

A CLINICALLY RELIABLE METHOD TO DETERMINE SIGNIFICANT REFERENCE AMH RANGES FOR IVF PATIENTS USING A NEW PRE-MIX PROTOCOL FOR AMH GEN II ASSAY

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CONTEXT

Beckman Coulter identified in 2013 a source of bias responsible for falsely low anti-müllerian hormone results with their AMH Gen II Assay. The new protocol is known to inhibit the complement interference caused by the old protocol.

OBJECTIVES

The main goal of this study consists of correlating AMH levels measured with the new protocol to clinical reference ranges.

As a secondary objective, the old and new protocol for AMH analysis will be compared to determine if the bias source is eliminated.

METHODS

Blood collection: 197 non-pregnant women were approached for blood samples between October and November 2013.

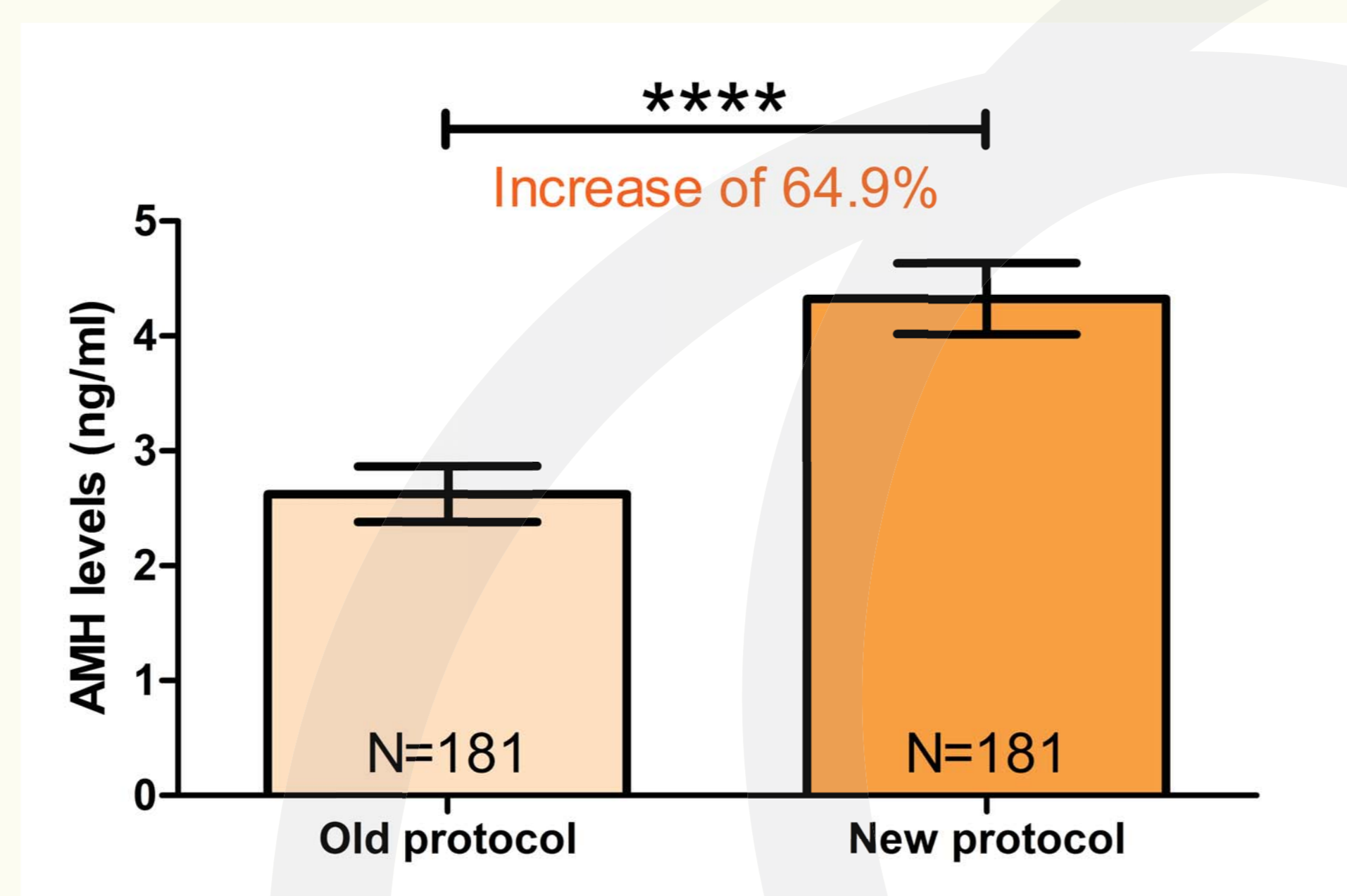
Hormonal assay: AMH levels were measured using both old and new protocol. FSH and Estradiol levels were also measured as part of routine.

