MEP FRIENDS OF THE LIVER

22 MARCH EUROPEAN PARLIAMENT

EASL The Home of Hepatology

The EASL HCV treatment guidelines: Who should be treated and when

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EASL Recommendations on Treatment of Hepatitis C 2016☆

European Association for the Study of the Liver*

- Help physicians and patients in the clinical decision-making process by describing the current optimal management of patients with acute and chronic HCV infections

- Recommendations apply to drugs approved by the European Medicines Agency and other national European agencies at the time of their publication

How are guidelines developed

- EASL chooses a panel of experts
- Experts review the literature, and grade according to the evidence
- EASL GB approves the recommendations
- Guidelines are regularly updated

Evidence quality	Notes	Grading
High	Further research is very unlikely to change our confidence in the estimate of effect	A
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate	B
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Any change of estimate is uncertain	C
Recommendation	**Notes**	**Grading**
Strong	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost	1
Weak	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, higher cost or resource consumption	2

Screening strategies

- Should be defined according to the local epidemiology of HCV infection – ideally within **National Plans**
- Presently based on anti-HCV antibodies
- Rapid diagnostic tests using serum, plasma, finger stick whole blood or saliva, can be used to **improve access to care**
- If anti-HCV is positive confirmation is needed, using:
  - HCV RNA
  - **Core antigen – easier to access**

Goal of treatment

- **Cure HCV infection**, in order to prevent:
  - Hepatic cirrhosis, complications of cirrhosis, liver cancer, severe extra-hepatic manifestations and death (A1)
- The endpoint of therapy is:
  - undetectable HCV RNA in 12 weeks (SVR12) and/or 24 weeks (SVR24) after the end of treatment (A1).
  - **Undetectable HCV core antigen** 12 weeks (SVR12) and/or 24 weeks(SVR24) after the end of treatment
- In patients with advanced disease, HCV eradication reduces the possibility of complications as well as liver cancer (A1)

Who should be treated?

- **All patients with compensated or decompensated chronic liver disease due to HCV must be considered for therapy (A1)**

Universal access to treatment

Patients who should be treated without delay

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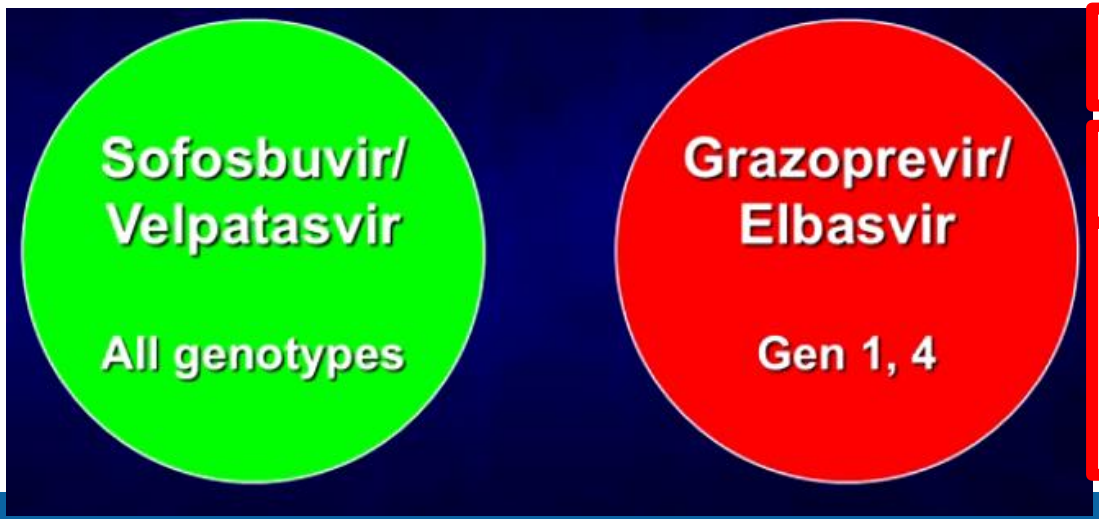
- Significant fibrosis or cirrhosis, even decompensated (Child-Pugh B or C)
- Significant extra-hepatic manifestations
- HCV recurrence after liver transplantation
- High risk of transmitting HCV
  - Active PWID
  - MSM with high-risk sexual practises
  - Haemodialysis patients,
  - Incarcerated individuals
- Women of child-bearing age who wish to get pregnant

Who should be treated?

