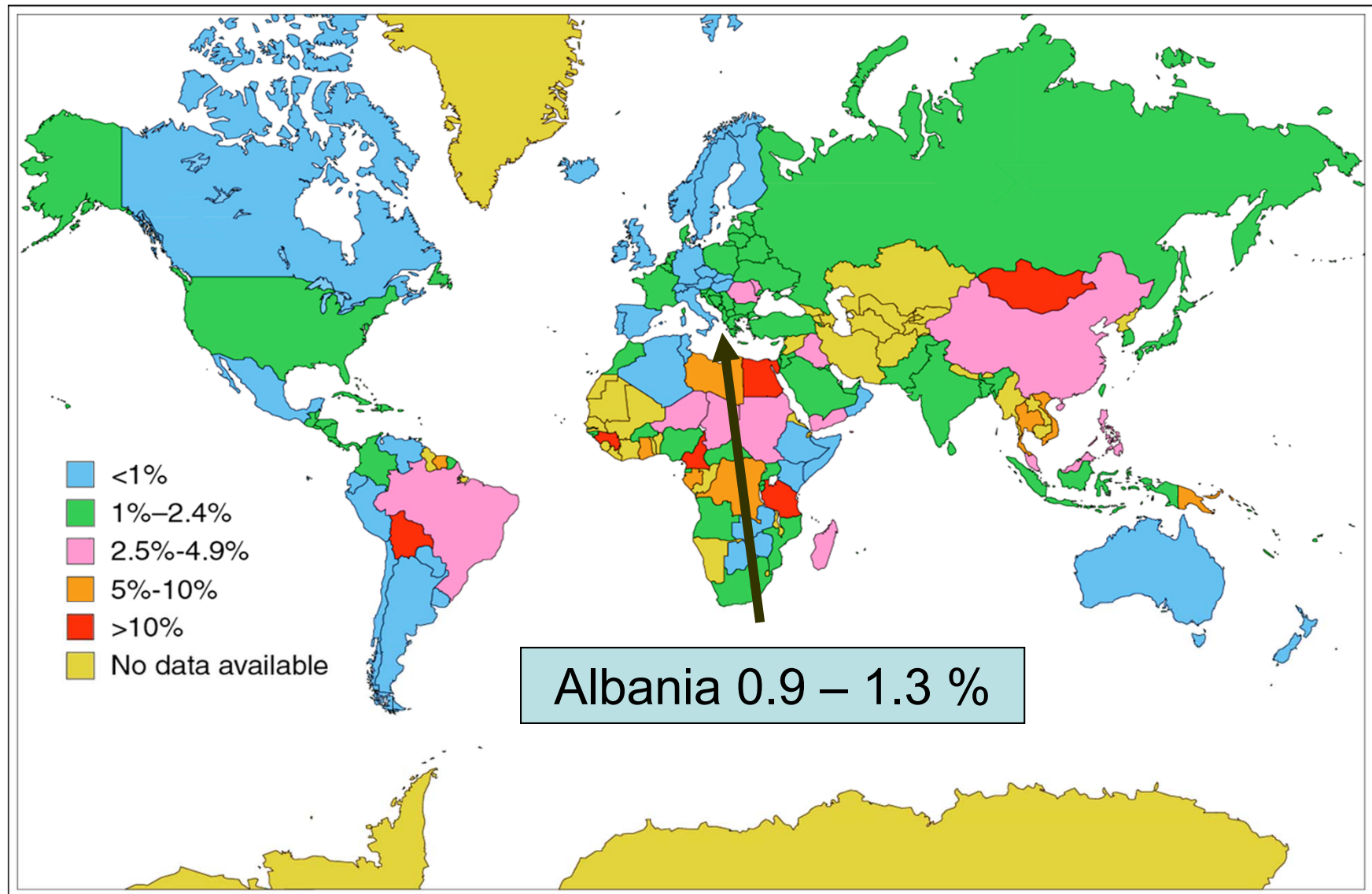


# **Hepatitis C treatment and follow up – challenges in Albania**

***Jovan BASHO***

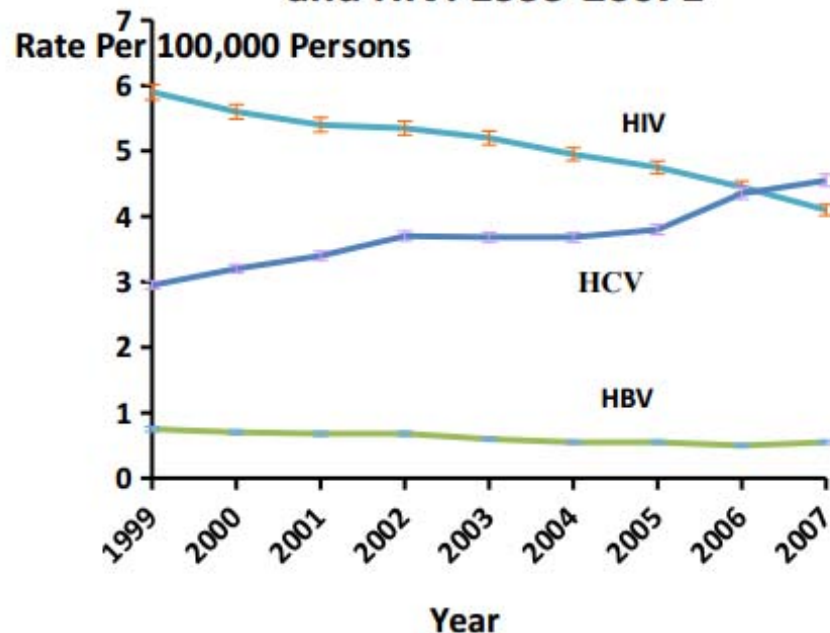
***Service of Hepatology/Gastroenterology  
UHC "Mother Tereza", TIRANA***

# HCV infection: Global prevalence



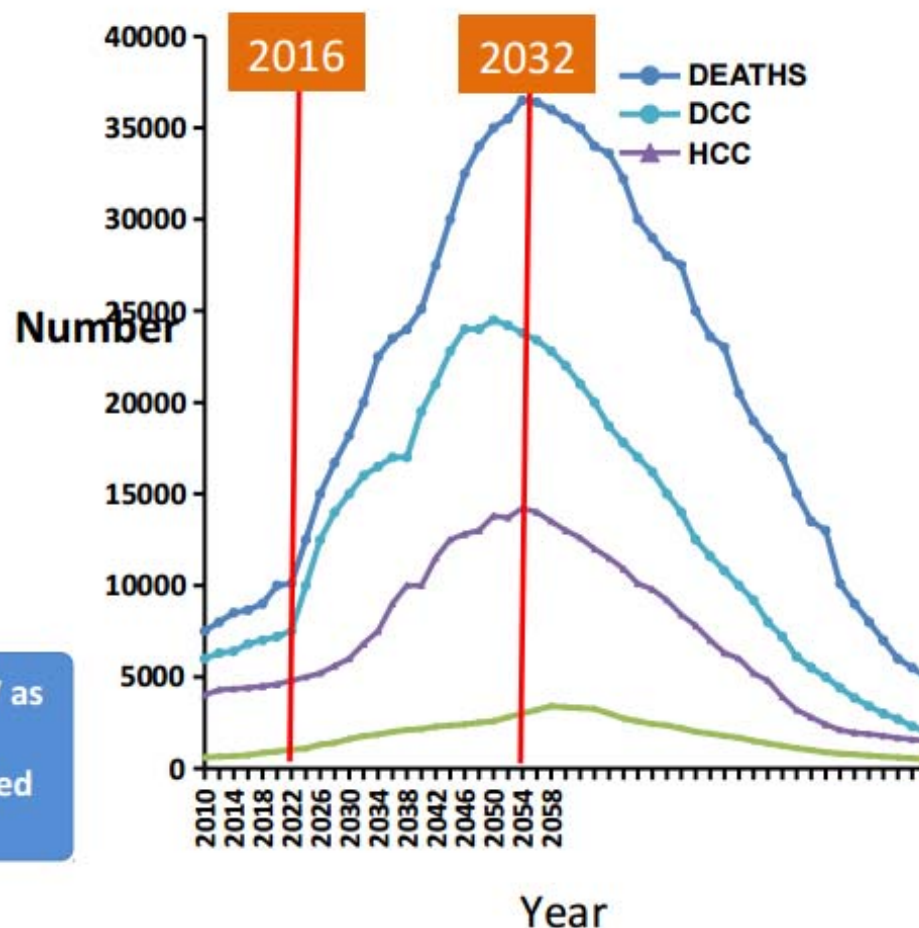
# Increased Morbidity and Mortality Due to HCV Now and in the Future

**Mortality Rates of HBV, HCV and HIV: 1999-2007**



- By 2007 hepatitis C-associated deaths had overtaken HIV as a cause of mortality in the United States.
- New policies and commitments to detect and link infected persons to care and successful treatment are needed.

