

# Technical assessment and reliability of controlled attenuation parameter (CAP) with M probe in NAFLD

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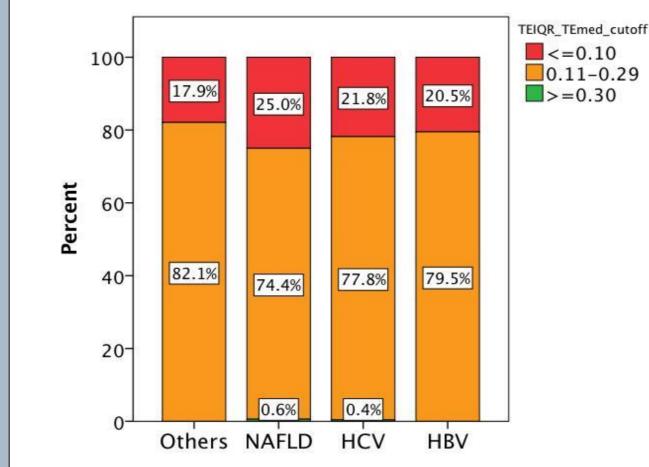
## **Introduction and Aims**

In clinical practice the use of imaging and liver biopsy is changing<sup>(1)</sup>. Risk stratification and prognosis of liver disease is accepted for HCV, HBV etiology and proposed for NAFLD (non alcoholic fatty liver disease) patients through non invasive fibrosis assessment like liver stiffness measurement (LSM) by transient elastography (TE). This assessment can be performed together with controlled attenuation parameter (CAP) for the detection of fatty liver.

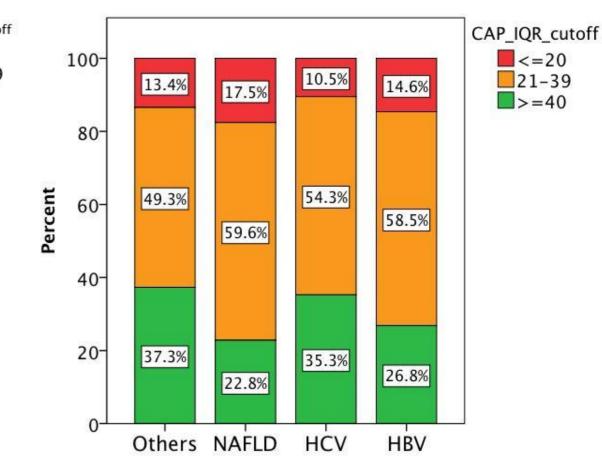
Here we aimed:

- i) to compare CAP/Median results, in a real life experience setting through:
  - a. recently proposed cut off related to optimal stratification of steatosis<sup>(2)</sup>;
  - b. reliability based on interquartile range  $(CAP/IQR)^{(3)}$ ;
- ii) to predict any increase of fibrosis in these NAFLD patients using TE<sup>(4, AISF-SIMG)</sup>.









## > NAFLD SAMPLE

Table 2: NAFLD Sample characteristics and group comparisons by Anova or Chi-squared tests

NAFLD patients N= 221	Total	CUT OFF CAP-median dB/m				Test group
		<b>≤ 248</b> N=42 (19%)	>248 ≤268 N=32 (15%)	>268 ≤280 N=20 (9%)	> <b>280</b> N=127 (57%)	comparison
Gender F n(%) M n(%)	82 (37.1) 139 (62.9)	22 (52.4) 20 (47.6)	16 (50.0) 16 (50.0)	8 (40.0) 12 (60.0)	36 (28.7) 91 (71.6)	χ <sup>2</sup> =10.7, p =0.013
TE kPa,median mean(SD) [IQR]	6.0 (4.3) [2.3]	4.7 (2.6)	5.3 (4.1)	5.1 (2.6)	6.8 (4.8)	F=3.4, p=0.019
Cut Off	8.8 (0.5)	4.1 (1.1) () 13.1 (2.3)	4.6 (1.4)  26.3 ()	4.4(1.2) 8.8 () 13.8 ()	5.1 (1.2) 88 (0.6) 15.4 (8.1)	F=7.9, p<0.001 F=0.1, p=977 F=0.8, p=0.521
TE kPa IQR /TE kPa median (%) mean (SD)	17.4 (10.3)	19.6 (12.7)	17.7 (13.8)	17.6 (7.6)	16.5 (8.6)	F=1.0, p=0.399
CAP median (dB/m) mean (SD)	288 (56.3)	205 (47.3)	258 (5.8)	274 (3.8)	324 (30.7)	F=165, p<0.001
CAP IQR (dB/m) mean (SD)	31.6 (15.8)	40.5 (21.9)	31.2 (13.6)	32.7 (11.7)	28.7 (13.4)	F=6.3, p<0.001
CAP IQR (dB/m) Cut Off >40 (n=45, 20% of NAFLD) mean (SD)	53.8 (17.6)	58.2 (23.2)	50.3 (12.6)	48.8 (11.9)	51.9 (13.9)	F=0.6,p=0.625

