

# TRANSIENT ELASTOGRAPHY (FIBROSCAN®) - THE NORMAL VARIABILITY BETWEEN TWO MEASUREMENTS

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**Background and aims:** Transient elastography (Fibroscan®), a noninvasive method for liver fibrosis assessment is considered a candidate for monitoring the evolution of a chronic liver disease. This study aims to establish the normal variation between two consecutive measurements and what difference between two values should be considered significant in terms of improvement or aggravation of a liver disease.

**Methods and patients:** 202 patients underwent two consecutive liver stiffness measurements performed by the same experienced physician (over 500 maneuvers) at the same site, on the median axillary line in the first intercostal space under the liver dullness upper limit, with the patient in dorsal decubitus. Only valid measurements (according to manufacturer's recommendations) were analyzed. We used the average value of the two measurements for stratification, cut-offs of 5.5, 7.1, 9.5, 14.5 KPa for F1-F4 and 7.1 Kpa as a limit for significant/non-significant fibrosis.

**Results:** The differences between the two measurements ranged from 0 to 5.3 KPa (0-54% of one of the values). We found a mean variation between two measurements of 13%, with a standard deviation of 0.122 (12.2%).

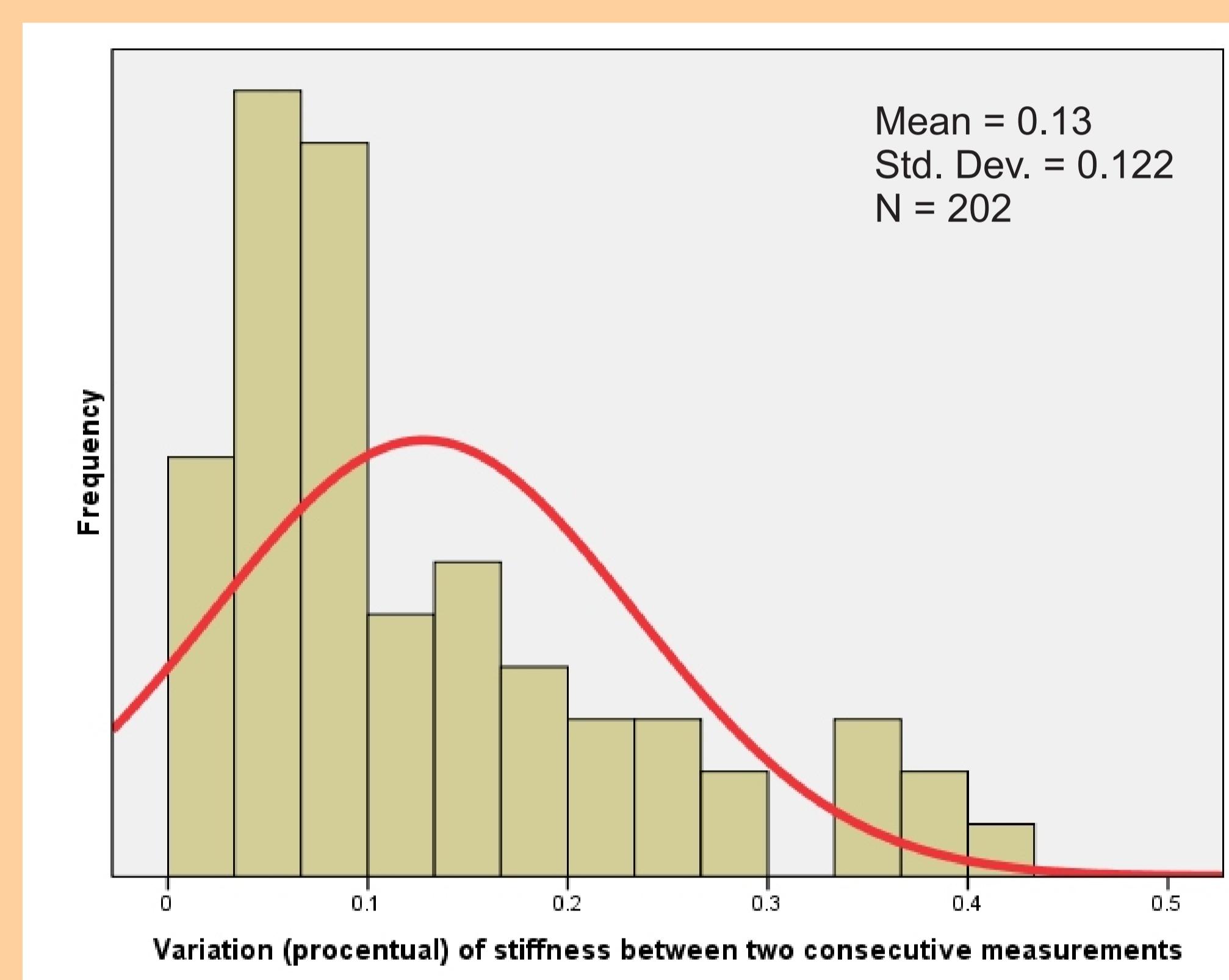
## Descriptive statistics:

Total: 202 patients

Man : 98 (48.5%)

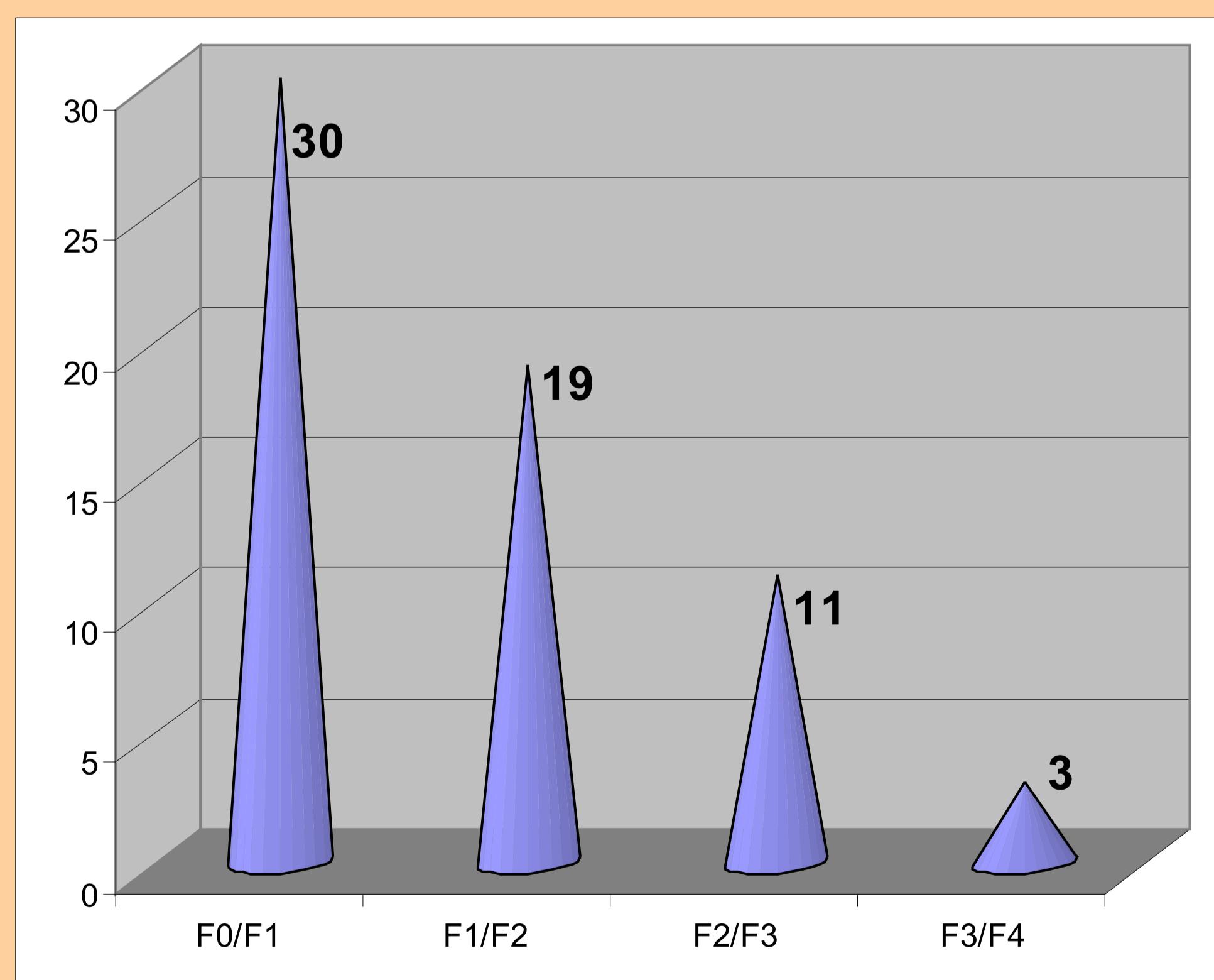
Average corresponding Metavir stage: F1-57, F2-42, F3-60, F4-43

	Min	Max	Mean / Stdev
Age:	19	73	45.32±12.34
BMI:	18.4	28.3	22.8±3.7
1st measurement stiffness	3.2	67.8	10.68±10.68
1st measurement IQR	0.3	15.6	1.9±2.29
1st measurement success	63	100	92.74±11.67
2nd measurement stiffness	3.2	62.7	10.43±10.58
2nd measurement IQR	0.2	13.7	2±2.56
2nd measurement success	64	100	92.53±14.91