**Morbidity and Mortality Predictions2**



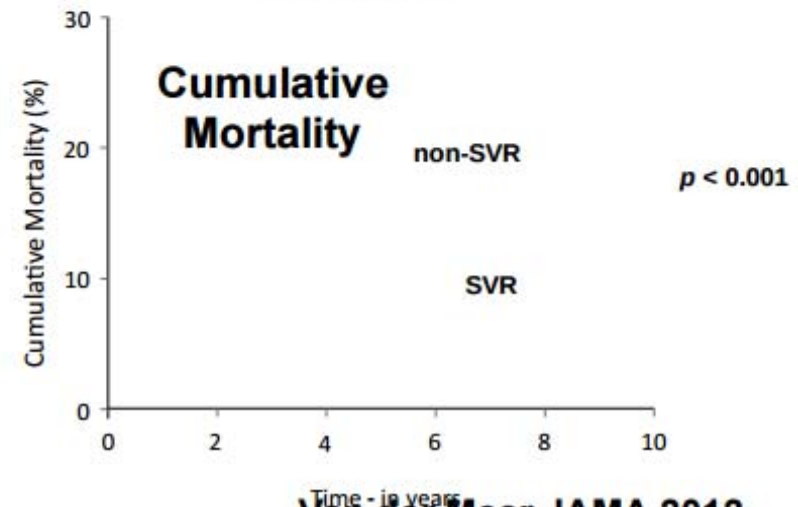
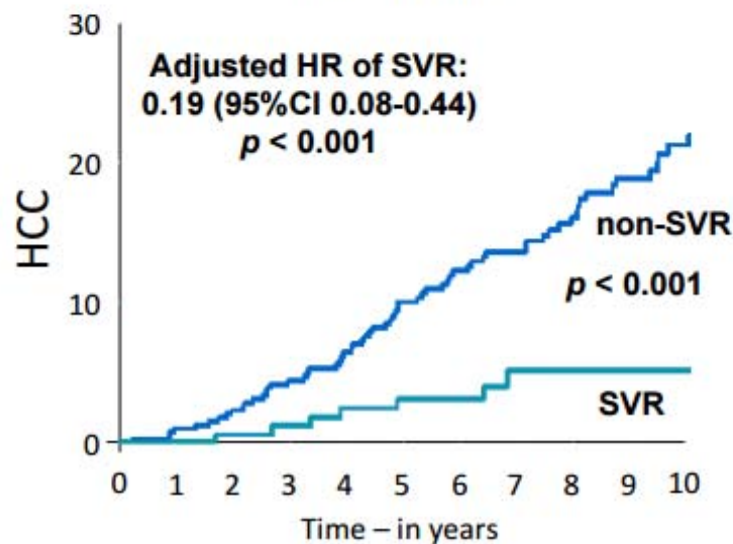
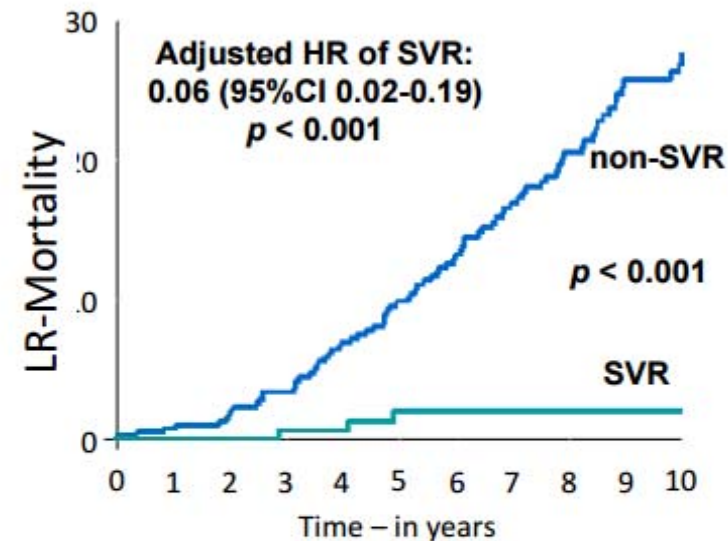
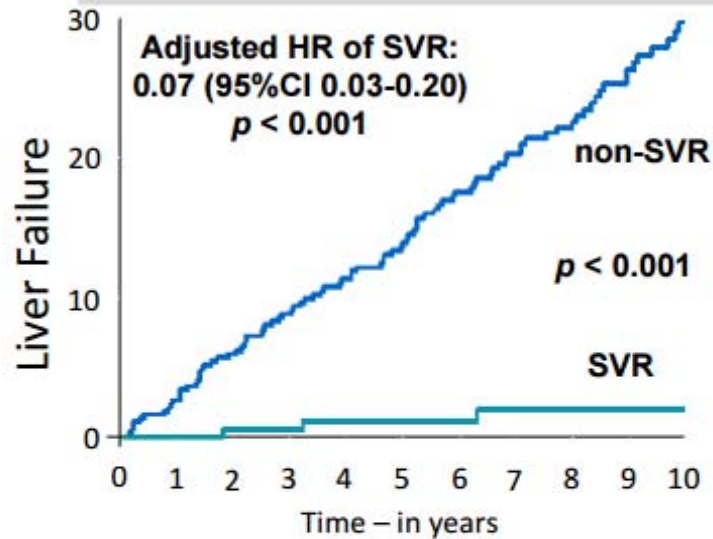
DCC, decompensated cirrhosis