Correlating clinical data: AMH levels measured with the new protocol were correlated with the antral follicle count (AFC) and number of ovarian punctures (OP).

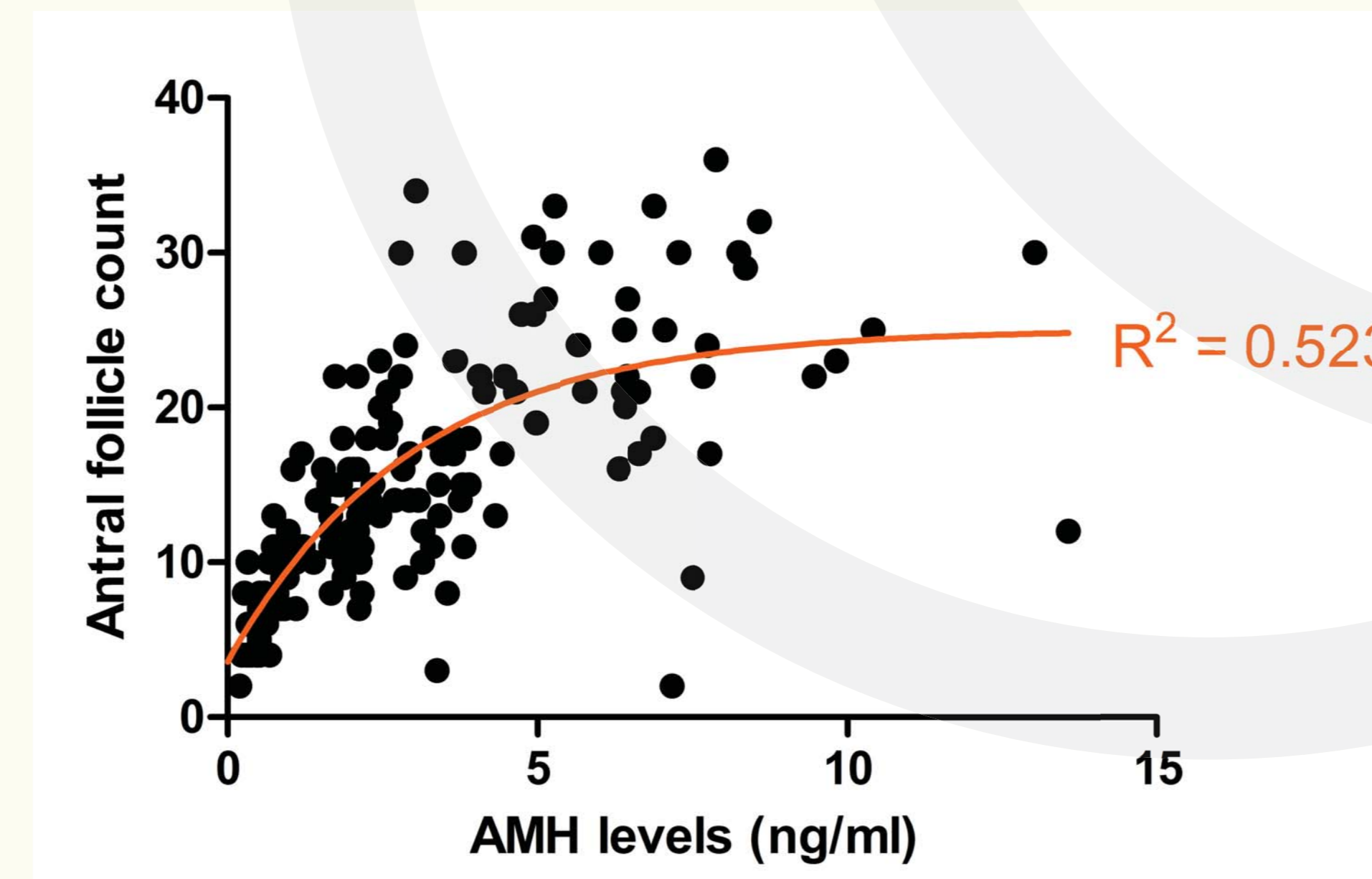
Establishment of reference ranges: Creation of tables giving the predicted AFC or OP number according to AMH levels measured.