## Methods

- CAP values obtained by FibroScan ®CAP (Echosense Paris) range from 100 to 400 dB/m, and the final result is the median value of 10 valid measurements (note that CAP is calculated simultaneously with TE LSM in kPa range 0-75).
- ◆ Only patients (pts) with 10 valid LSM measurements were included, whereas "poorly reliable" values (TE-IQR/TE-Med >0.30 with TE-Med ≥7.1 kPa) were excluded from the analysis.
- Among 952 patients consecutively examined after primary care referrals in twelve months period, 38 were excluded, i.e.:
  - 3 pts for less than 10 LSM for more than 2.7 cm skin-liver thickness,
  - 35 pts (3.6%) were poorly reliable.
- CAP value groups were defined according to recently proposed cut off<sup>(2)</sup>: S0 (<248dB/m), S1 (<268), S2 (<280), S3 (>280). CAP/IQR cut off (<40 value).</p>
- Difference among groups were analyzed by ANOVA test for continuous variable and Chi squared test for categories variable.

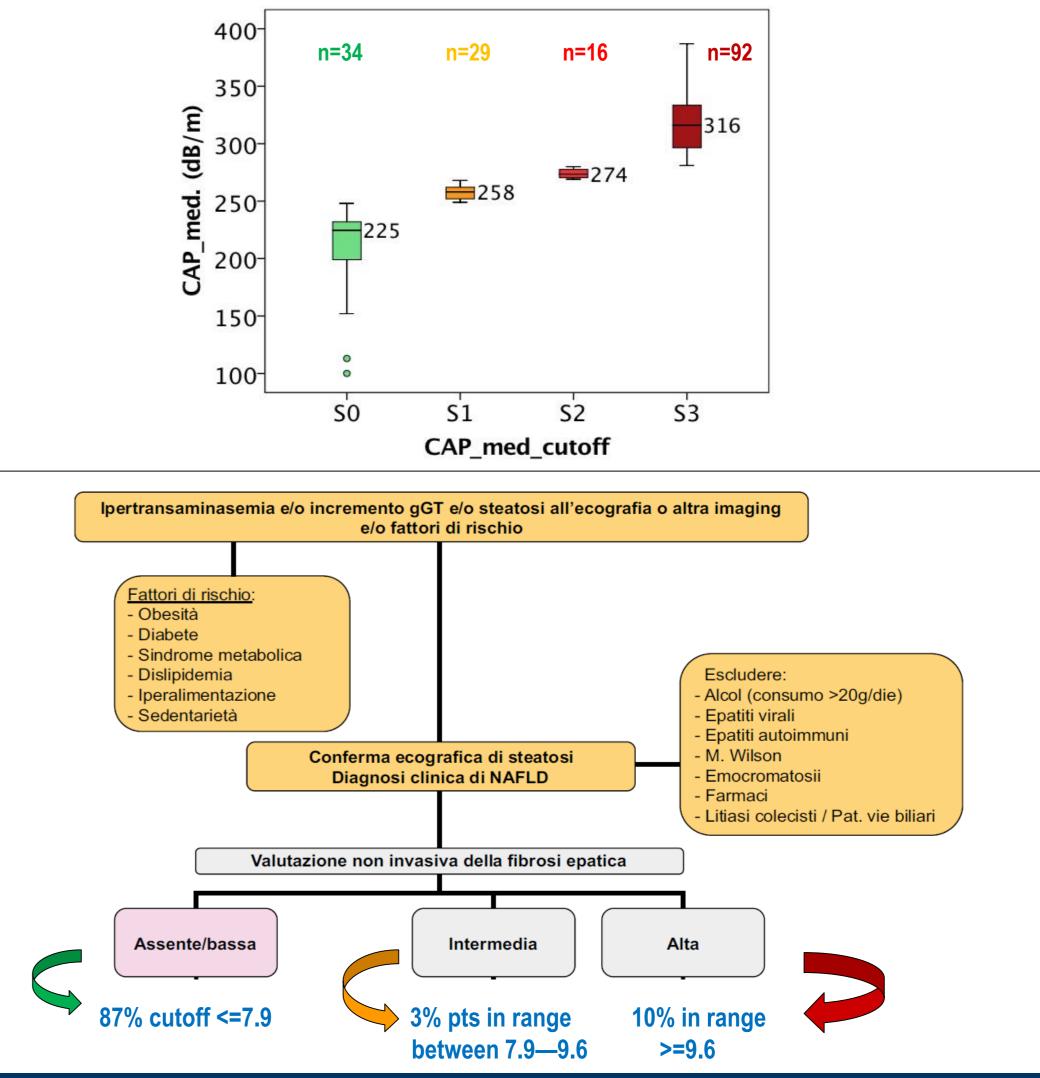
## Results

## > WHOLE SAMPLE

Descriptive statistics and differences among CAP value groups were summarize in Table 1:

□ TE-kPa median value( <7.9; >9.6) defined low and high risk of progression respectively.