Adapted from Ly KN et al. *Ann Intern Med.* 2012;156:271-278.

Adapted from Rein DB et al. *Dig Liver Dis.* 2011;43:66-72.

# Mortality and Morbidity Reduced with SVR

- 530 adults in Europe prospectively followed for median 8.4 years after HCV treatment
- 192 (36%) achieved SVR







# Hepatitis C: beyond the liver....

**Liver**

**Portal  
hypertension**

**Liver failure**

**HCC**

**Systemic**

**Diabetes**

**Cryoglobulinaemia**

**Lymphoma**

**Fatigue**

**Depression**

**Cognition**

**Atherosclerosis**

Negro F, Forton D, Craxi A, Sulkowski MS, Feld JJ, Manns MP. Extrahepatic Morbidity and Mortality of Chronic Hepatitis C. *Gastroenterology*. 2015;149:1345-60

# Utility of HCV Virological Tools

1. Diagnosis of HCV infection
2. Decision to treat
3. Choice of optimal therapy
4. Monitoring of virological response

# 1. Diagnosis of HCV infection

a. Anti HCV positive:

- ALT
- HCV RNA
- Genotype HCV
- biopsy of the liver,  
or fibroscan,  
or fibrotest

## 2. Decision to treat

- a. Treat all patients (impossible for Albania)
- b. Treat selected patients

Albania in 2015: 1. patients F3 - F4 (g.1)

2. patients with cryoglobulinemia

Proposition for 2017:

1. Treat all patients  $\geq$  F3 (all genotypes)

2. Special groups:

- pts with co-infection HIV or HCV
- pts with an indication for organ transplantation
- pts with clinically significant extra-hepatic manifestation



# Restricted indications of DAAs in Europe



### 3. Choice of optimal therapy (1)

Drug in reimbursement list (Albania 2016)

1. Pegylated INF alfa 2 a/b + Ribavirin
2. Sofosbuvir + Pegylated INF alfa 2 a/b + Ribavirin
3. Sofosbuvir + Ledipasvir (Harvoni)
4. Ombitasvir + Paritaprevir + Ritonavir + Dasabuvir

