmd=93) | 0.73 (0.55-0.98) (nmd=3) | 0.66 (0.49-0.87) |
| Albumin, g/dL | 4.28 ± 0.4 (3.00-5.60) (nmd=13) | 4.23 ± 0.44 (2.60-5.70) (nmd=86) | 4.14 ± 0.56 (3.00-5.60 (nmd=4)) | 4.23 ± 0.45 (2.90-5.70) |
| Haemoglobin, g/dL | 13.95 ± 1.76 (10.00-17.80) (nmd=11) | 13.84 ± 1.63 (8.20-18.80) (nmd=44) | 13.91 ± 1.97 (10.40-17.90) | 13.86 ± 1.68 (8.20-18.80) |
| Platelets count, /1000 mm3 | 209.50 (170.00-265.25) (nmd=7) | 216.00 (168.00-264.00) (nmd=27) | 216.00 (165.00-262.00) | 215.00 (168.00-264.00) |
| INR | 1.10 (1.00-1.22) (nmd=5) | 1.01 (0.95-1.10) (nmd=42) | 1.00 (0.94-1.16) (nmd=2) | 1.02 (0.96-1.10) |
| Fibrosis stage*, n (%) | | | | |
| F0 | - | 5 (0.8) | - | 5 (0.6) |
| F1 | 12 (8.5) | 82 (12.3) | 7 (12.7) | 101 (11.7) |
| F2 | 29 (20.6) | 134 (20.1) | 5 (9.1) | 168 (19.5) |
| F3 | 35 (24.8) | 179 (26.9) | 14 (25.5) | 228 (26.5) |
| F4 | 3 (2.1) | 19 (2.9) | 1 (1.8) | 23 (2.7) |
| F5 | 3 (2.1) | 28 (4.2) | 6 (10.9) | 34 (3.9) |
| F6 | 3 (2.1) | 11 (1.7) | 3 (5.5) | 20 (2.3) |
| Unknown | 56 (39.7) | 208 (31.2) | 19 (34.5) | 283 (32.8) |
| Antiviral treatment history n (%) | | | | |
| Number of experience | | | | |
| 1 | 40 (85.1) | 157 (69.2) | 16 (94.1) | 213 (73.2) |
| >1 | 7 (14.9) | 70 (30.8) | 1 (5.9) | 78 (26.8) |
| Treatment regimens | | | | |

| | | | | |
|---|---|---|---|---|
| PegINF+RBV | 35 (74.5) | 145 (63.9) | 16 (94.1) | 196 (67.4) |
| PegINF+RBV/ Peg INF+RBV | 6 (12.8) | 66 (9.9) | 1 (5.9) | 73 (25.1) |
| INF + RBV | 5 (10.6) | 12 (5.3) | - | 17 (5.8) |
| INF+RBV / PegINF+RBV | 1 (2.1) | 4 (1.8) | - | 5 (1.7) |
| Treatment responses | | | | |
| Relapsers | 11 (23.4) | 84 (37.0) | 6 (35.3) | 101 (34.7) |
| Non-responders | 6 (12.8) | 65 (28.6) | 8 (47.1) | 79 (27.1) |
| Discontinued due to AEs | 2 (4.3) | 18 (7.9) | 1 (5.9) | 21 (7.2) |
| Parsiel responders | 3 (6.4) | 4 (1.8) | - | 7 (2.4) |
| Breaktrough | - | 2 (0.9) | 1 (5.9) | 3 (1.0) |
| Unknown | 25 (53.2) | 54 (23.8) | 1 (5.9) | 80 (27.5) |
| HBV co-infection, n (%) | 2 (1.4) | 15 (2.3) | 1 (1.8) | 18 (2.1) |
| HIV co- infection, n (%) | 1 (0.7) | 1 (0.2) | 2 (3.6) | 4 (0.5) |
| HBV-HDV co-infection , n (%) | - | 1 (0.2) | - | 1 (0.1) |
| Associated diseases n (%) | 62 (44.0) | 452 (67.9) | 43 (78.2) | 557 (64.6) |
| Number of diseases | | | | |
| 1 | 46 (74.2) | 310 (68.6) | 28 (65.1) | 384 (68.9) |
| >1 | 16 (25.8) | 142 (31.4) | 15 (34.9) | 173 (31.1) |
| Definition of disease | | | | |
| Cardiovascular[α] | 28 (19.9) | 164 (24.6) | 11 (20.0) | 203 (23.5) |
| Diabetes mellitus | 16 (11.3) | 76 (11.4) | 12( 21.8) | 104 (12.1) |
| Chronic renal failure | 15 (10.6) | 51 (7.7) | 11 (20.0) | 77 (8.9) |
| Lung diseases[ϕ] | 7 (5.0) | 39 (5.9) | 1 (1.8) | 47 (5.5) |
| Hematologic diseases[#] | - | 17 (2.6) | 4 (7.3) | 21 (2.4) |
| Neurological diseases[η] | 4 (2.8) | 16 (2.4) | 1 (1.8) | 21 (2.4) |
| Psychiatric diseases[ψ] | 3 (2.1) | 16 (2.4) | 1 (1.8) | 20 (2.3) |
| Thyroid diseases[m] | 3 (2.1) | 16 (2.4) | 1 (1.8) | 20 (2.3) |
| Oncologic diseases[µ] | 2 (1.4) | 14 (2.1) | - | 16 (1.9) |
| Bone-joint diseases[ω] | - | 10 (1.5) | - | 10 (1.2) |
| Dermatological diseases[τ] | - | 7 (1.1) | 1 (1.8) | 8 (0.9) |
| Substance use | 1 (0.7) | 6 (0.9) | - | 7 (0.8) |
| Kidney transplantations | 1 (0.7) | 3 (0.5) | 2 (3.6) | 6 (0.7) |
| Rheumatologic diseasesβ | 1 (0.7) | 3 (0.5) | - | 4 (0.5) |
| Otherυ | 2 (1.4) | 49 (7.4) | 3 (5.5) | 54 (6.3) |
| Modification of concomitant medications, n (%) | 35 (24.8) | 62 (9.3) | 16 (29.1) | 113 (13.1) |

