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NON INVASIVE MEASUREMENT OF VALSALVA LEAK POINT PRESSURE – A NEW AND INNOVATIVE DEVICE

Hypothesis / aims of study

The aim of this study is to show the development of a new device for non invasive measurement of valsalva leak point pressure based on the physical law of Paschal

Study design, materials and methods

Between October 2006 and October 2007 we tested the device in 84 patients during the urodynamic study.

The transducers were zeroed to the atmosphere, and we tested the with an empty bladder, at 150 ml and 300 ml of filling and at maximum cystometric capacity

The patient was instructed to do a valsalva maneuver in the device and the results were compared to abdominal and vesical pressure measured with the urodynamic equipment

Abdominal pressure absolute was the total value of the pressure generated with the valsalva and abdominal delta pressure was the difference between the absolute pressure and the basal pressure

The same definitions were applied to vesical pressure.

We also tested if bladder capacity, presence of prolapse grader than stage 2 (POP definition), presence of uninhibited bladder contractions and presence of urinary stress incontinence had any influence in the results

Results

We analysed the correlation between the measurement form the device at different volumes with the measures (Abdominal absolute , Abdominal delta , Vesical absolute, Vesical delta) with the urodynamic equipment .There was good correlation between the device and measurements at urodynamics , with better correlation with Abdominal absolute. The degree of correlation between two quantitative (numeric) variables (x and y) is expressed by the correlation coefficient (r). Which measures the degree of linear relation between the two? Its value does not depend on the units in which x and y is expressed. Its large value indicates a strong relationship

TABLE 1-Correlation and determination coefficients of “Menezes” measures and other measures according to vesical volume

	0 ml (n=83)			150ml (n=80)			300ml (n=65)			CIS (n=45)		
	R	R square	p-value	R	R square	p-value	R	R square	p-value	R	R square	p-value
Abd Abs	**0.911**	**0.830**	**<0.001**	**0.856**	**0.733**	**<0.001**	**0.896**	**0.804**	**<0.001**	**0.875**	**0.766**	**<0.001**
ABD delta	0.905	0.819	<0.001	0.743	0.552	<0.001	0.879	0.772	<0.001	0.853	0.728	<0.001
VES O ABS	0.889	0.790	<0.001	0.815	0.664	<0.001	0.883	0.779	<0.001	0.824	0.678	<0.001
VES O Delta	0.891	0.795	<0.001	0.805	0.648	<0.001	0.875	0.765	<0.001	0.817	0.668	<0.001

Most patients had no prolapse. The presence of prolapsed did not influence the results . All correlation coefficients were higher than 0.80

TABLE 2

Correlation and determination coefficients of “Menezes” measures and other measures for prolapse

	Yes				No			
	n	R	R square	p-value	n	R	R square	p-value
Abd Abs	2	1.0	1.0	...	39	0.913	0.833	<0.001
ABD delta	2	1.0	1.0		39	0.903	0.815	<0.001
VES O ABS	2	1.0	1.0		39	0.889	0.791	<0.001
VES O Delta	2	1.0	1.0		39	0.889	0.791	<0.001

37 of patients (44 %) presented with bladder uninhibited contractions (BUC) . The presence of BUC did not influence the results

Correlation and determination coefficients of “Menezes” of exam 1 measures and other measures according to presence of BUC)

TABLE 3

	Yes				No			
	N	R	R square	p-value	n	R	R square	p-value
Abd Abs	46	0.951	0.905	<0.001	37	0.871	0.759	<0.001
ABD delta	46	0.947	0.896	<0.001	37	0.863	0.744	<0.001
VES O ABS	46	0.932	0.869	<0.001	37	0.864	0.747	<0.001
VES O Delta	46	0.934	0.873	<0.001	37	0.879	0.773	<0.001

32 patients (38%)presented with urinary stress incontinence (USI) .

TABLE 4

Correlation and determination coefficients of “Menezes” of measures and other measures according to presence of USI

	Yes				No			
	n	R	R square	p-value	n	R	R square	p-value
Abd Abs	31	0.855	0.732	<0.001	52	0.929	0.864	<0.001
ABD delta	31	0.805	0.648	0.001	52	0.932	0.868	<0.001
VES O ABS	31	0.837	0.700	<0.001	52	0.914	0.835	<0.001
VES O Delta	31	0.814	0.663	0.001	52	0.917	0.840	<0.001

Interpretation of results

There was good correlation between the device measurements and mainly the abdominal absolute measurement at the urodynamic. Prolapse , presence of USI and presence of BUC did not influence the measurement from the device

Concluding message

This is a new way to measurement the leak point pressure in a non invasive basis , eliminating all the bias from catheters . Also as it is a portable device it could be used at the office and operating room to a more objective definition of exertion . It could even be used to generate a new classification of prolapse with objective pressure data

Specify source of funding or grant	**Laborie Medical Tech**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Hospital Mater Dei**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**