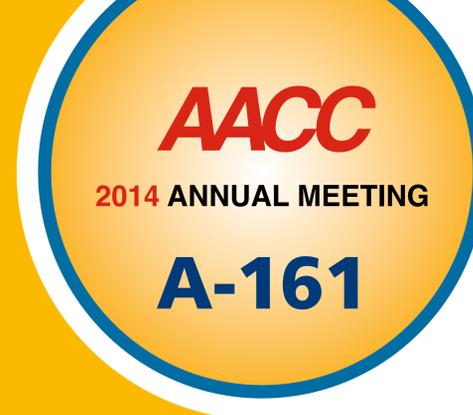


LOW TESTOSTERONE CONCENTRATIONS: ONLY MASS SPECTROMETRY?



A. Fortunato¹, M. Caputo², P. Garofalo³, C. Marchetti¹, R. Castello⁴

¹Laboratorio di Chimica Clinica ed Ematologia Ospedale "S. Bortolo", Vicenza, Italy

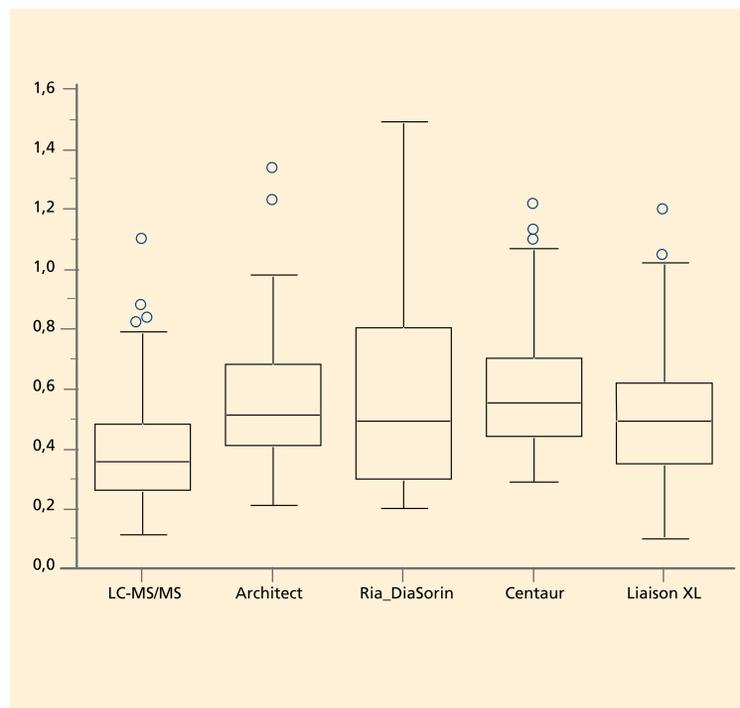
²Laboratorio Chimica Clinica e Microbiologia, Ospedale "Orlandi", Bussolengo (VR), Italy