### 3. Choice of optimal therapy (2)

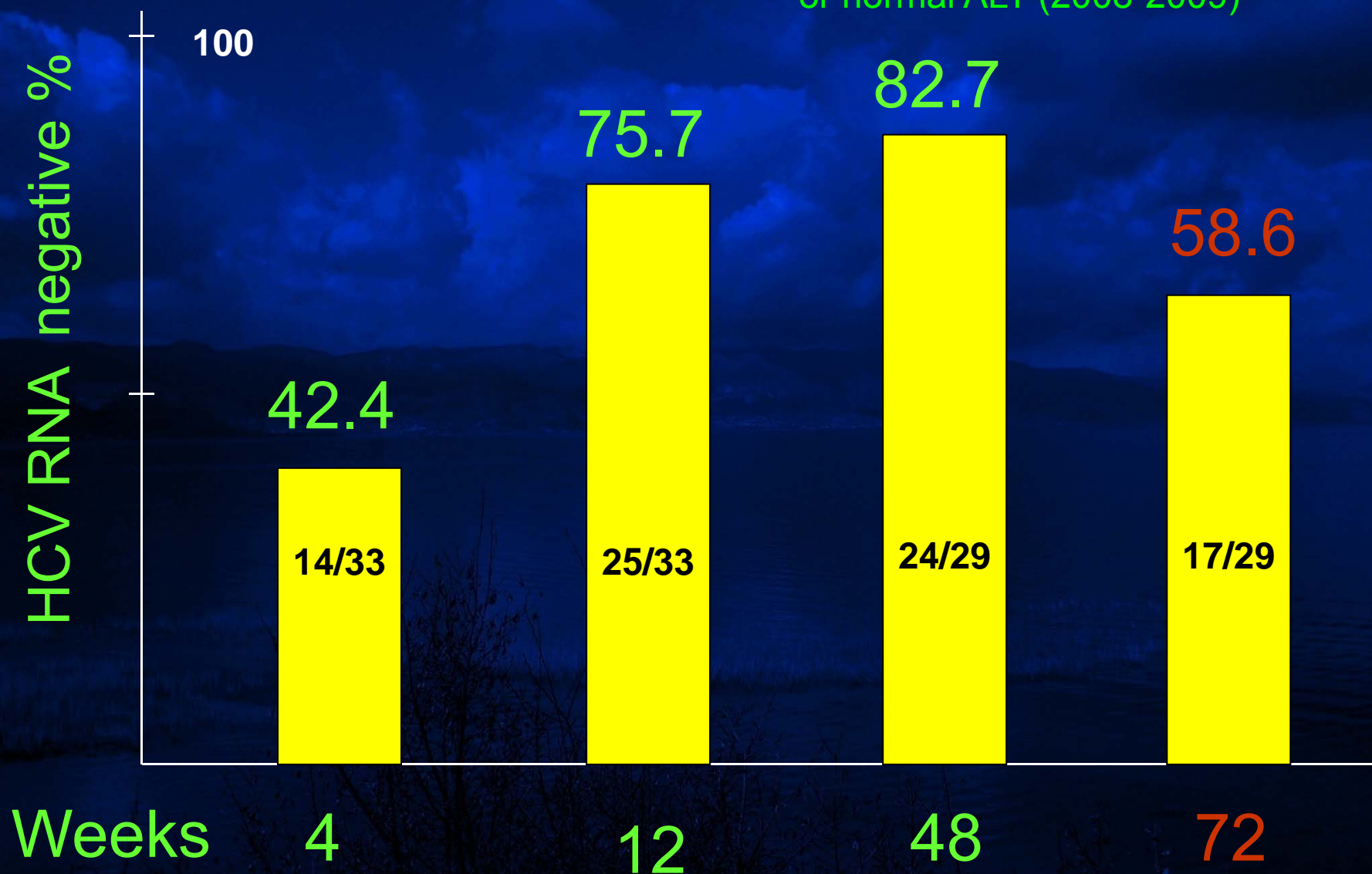
Treatment with Pegylated INF alfa 2 a/b +  
Ribavirin

More than 350 pts were treated or are  
under the treatment (last three yrs.).

(Service of Hepatology/Gastroenterology UHC, Tirana)

# RESULTS

Study: PANTERA ML 21634, center 141318  
Patients with HCV g1b with elevated  
or normal ALT (2008-2009)



Dg: chronic hepatitis C, 1b. Period of treatment: 48 w

### 3. Choice of optimal therapy (3)

#### Treatment with DAAs in Albania (48 pts)

##### 1. Sofosbuvir + Pegylated INF alfa 2 a + Ribavirin

- 13 pts were treated (12 weeks). 11/13 HCV RNA was negative after 24 weeks of follow-up (relapse in two pts treated with Sofo + RIBA)
- 15 pts are under the treatment (HCV RNA week 4, negative in all)
- 9 pts are approved and waiting for treatment

##### 2. Sofosbuvir + Ledipasvir (Harvoni)

- 9 pts were treated (12 weeks) waiting for HCV RNA after 24 weeks
- 2 pts are under the treatment

##### 1. Ombitasvir + Paritaprevir + Ritonavir + Dasabuvir

- 10 pts were treated (12 weeks) waiting for HCV RNA after 24 weeks

## 4. Monitoring of virological response (1)

-Protocol for which type of treatment:

1. Combined treatment: Peg INF + RIBA
  - a. Monitor HCV RNA during treatment  
(weeks 4, 12, 24, ..... w 24 during FU)
  - b. Early diagnosis of side effects and  
treatment of them in time.