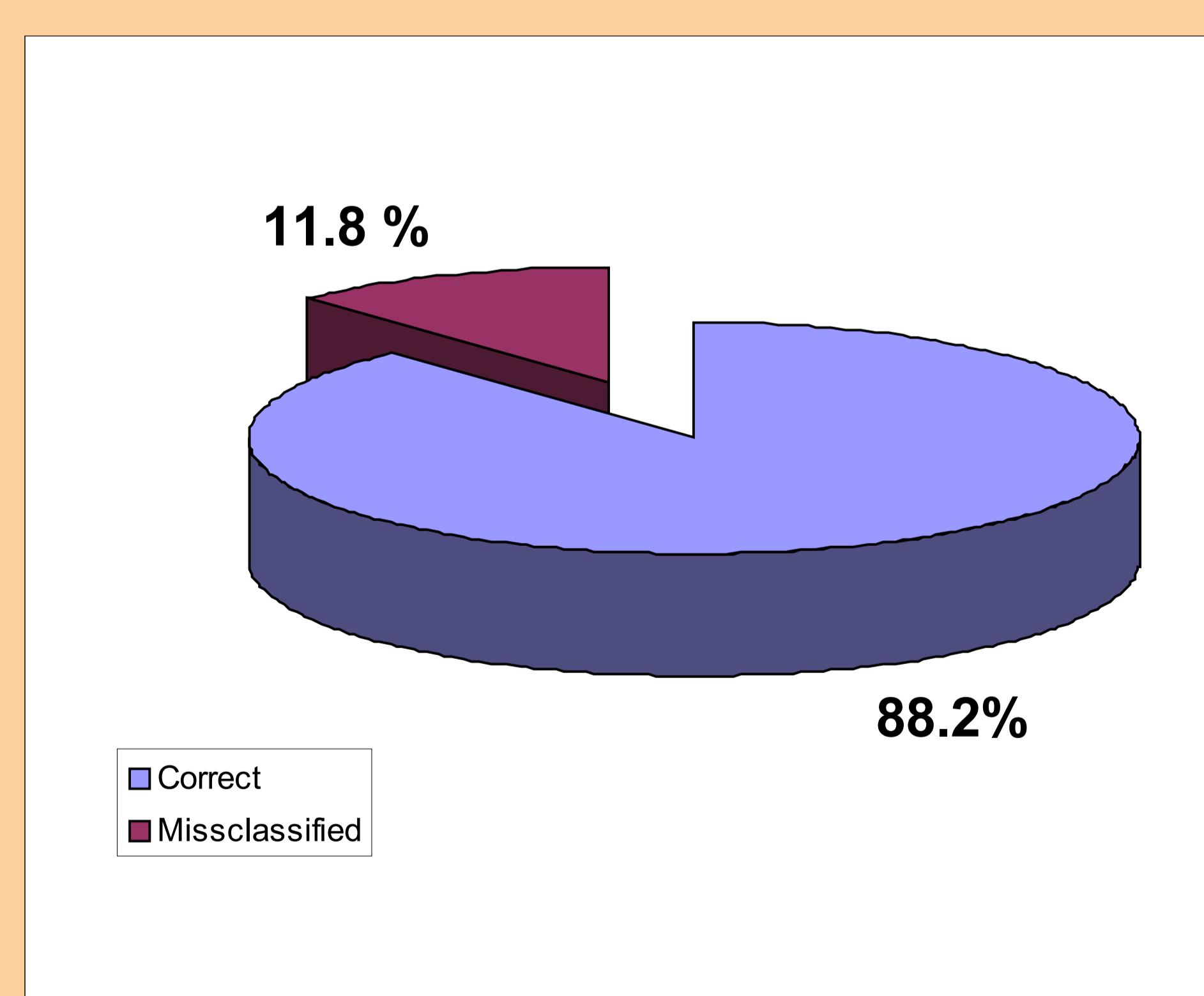


Discordance between measurements was associated with BMI ( $p=0.007$ ,  $r=0.474$ ) and not influenced by sex or age. The difference of two measurements increases as median stiffness increases ( $p< 0.0001$ ,  $r=0.575$ ) and is also related to IQR ( $p< 0.0001$ ,  $r=0.556$ ).

Based on the mentioned cut-offs, 63 (31.1%) patients were categorized in two different stages by the two different measurements (3 for F3/F4, 11 for F2/F3, 19 for F1/F2 and 30 for F0/F1). The maximum difference between two measurements would be of one corresponding Metavir stage. For significant/not significant fibrosis (cut-off 7.1 KPa), 24 (11.8%) patients were misclassified.



Patients missclassified by the two measurements (Metavir corresponding stage)



Patients missclassified by the two measurements (significant/no significant fibrosis)

**Conclusions:** There is a normal variability between two liver stiffness measurements of  $13\% \pm 12.2\%$ . Therefore only a variation of minimum 25.2% between measurements performed in evolution should be considered significant as a proof of a liver disease improvement or worsening.

The larger number of patients who have been misclassified for F0/F1 than for F3/F4 is consistent with the findings of other studies that showed a better concordance of elastography with liver biopsy for higher stages of fibrosis.

Using stricter validation criteria (a lower IQR and a larger number of valid measurements) and classifying fibrosis as no significant/ significant/ cirrhosis may enhance the use of Fibroscan® as a monitoring tool.

**Disclosure:** Nothing to disclose