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NATURAL HISTORY AND MANAGEMENT OF HEPATITIS C IN CHILDREN: 25 YEARS EXPERIENCE OF A REFERENCE CENTRE IN NORTHERN ITALY

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Introduction

- **Chronic HCV infection** is usually asymptomatic during childhood and tends to have a more indolent course than that in adults. However chronic HCV infection can lead to severe complications in early adulthood such as cirrhosis, hepatic cancer, liver failure.
- **The treatment** of chronic HCV infection has changed since the development of direct-acting antiviral agents (DAAs) which have been recently approved for pediatric use.
- **Transient elastography** is a non invasive tool not well codified in pediatric population

Objectives

To describe the **natural history** of a pediatric HCV population

To evaluate the **effectiveness and safety of new drugs (DAAs).**

To evaluate the role of **transient elastography** in the management of chronic HCV infection in children.

Study Design

Single-center retrospective study at **Paediatric Infectious Disease Unit of Luigi Sacco Hospital** (Milan, Italy) from January 1997 to January 2022 with

Methods

Inclusion criteria
HCV RNA > 15 UI/ml at least 6 months after 18 months of age + Age < 18 yrs

- Clinical and biochemical **FUP**: every 6 months
- Abdomen-US: once a year.
- If patients **treated:**
- HCV-RNA and transaminase at T0-2-4-8-12
- 12-48 weeks post-treatment (SVR12)
- Afterwards the follow up continued annually
- Fibroscan: before and after 1 yr

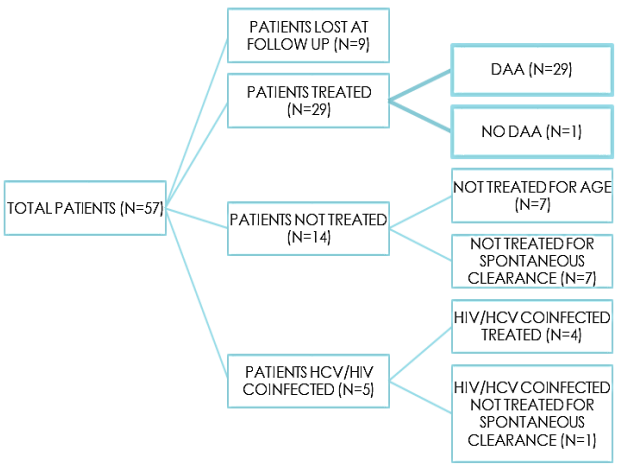
Results

- Our cohort consists of **57** patients *(Table 1)*
- The **median duration** of follow up was **10 years** (range 1-25 years).

Table 1. Main characteristics of our population

	N°	%
M	23	40
Median Age (years, months)	19.5 (IQ 5,4-34-7)	
Genotype		
1a	14	26
1b	16	30
2	8	15
3	10	19
4	4	8
Infection transmission		
Vertical	51	90
Horizontal	6	10
HCV/HIV coinfected	5	9

Figure 1. Population subgroups



- All patients were asymptomatic at the time of diagnosis except for one HCV/HIV coinfected with vertical transmission who had cirrhosis and portal hypertension.

Results 2

TERAPEUTIC REGIMEN

- Therapeutic regimens are summarized in *(Table 2).* Among HCV patients, 28/29 were treated with DAAs. Median age of treated patients was 16 years (12-24 years).In HCV/HIV group all patients were taking antiretroviral therapy HIV viral load was undetectable throughout entire follow-up.

Table 2. Therapeutic regimens

Type of drug	N°	%	Weeks
DAAs			
Sofosbuvir/Ledipasvir	14	42	12 (n=14)
Ombitasvir/paritaprevir/ritonavir + dasabuvir	6	18	12 (n=5); 24 (n=1)
Glecaprevir/pibrentasvir	9	27	8 (n=8); 12 (n=1)
Sofosbuvir+Ribavirin	2	7	12 (n=1); 24 (n=1)
Sofosbuvir/Velpatasvir/Voxilaprevir	1	3	8 (n=1)
No DAA			
Interferon + Ribavirin	1	3	24 (n=1)

Results 3: Efficacy

Clinical respose

- The infection persisted clinically silent throughout its course. No liver disease progression was seen in any of our patient throughtout for all the duration of follow up.
- The only HIV/HCV patient who was symptomatic before starting therapy showed no liver disease progression.

Biochemical response

- Median values of liver transaminasis and HCV RNA before and after therapy are summarised in *Table 3.* 14/33 patients (42%) showed **mild hypertransaminasemia** before starting therapy, which resolved after the end of treatment (Figure 3a-3b)
- **HCV RNA was undetectable** in all treated patients **at the end of the therapy**, after 12 weeks from treatment (SVR12) and for all the duration of the follow up. (Figure 2)

Table 3.Biochemical response to treatment

	BEFORE THERAPY	AFTER THERAPY
	Median (Range)	Median (Range)
ALT	42 (19-184)	20 (11-32)
AST	34,96 (24-92)	24 (12-44)
HCV RNA	3.900.228 (37.118-9.481.391)	0 (0)

Radiological response

- **Abdomen ultrasound** was made in all patients before starting therapy. 8/33 patients (24%)
- After treatment, ultrasound was normal in 4/8 (50%) patients with alterations before therapy, while the remaining 4 had no further progression.

Table 5 – Liver stiffness value pre and post therapy in patients with altered baseline TE

	pre-therapy (kPa)	post-therapy (kPa)
Patient 1	7,1	6,8
Patient 2	14,6	11,8
Patient 3	7,6	6,5
Patient 4	9,8	6,5

Safety

No seriouse adverse event were reported
No complications of hepatic disease
No HIV related adverse event
Mild side effects were reported in 8 patients.

Conclusions

- The natural course of infection showed mild disease activity and low degree of progression also in a long-term follow-up.
- Our results confirmed efficacy and safety of DAA therapy in HCV infection in paediatric population, even in the coinfected HCV/HIV population.
- Our results suggest a possible implementation in the use of transient elastography.