Table 2. Virological responses according to patients characteristics

| | Virological responses [negative/tested (%)] | | | |
|---|---|---|---|---|
| **Variable** | **Week 4 (RVR)** | **Week 8** | **EOT** | **Week 12 (SVR12)** |
| All patients | 690/759 (90.9) | 596/605 (98.5) | 779/788 (98.9) | 791/798 (99.1) |
| Genotypes | | | | |
| Genotype 1a (n=141) | 119/123 (96.7%)a | 108/109 (99.1) | 132/133 (99.2) | 125/127 (98.4) |
| Genotype 1b (n=666) | 533/587 (90.8%)a | 455/463 (98.3) | 597/604 (98.8) | 616/620 (99.4) |
| Genotype 4 (n:55) | 38/49 (77.6%)b | 33/33 (100) | 50/51 (98.0) | 50/51 (98.0) |
| p value | < 0.001 | 0.630 | 0.785 | 0.410 |
| Non-cirrhotic/compensated cirrhotic | | | | |
| Non-cirrhotic (n=789) | 633/689 (91.9) a | 543/551 (98.5) | 713/720 (99.0) | 727/731 (99.5) |
| Compensated cirrhotic (n=73) | 57/70 (81.4) b | 53/54 (98.1) | 66/68 (97.1) | 64/67 (95.5) |
| p value | 0.004 | 0.571 | 0.178 | 0.016 |
| Response of previous therapy | | | | |
| Treatment-naïve (n=571) | 438/484 (90.5) | 376/384 (97.9) | 506/512 (98.8) | 510/516 (98.8) |
| Treatment-experienced (n=291) | 252/275 (91.6) | 220/221 (99.5) | 273/276 (98.9) | 281/282 (99.6) |
| p value | 0.599 | 0.166 | 1.000 | 0.431 |

Table 3. Median laboratory parameters changes between baseline and 12 weeks post-treatment