## 4. Monitoring of virological response (2)

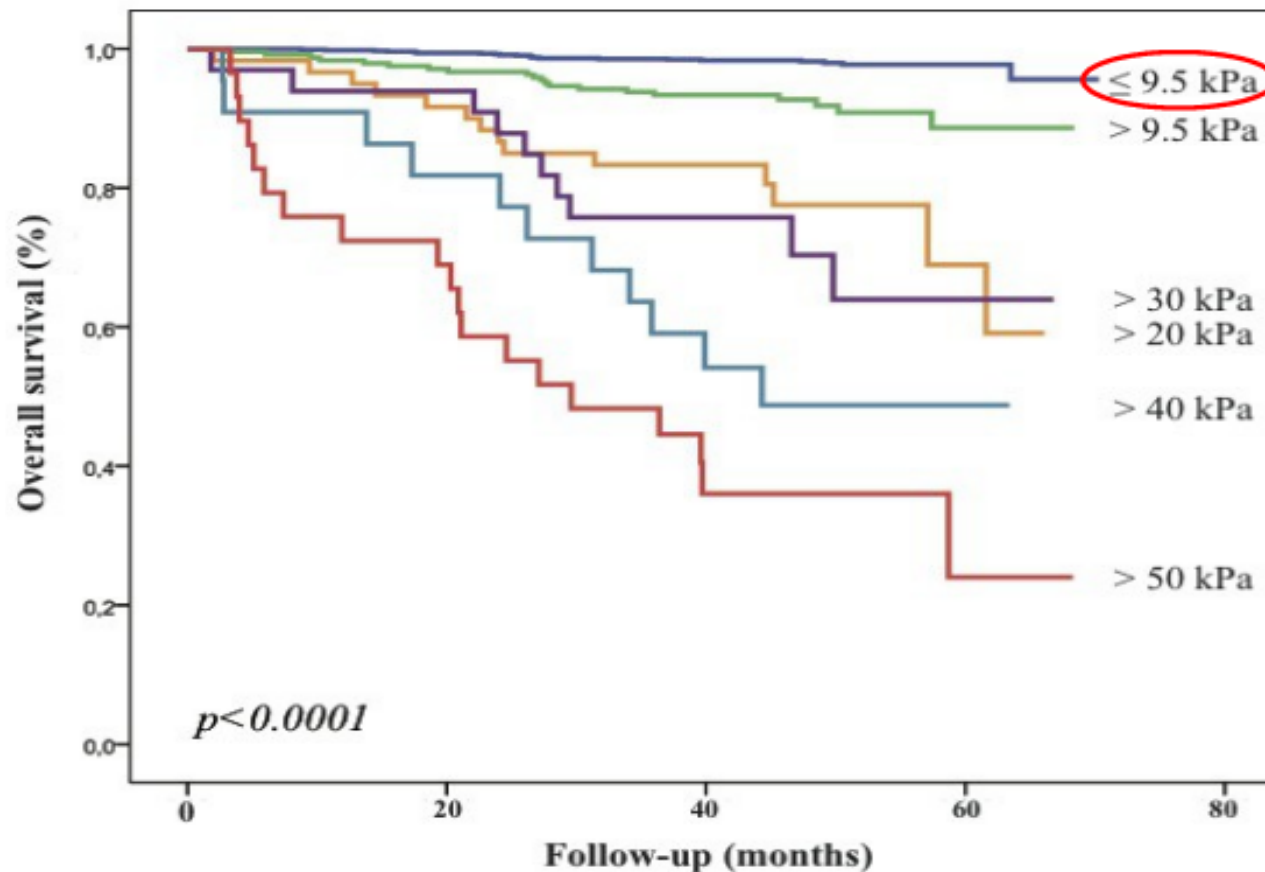
-Protocol for which type of treatment:

1. DAAs with or without RIBA

HCV RNA during the treatment  
(week 4, 8, ..... w 24 of FU)