³UOC Endocrinologia AOOR "Villa Sofia-Cervello", Palermo, Italy

⁴UOC Medicina generale indirizzo endocrinologico, AOUI, Verona, Italy

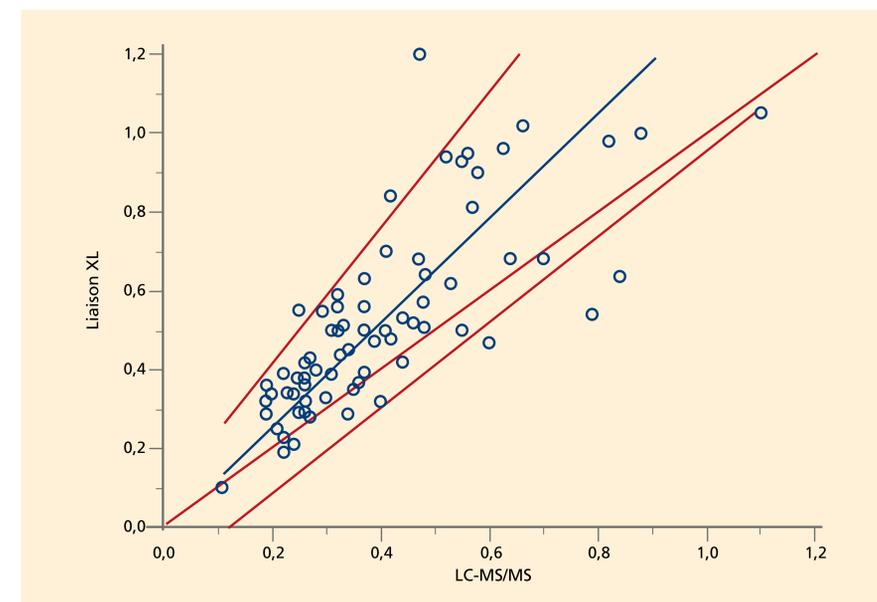
BACKGROUND

Total testosterone level measurement is the most requested one among steroid hormones assays. Unfortunately, the diagnostic accuracy at low concentrations of the most common immunoassays proved to be insufficient. In 2007 the Endocrine Society recommended the determinations of testosterone in children and in women has to be done only with one reference method (extraction, chromatography and determination by mass spectrometry). Due the method related difficulties in most of the laboratories the testosterone determinations are still done by immunoassays.



SAMPLES AND METHODS

We measured testosterone with three different fully automated immunoassays present in most of the clinical labs and repeated the determinations both with a commercial RIA and LC-MS/MS method. The latter one, considered the reference method, has been done in the Perkin Elmer labs (Turku, Finland), with updated equipment, by skilled personnel and determinations carried out in replicated. The serum samples were collected from 70 patients, male and female in pediatric age. The obtained concentrations by LC-MS/MS, considered as reference, ranged from 11 to 110 ng/dL.



RESULTS

The distribution of the concentrations obtained with the methods used should be noted that, although the averages and medians of the concentrations obtained with the LC-MS/MS method are less, the differences are not such as to distort the clinical information can be obtained: the 3 automated methods show values ranging from 10 to 134 ng/dL with correlations coefficients respectively to LC-MS/MS ranging from 0,829 to 0,934; whereas the RIA method shows a higher concentration's dispersal, values ranging from 20 to 149 ng/dL and a worse correlation to the reference method. ($r=0,705$).

	N	Mean	95% CI	Variance	SD	RSD	SEM	Median	95% CI	Min	Max	2.5 - 97.5 P	Normal Distr.
LC-MS/MS	70	0,401	0,36 - 0,45	0,036	0,189	0,471	0,023	0,355	0,31 - 0,41	0,11	1,1	0,190 - 0,870	<0,0001
Architect	70	0,558	0,51 - 0,61	0,046	0,213	0,382	0,026	0,51	0,48 - 0,55	0,21	1,34	0,283 - 1,167	<0,0001
RIA_DiaSorin	70	0,583	0,50 - 0,67	0,122	0,349	0,599	0,042	0,49	0,41 - 0,57	0,2	1,49	0,200 - 1,348	0,0164
Centaur	70	0,584	0,54 - 0,63	0,042	0,205	0,351	0,025	0,55	0,49 - 0,58	0,29	1,22	0,320 - 1,122	0,0004
Liaison® XL	70	0,519	0,46 - 0,58	0,055	0,234	0,450	0,028	0,49	0,41 - 0,52	0,1	1,2	0,195 - 1,042	0,0048

CONCLUSIONS

The position of the scientific community on total blood testosterone measurement at low concentrations is critical to the use of direct immunoassays because without the necessary diagnostic accuracy, and recommends the use of methods that are not within the reach of general laboratories. Our results, although preliminary, open an interesting perspective on the possibility of arriving at a reasonable future to employ even the immunoassays, certainly more feasible, as an aid to diagnosis of common and important endocrine syndromes of the woman and the child.