- Treatment is **not** recommended in patients with limited life expectancy due to non-liver-related comorbidities (B2)
- National elimination plans require the development of economic partnerships and planning to expedite unrestricted access to treatment (B1)

To succeed, HCV elimination will require national plans together with forecasted budgeting to expedite unrestricted access to treatment

All treatments are Interferon-free



8 or 12 weeks

16 or 24 weeks

Fixed-dose combinations
1 or 2 pill/day

To which extent are the EASL guidelines being followed?

- Difficult to evaluate
- Guidelines are translated in several languages
- They are very influential in National Guidelines
- They are very influential in the definition of National Plans

Thank you!

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Active drug addicts and patients on stable maintenance substitution

- Prevalence of HCV among PWIDs is approximately 65%, raising to >80% on chronic users
- PWIDs should all be tested for anti-HCV antibodies and if negative, annually (A1).
- Should be provided with clean drug injecting equipment and access to opioid substitution therapy as part of widespread comprehensive harm reduction programs, including in prisons (B1)
- Pre-therapeutic education should include discussions of HCV reinfection risk, and harm reduction strategies (B1)
- HCV treatment for PWIDs should be considered on an individualized basis and delivered within a multidisciplinary team setting (A1).

Who should be treated?

- Patients with decompensated cirrhosis and an indication for liver transplantation with a MELD score ≥18-20 should be transplanted first, and treated after transplantation
- If the waiting time for transplantation is more than 6 months, they can be treated before transplantation (B1)

Who should be treated?

- Patients with decompensated cirrhosis and an indication for liver transplantation with a MELD score ≥18-20 should be transplanted first, and treated after transplantation
- If the waiting time for transplantation is more than 6 months, they can be treated before transplantation (B1)

Active drug addicts and patients on stable maintenance substitution

- Prevalence of HCV among PWIDs is approximately 65%, raising to >80% on chronic users
- PWIDs should be routinely and voluntarily tested for anti-HCV antibodies and if negative, annually (A1).
- Should be provided with clean drug injecting equipment and access to opioid substitution therapy as part of widespread comprehensive harm reduction programs, including in prisons (B1)
- Pre-therapeutic education should include discussions of HCV reinfection risk, and harm reduction strategies (B1).
- PWIDs should be counselled to moderate alcohol intake, or to abstain if there is evidence of advanced liver disease (A1).

Active drug addicts and patients on stable maintenance substitution

- PWIDs should be counselled to moderate cannabis use, or to abstain if there is evidence of advanced liver disease (B2).
- HCV treatment for PWIDs should be considered on an individualized basis and delivered within a multidisciplinary team setting (A1).
- Pre-therapeutic assessment should include an evaluation of housing, nutrition and drug and alcohol use. PWIDs should be linked into social support services and peer support, if available (A1).
- A history of intravenous drug use and recent drug use at treatment initiation are not associated with reduced SVR and decisions to treat must be made on a case-by-case basis (B1).

Active drug addicts and patients on stable maintenance substitution

- Drug and alcohol users or any other patients with on-going social issues and/or history of psychiatric disease, and those with more frequent drug use during therapy, are at risk of lower adherence and reduced likelihood of achieving SVR.
- More closely monitoring during therapy is needed (B1).
- The anti-HCV regimens that can be used in PWIDs are the same as in non-PWIDs. They do not require specific methadone and buprenorphine dose adjustment, but monitoring for signs of opioid toxicity or withdrawal should be undertaken (B1).
- Awareness should be raised that liver transplantation is a therapeutic option in those with a history of intravenous drug use (B1).