| Variables | Follow-up time points | | | | | |
|---|---|---|---|---|---|---|
| | Baseline | Week 4 | Week 8 | Week 12 | FU12 | p value |
| Genotype 1a (n= 127) | | | | | | |
| ALT, IU/L (number of complete cases= 94) | 44.50 (30.75-67.50)a | 25.50 (15.75-43.00)b | 22.00 (12.68-34.50)b | 20.00 (14.00-33.00)b | 25.00 (16.00-33.00)b | <.001 |
| AST, IU/L ( number of complete cases= 91) | 39.00 (29.00-54.00)a | 25.00 (17.00-38.00)b | 22.00 (15.00-33.00)cd | 18.00 (13.00-29.00)c | 25.00 (17.00-33.00)bd | <.001 |
| Haemoglobin, g/dL (number of complete cases= 63) | 13.88 ± 1.90a | 12.91 ± 1.99bc | 12.71 ± 2.35bc | 12.58 ± 1.92b | 13.14 ± 1.98c | <.001 |
| Platelets count, /1000 mm³ (number of complete cases= 78) | 209.5 (166.8-272.0) | 219.0 (175.5-278.0) | 217.0 (174.8-267.3) | 221.5 (177.5-272.0) | 222.5 (197.0-288.3) | .088 |
| Genotype 1b (n= 620) | | | | | | |
| ALT, IU/L (number of complete cases= 485) | 41.00 (28.00-62.50)a | 19.00 (13.00-34.00)b | 17.00 (12.00-30.00)c | 16.00 (12.00-24.00)d | 18.00 (13.00-27.00)c | <.001 |
| AST, IU/L (number of complete cases= 482) | 37.00 (25.75-54.00)a | 21.00 (16.58-32.00)b | 19.0 0 (16.00-27.00)c | 18.00 (15.00-25.00)d | 20.00 (16.00-25.00)c | <.001 |
| Haemoglobin, g/dL (number of complete cases = 401) | 13.81 ± 1.64ab | 13.83 ± 1.67a | 13.71 ± 1.71b | 13.66 ± 1.71b | 13.79 ± 1.68b | .002 |
| Platelets count, /1000 mm³ (number of complete cases= 422) | 215.0 (164.8-260.0)a | 217.0 (178.0-262.5)b | 214.0 (171.0-257.0)a | 219.5 (176.8-264.0)b | 216.0 (178.0-266.0)b | .001 |
| Genotype 4 (n= 51) | | | | | | |
| ALT, IU/L (number of complete cases= 48) | 32.00 (22.25-55.50)a | 16.00 (12.00-27.50)b | 14.50 (11.25-19.75)b | 15.00 (12.00-19.75)b | 17.00 (12.00-23.00)b | <.001 |
| AST, IU/L (number of complete cases= 48) | 31.00 (21.25-53.00)a | 18.00 (14.00-22.00)b | 16.00 (12.00-21.75)b | 16.00 (12.00-19.00)b | 18.50 (14.00-22.75)b | <.001 |
| Haemoglobin, g/dL (number of complete cases= 48) | 14.07 ± 2.04a | 13.19 ± 2.33b | 13.00 ± 2.13b | 12.85 ± 2.08b | 13.28 ± 2.20b | <.001 |
| Platelets count, /1000 mm³ (number of complete cases= 48) | 217.0 (167.5-269.5) | 242.0 (192.3-295.8) | 220.5 (187.0-282.5) | 231.5 (186.3-284.5) | 237.0 (186.0-278.0) | .081 |
| Total (n= 798) | | | | | | |
| ALT, IU/L (number of complete cases= 627) | 41.00 (28.00-64.00)a | 20.00 (13.00-34.00)b | 17.00 (12.00-31.00)c | 17.00 (12.00-25.00)d | 19.00 (13.00-27.00)c | <.001 |
| AST, IU/L (number of complete cases= 621) | 37.00 (26.00-54.00)a | 21.00 (16.00-32.00)b | 19.00 (15.00-27.00)c | 18.00 (14.00-24.00)d | 20.00 (16.00-26.00)c | <.001 |
| Haemoglobin, g/dL (number of complete cases= 512) | 13.84 ± 1.71a | 13.65 ± 1.81b | 13.52 ± 1.88b | 13.45 ± 1.81b | 13.67 ± 1.79b | <.001 |
| Platelets count, /1000 mm³ (number of complete cases= 548) | 214.0 (166.0-261.0)a | 217.5 (178.0-267.0)b | 214.0 (175.0-259.5)b | 220.0 (177.3-267.0)b | 218.5 (181.3-269.8)b | <.001 |

