Cutting cost and time - HCV immunoassay predicts clinical response rate to antiviral treatment

Reference No: B76124

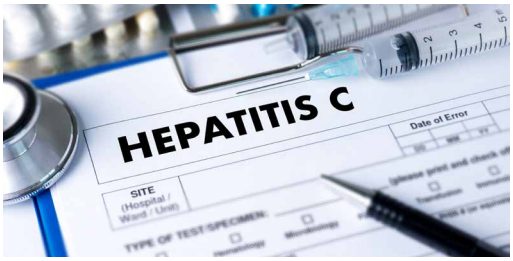
CHALLENGE

Each year, 3-4 million people become infected with the **hepatitis C virus (HCV).** In 30% of cases, the virus clears within 6 months of infection without treatment. However, an estimated **71 million people globally** develop a chronic course often resulting in cirrhosis or liver cancer[1]. For these patients, the introduction of **all-oral direct-acting antiviral (DAA)** therapy has revolutionized treatment and life options with a 95% cure rate. However, their **high treatment costs** not only largely limit access to therapy but also poses a severe burden on the healthcare budget with total costs currently as high as **$150.000 per patient.** However, response to DAA treatment can **vary considerably** between patients in terms of HCV RNA negativity. With the potential to identify the response outcome for patients before treatment, shorter and individualized courses of DAA therapy are made possible and possess a significant benefit toward reducing overall treatment costs.

INNOVATION

Here, we present a method to **predict clinical response rate to DAA treatment** of patients with chronic HCV infection by virtue of early viral control. DAA treatment is known to alter distribution of **CD8+ memory T cell** subsets. **Prior** to starting the cost-intense DAA treatment, analysis of peripheral blood by **flow cytometry** for **frequency of CD8+ TEM lymphocytes** divides patients into "fast" and "slow" responders to DAA therapy. Measured frequencies of CD3+ and naive CD8+ T cells correctly **classified 82.6 %** of patients as "fast" (HCV RNA-negative by 4 weeks) or "slow"[2]. With a false-positive rate to predict a fast response of only 9.1 %, this method can reliably shorten treatment duration.

PREDICTED		OBSERVED		
		RESPONSE		(%)
		SLOW	FAST	
RESPONSE	SLOW	10	3	76.9
	FAST	1	9	90
		OVERALL CORRECT (%)		82.6



COMMERCIAL OPPORTUNITIES

- Cost-effective approach to shorter treatment: **under $100 in less than 4 h**
- Highly standardized flow cytometry-based assay with **commercially available kits**
- **Individually-tailored** assay principle can be extend to other analytical methods or biomarkers

DEVELOPMENT STATUS

Proof-of-concept *in vitro* and in HCV patient group

REFERENCES:

1. https://www.who.int/news-room/fact-sheets/detail/hepatitis-c
2. Hutchinson JA et al. Predicting Early Viral Control under Direct-Acting Antiviral Therapy for Chronic Hepatitis C Virus Using Pretreatment Immunological Markers. Front Immunol. 2018 Feb 7; 9:146.

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