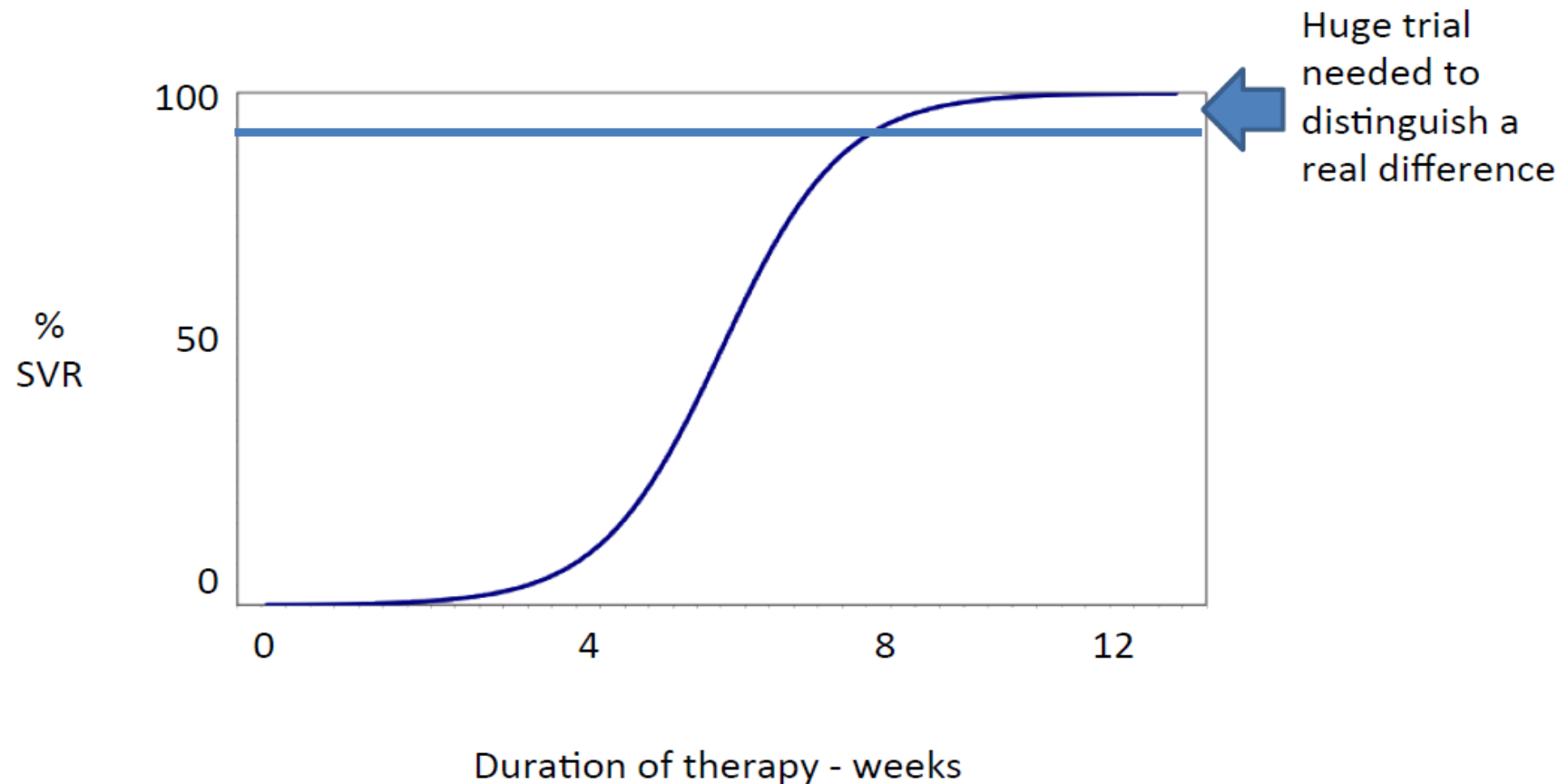
# Need to treat early/possibilities to treat

The value of liver stiffness measurement predicts survival in HCV patients



# We need to treat more patients

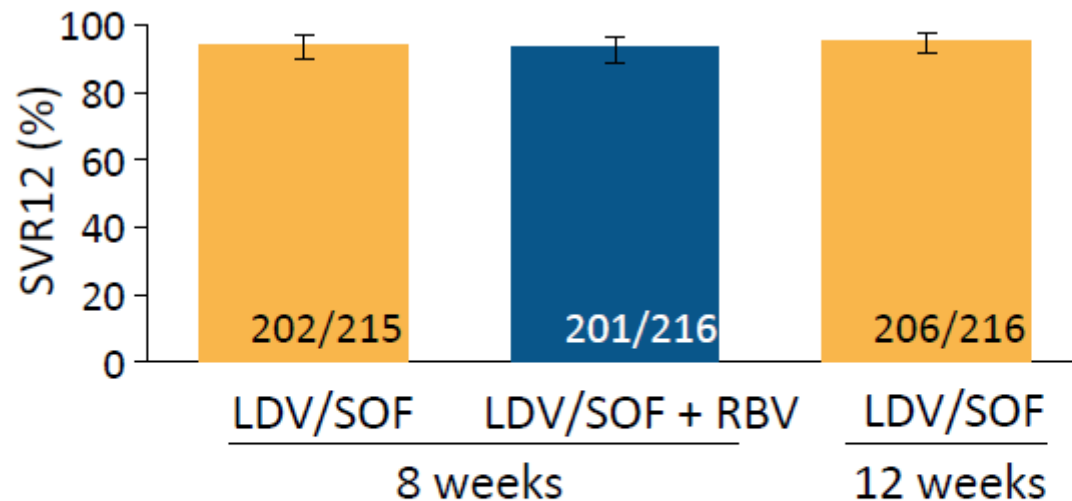
- a. All DAAs are effective
- b. Optimisation of therapy