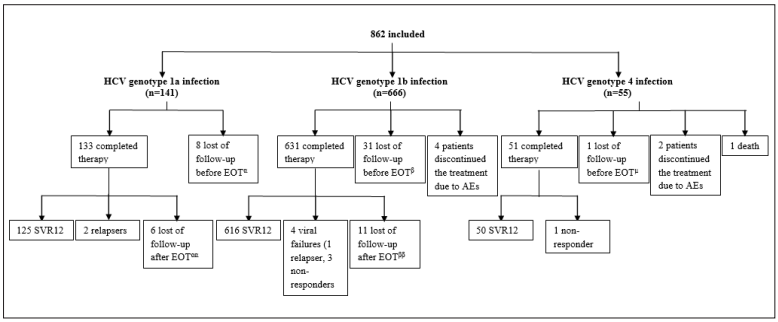
Table 4. Demographic and clinical characteristics of patients with virolojik failure

| | Patient No. 1 | Patient No. 2 | Patient No. 3 | Patient No. 4 | Patient No. 5 | Patient No. 6 | Patient No. 7 |
|---|---|---|---|---|---|---|---|
| Gender | Male | Female | Male | Female | Male | Female | Male |
| Age, years | 42 | 66 | 52 | 65 | 65 | 66 | 58 |
| Genotype | 1a | 1a | 1b | 1b | 1b | 1b | 4 |
| Response of current therapy | Relapser | Relapser | Relapser | Non-responder | Non-responder | Non-responder | Non-responder |
| Previous antiviral treatment | Treatment-naïve, non-cirrhotic | Treatment-naïve, compensated cirrhotic | Treatment-naïve, non-cirrhotic | Treatment-naïve, non-cirrhotic | Treatment-naïve, non-cirrhotic | Treatment-experienced, compensated cirrhotic | Treatment-naïve, compensated cirrhotic |
| HCV RNA, IU/mL | | | | | | | |
| Day 0 | 1.314.359 | 1.142.000 | 6.318.000 | 428.400 | 2.560.000 | 3.800.000 | 540.000 |
| Week 4 | - | Undetected | 118000 | - | 511 | 2.700.000 | 5.139.000 |
| Week 8 | Undetected | Undetected | Undetected | 127.000 | Undetected | 4.200.000 | Undetected |
| Week 12 | Undetected | Undetected | Undetected | 298.000 | 6.390 | 5.870.000 | 3156000 |
| FU 12 | 857.845 | 2.680.000 | 4.567.000 | 527.000 | 487.000 | 3.990.000 | 6.177.000 |
| ALT | 27 | 89 | 22 | 123 | 36 | 99 | 59 |
| AST | 19 | 103 | 22 | 100 | 30 | 157 | 67 |
| Hemoglobin | 14 | 12.10 | 16.20 | 13.10 | 14.30 | 12 | 13.10 |
| Platelet count | 161.000 | 90.000 | 219.000 | 176.000 | 255.555 | 64.000 | 100.000 |