RESULTS

Comparison between the old and new protocol for AMH levels



Antral follicle count according to AMH levels (new protocol) N=152



AMH levels (ng/ml)	AFC (in average)	Clinical interpretation
0 to 0,5	1 to 5	very low reserve
0,5 to 1	6 to 10	low reserve
1,1 to 3	11 to 17	limit reserve
3,1 to 6	18 to 22	normal reserve
6,1 and more	> 22	high reserve

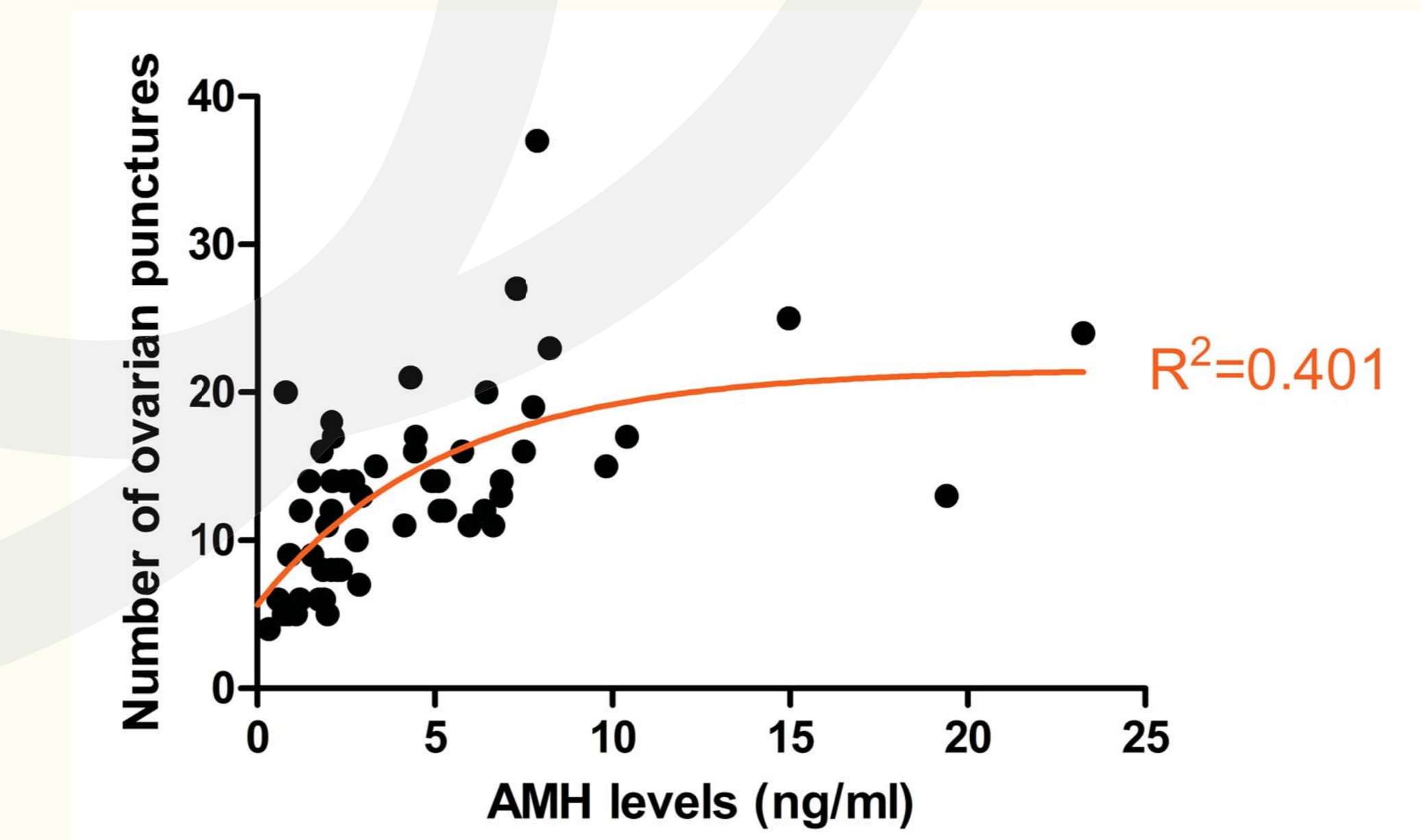
STATISTICS

All statistical tests were made with the GraphPad Prism program Version 5.04.

The histogram's statistical test was determined using the Student's t-test (**** p<0.0001).

The graphs' goodness of fit was measured using the One phase decay correlation test. The correlation is expressed with the R square test.

Number of ovarian punctures according to AMH levels (new protocol) N=57



AMH levels (ng/ml)	OP number (in average)
0 to 1	1 to 4
1,1 to 3	5 to 10
3,1 to 6	11 to 15
6,1 to 10	16 to 19
10,1 and +	> 20

CONCLUSIONS

The new protocol for the AMH Gen II Assay seems to have eliminated the complement interference, which was a source of bias.

AMH seems to be a good potential biomarker to predict the number of antral follicles or even the number of ovarian punctures.

PERSPECTIVES

Increasing the sample size would be relevant, in order to obtain a better correlation between AMH with AFC or OP number.

Other hormones, such as follicle stimulating hormone (FSH) and estradiol should be tested and correlated with AFC and OP number.

The type of stimulated IVF cycle may affect the number of AFC or OP. Comparing different cycles could be very helpful to MDs in determining more appropriate fertility treatments.