# Choose the best treatment for our patients

## a. Naïve pts G1

Sofosbuvir/ledipasvir  $\pm$  RBV for 8 weeks vs 12 weeks in treatment-naïve non-cirrhotic G1 HCV-infected patients

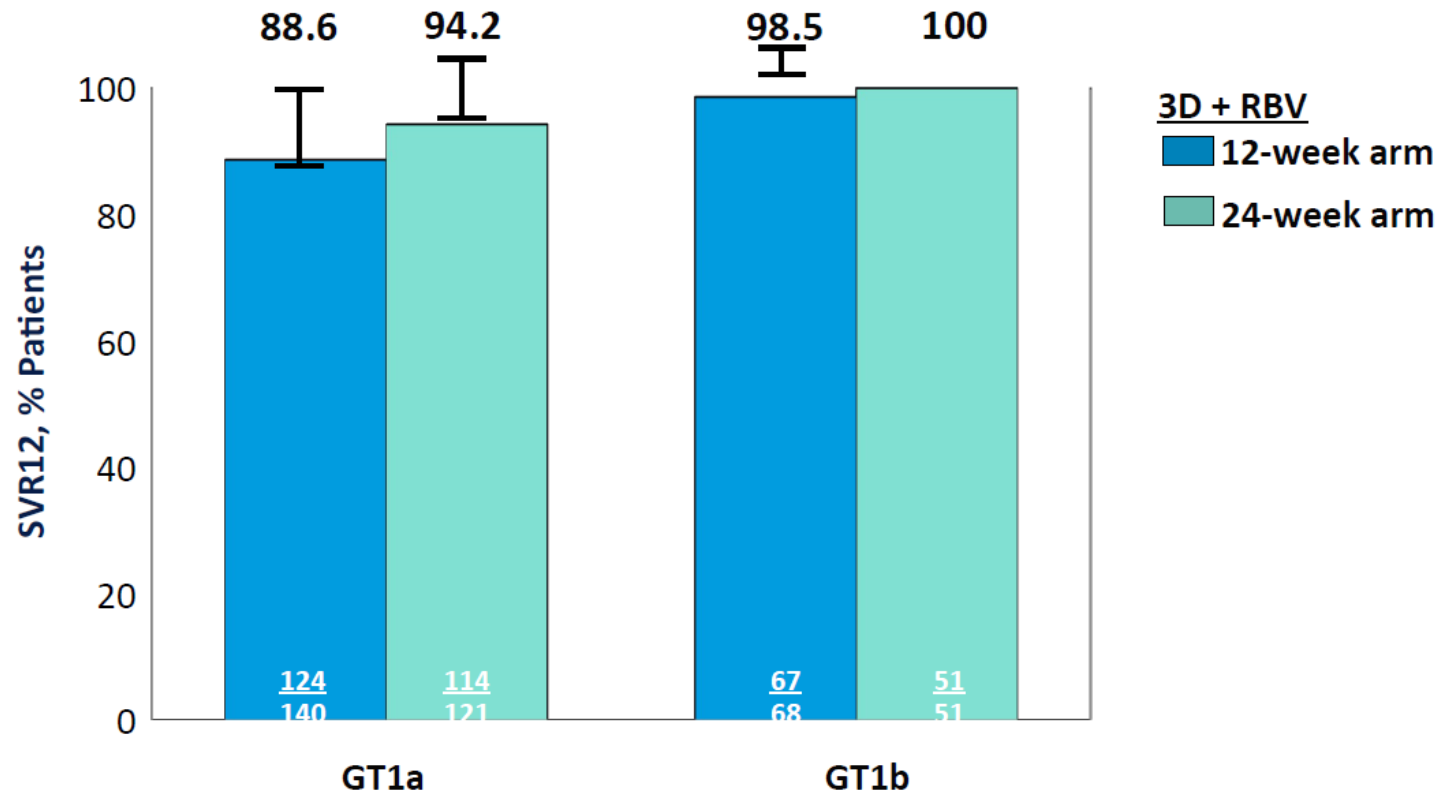


- 8 weeks without RBV not statistically inferior
- Without cirrhosis 8 weeks is the right duration

# Choose the best treatment for our patients

## b. Experienced pts

TURQUOISE-II: SVR12 rates in GT1 treatment-naïve and experienced cirrhotic patients by HCV genotype



# Conclusions

- HCV is an curable disease
- For many countries: Peg INF + RIBA
- DAAs
  - Not for all pts (in our country).
  - Optimisation of treatment (Need to treat more pts)
  - Viral resistance (a problem for the future)
  - Know HCV RNA in distance after treatment





Thank YOU

Albert Baja