Table 5. Adverse events and laboratory abnormalities

| **Patients, n (% patients with at least one event or one laboratory abnormalities)/Total patients** | **Genotype 1a (n= 141)** | **Genotype 1b (n= 666)** | **Genotype 4 (n= 55)** | **Total (n= 862)** |
|---|---|---|---|---|
| Any AEs | 93 (66.0) | 384 (57.7) | 38 (69.1) | 515 (59.7) |
| AEs or laboratory abnormalities leading to treatment discontinuation | - | 4 (0.60) | 2 (3.6) | 6 (0.7) |
| Adverse events | | | | |
| Asthenia | 17 (12.1) | 68 (10.2) | 5 (9.1) | 90 (10.4) |
| Pruritus | 9 (6.4) | 38 (5.7) | 2 (3.6) | 49 (5.7) |
| Headache | 7 (5.0) | 38 (5.7) | 1 (1.8) | 46 (5.3) |
| Fatigue | 7 (5.0) | 34 (5.1) | 3 (5.5) | 44 (5.1) |
| Nausea | 4 (2.8) | 34 (5.1) | 1 (1.8) | 39 (4.5) |
| Insomnia | 5 (3.5) | 18 (2.7) | - | 23 (2.7) |
| Anorexia | 2 (1.4) | 18 (2.7) | 2 (3.6) | 22 (2.6) |
| Diarrhea | 4 (2.8) | 10 (1.5) | 2 (3.6) | 16 (1.9) |
| Dizziness | 3 (2.1) | 11 (1.7) | - | 14 (1.6) |
| Mild rash | 3 (2.1) | 4 (0.6) | 3 (5.5) | 10 (1.2) |
| Abdominal pain | - | 8 (1.2) | - | 8 (0.9) |
| Cough | - | 6 (0.9) | 1 (1.8) | 7 (0.8) |
| Fever[α] | - | 6 (0.9) | - | 6 (0.7) |
| Arthralgia | 1 (0.7) | 4 (0.6) | - | 5 (0.6) |
| Dry skin | 4 (2.8) | - | 1 (1.8) | 5 (0.6) |
| Palpitation | 2 (1.4) | 1 (0.2) | - | 3 (0.3) |
| Vomiting | - | 1 (0.2) | 1 (1.8) | 2 (0.2) |
| Chest pain | | 2 (0.3) | | 2 (0.2) |
| Other[αα] | 1 (0.7) | 37 (5.6) | - | 38 (4.4) |
| Haemoglobin | | | | |
| <10 – 8 g/dL | 14 (9.9) | - | 7 (12.7) | 21 (2.4) |
| <8 – 6.5 g/dL | 2 (1.4) | - | 1 (1.8) | 3 (0.3) |
| Total bilirubin | | | | |
| >1.5 – 3 x ULN | 6 (4.3) | 28 (4.2) | 4 (7.3) | 38 (4.40) |
| >3 – 10 x ULN | - | 2 (0.3)[βμ] | 2 (3.6)[βμ] | 4 (0.5) |
| ALT | | | | |
| >3 – 5 x ULN | 1 (0.7) | 7 (1.1) | - | 8 (0.9) |
| >5 – 20 x ULN | - | 1 (0.2)[β] | 1 (1.8)[β] | 2 (0.2) |
| AST | | | | |
| >3 – 5 x ULN | 1 (0.7) | 7 (1.1) | - | 8 (0.9) |
| >5 – 20 x ULN | - | 1 (0.2)[β] | 1 (1.8)[β] | 2 (0.2) |

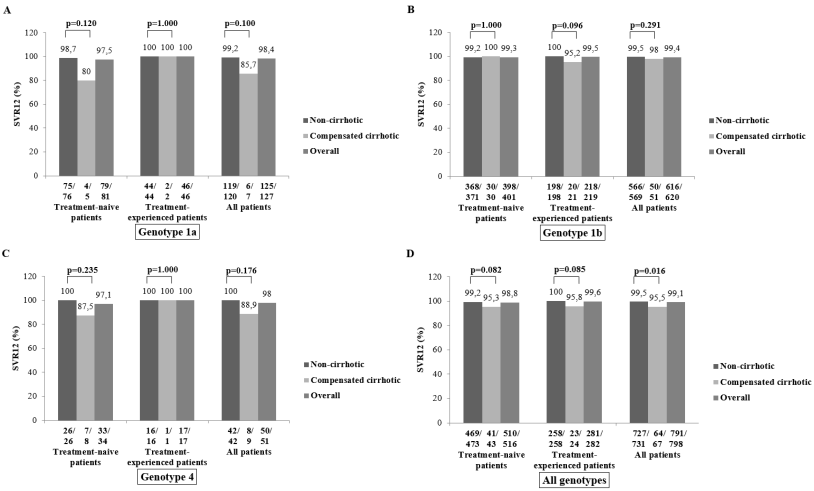
Figure 1




Study Flowchart

EOT: end of treatment; AEs: adverse events; SVR12: sustained virological response at week 12 post-treatment
[α]Seven patients with treatment-naïve non cirrhosis, one patient with treatment-experienced non-cirrhosis; [αα]Five patients with treatment-naïve non cirrhosis, one patient with treatment-naïve cirrhosis, one patient with treatment-experienced non-cirrhosis; [β]Twenty three patients with treatment-naïve non-cirrhosis, two patients with naïve cirrhosis, five patients with treatment-experienced non-cirrhosis, one patient with treatment-experienced cirrhosis; [ββ]Ten patients with treatment-naïve non-cirrhosis, one patient with treatment-experienced non-cirrhosis; µOne patient with treatment-naïve non-cirrhosis

Figure 2




Rates of virological response to ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin. (A); At post-treatment week 12 according to treatment regimen in patients with and without cirrhosis by genotype 1a (B); At post-treatment week 12 according to treatment regimen in patients with and without cirrhosis by genotype 1b (C); At post-treatment week 12 according to treatment regimen in patients with and without cirrhosis by genotype 4 (D); At post-treatment week 12 by all genotypes

SVR12: sustained virological response at week 12 post-treatment