### The following two plots refer to reliable values of NAFLD group



#### Table 1: Whole Sample characteristics and group comparisons by Anova or Chi-squared tests

		Total	C	Test group comparison			
All patiets N=914			<b>S0</b> ≤ 248 N=429 (46.9%)	<b>S1 &gt;248</b> <b>≤268</b> N=121 (13.2%)	S2 >268 ≤280 N=64 (7%)	<b>S3</b> > <b>280</b> N=300 (32.8)	
Gender F M	n(%) n(%)	434 (46.9) 480 (52.3)	238 (55.5) 191 (45.5)	65 (53.7) 56 (46.3)	28 (43.8) 36 (56.2)	103 (34.3) 197 (65.7)	χ <sup>2</sup> =34.0, p <0.001
Age (years)	mean (SD)	60.5 (13.8)	60.3 (14.5)	59.3 (14.1)	61.1 (14.5)	61.2 (12.6)	F=0.6, p=0.610
Diagnosis <u>NAFLD,</u> HCV, HBV, Other,	n (%) n (%) n (%) n (%)	221 (24.2) 524 (57.3) 60 (6.6) 109 (11.9)	<u>42 (9.8)</u> 291 (67.8) 28 (6.5) 68 (15.9)	<u>32 (26.4)</u> 69 (57.0) 12 (9.9) 8 (6.6)	20 (31.2) 34 (53.1) 3 (4.7) 7 (11.0)	<u>127 (42.3)</u> 130 (43.3) 17 (5.7) 26 (8.7)	χ <sup>2</sup> =111.8, p <0.001
Total measures	mean (SD)	26.7 (16.2)	26.2 (15.5)	28.0 (15.5)	27.0 (18.9)	26.8 (16.9)	F=0.4, p=0.730
Valid measures	mean (SD)	22.0 (12.8)	23.1 (13.3)	23.4 (13.3)	22.7 (15.5)	19.5 (10.9)	F=5.5, p=0.001
TE kPa,median [ IQR ]	mean (SD)	8.7 (8.1) [5.2]	8.5 (7.9)	7.5 (5.4)	8.6 (8.5)	9.5 (8.9)	F=2.1, p=0.096
TE kPa IQR	mean (SD)	1.5 (2.0)	1.4 (1.6)	1.3 (1.2)	1.5 (1.9)	1.8 (2.6)	F=3.3, p=0.021
TE kPa IQR /TE kPa m	edian (%) mean (SD)	17.0 (8.0)	16.8 (7.9)	16.7 (8.9)	17.3 (7.9)	17.4 (8.8)	F=0.3, p=0.799
CAP median (dB/m)	nean (SD)	255 (59.5)	206 (36.9)	257 (5.8)	274 (3.4)	321 (30.9)	F=824,p<0.001
CAP IQR (dB/m)	mean (SD)	36.2 (17.7)	39.9 (20.0)	36.5 (15.5)	33.6 (12.4)	31.4 (14.5)	F=14.8, p<0.001
CAP IQR (dB/m) CUT C (n=283, 31% of all)	)FF>40 mean (SD)	55.2 (18.2)	57.5 (20.2)	52.1 (15.2)	50.0 (14.1)	52.3 (14.1)	F=2.2, p=0.088

□ CAP-median dB\m cut off >280 (S3) was mainly observed in male gender;

in 24,8% of HCV and 57.4% of NAFLD etiology;

□ CAP-IQR>40 occurred in 31% overall

□ CAP-IQR>40 occurred in 20% in NAFLD ethiology

## Conclusions

S3 grade steatosis defined by 280 dB\m cut off occurred in 57% with NAFLD etiology and one of four pts with HCV etiology.

In 19% of clinically diagnosed NAFLD steatosis was not confirmed by CAP values. In NAFLD group, applying CAP-IQR>40, 20% of pts could have low validity steatosis grade stratification.

The prevalence of high risk of fibrosis progression in clinically diagnosed NAFLD according to AISF-SIMG algorithm was 10% of 221 consecutive pts in real practice.

## References

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(4) Documento AISF\SIMG NAFLD Modello Gestione Condivisa Gennaio 2016



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