

## ARE THERE ANY DIFFERENCES BETWEEN SALINE AND FLUOROSCOPIC CMG IN MEASURING COUGH LEAK POINT PRESSURE?

### Hypothesis / aims of study

Leak point pressure has been used as a measurement of urethral function by assessing the strength of the urethral sphincter mechanism when the bladder is full. The lowest intravesical pressure at which urine starts to leak during a cough without a detrusor contraction is called the cough leak point pressure (CLPP). The leakage can either be directly visualised during saline CMG or radiologically observed during fluoroscopic CMG.

The correlation between fluoroscopic and direct visualisation of leak point pressure is unknown. This study is intended to determine if there is significant difference in these two test modalities for obtaining CLPP in women with urodynamic stress incontinence.

### Study design, materials and methods

Women were recruited with consent from the urodynamic clinic in a tertiary referral centre whilst undergoing either saline or fluoroscopic cystometrogram (CMG) for their lower urinary tract symptoms. They were diagnosed as having urodynamic stress incontinence (USI) with or without detrusor overactivity on dual channel cystometry at their initial visit. During the same UDS, Cough leak point pressure (CLPP) was obtained at maximum bladder capacity in the standing position. Subjects were asked to perform coughs at different intensities starting from low, gradually increasing until leakage was demonstrated. This was repeated once for confirmation. The coughs were performed with a pause between each so they did not have an effect on each other. The CLPP was noted as the lowest vesical pressure with cough when urinary leakage was demonstrated either on simple visualisation on saline Cystometry or radiologically in fluoroscopic CMG.

Two weeks later the subject underwent saline CMG. Two groups of patients were identified, one having saline CMG on both visits and second group with fluoroscopic CMG one first and saline cystometry on second visit. The Wilcoxon signed rank test was used to compare results within the groups and the Mann-Whitney U test to compare overall difference in each group. Statistical analysis was carried out using the SPSS program version 14.0 (SPSS Inc., Chicago, Illinois, USA).

### Results

Of the 24 subjects who were able to perform CLPP 14 had Saline CMG on both visits and the other 10 fluoroscopic CMG on first visit and saline CMG on the second visit. Wilcoxon signed rank test showed no significant difference between visit 1 and 2 for either of the groups. The mean difference of the saline CMG and the fluoroscopic CMG was very similar, -0.71 and -2.2 respectively. The Mann-Whitney U test of these groups did not show any significance beyond 0.05 level: U=67; exact p=0.874 (two-tailed) (table 1) The final urodynamic diagnosis shown in table 2. There were similar numbers of USI and UMI in each group. The data is summarised and presented as tables and figures.

Table 1: Saline vs Fluoroscopy CMG

CLPP	n	Mean of Average of the two episode	Paired Differences		Wilcoxon Signed Ranks Test (p)*	Mann-Whitney U (p)*
			Mean of Difference (Bias)	Std. Deviation		
Saline CMG Group	14	134.1	-0.71	30.13	0.795	0.874
Fluoroscopic CMG Group	10	143.4	-2.20	18.23	0.674	

\*Exact Signed (2-tailed)

Table 2: The number in each group with their diagnosis.

Groups	Final diagnosis	
	USI	UMI
Saline CMG Group	9	5
Fluoroscopic CMG Group	4	6

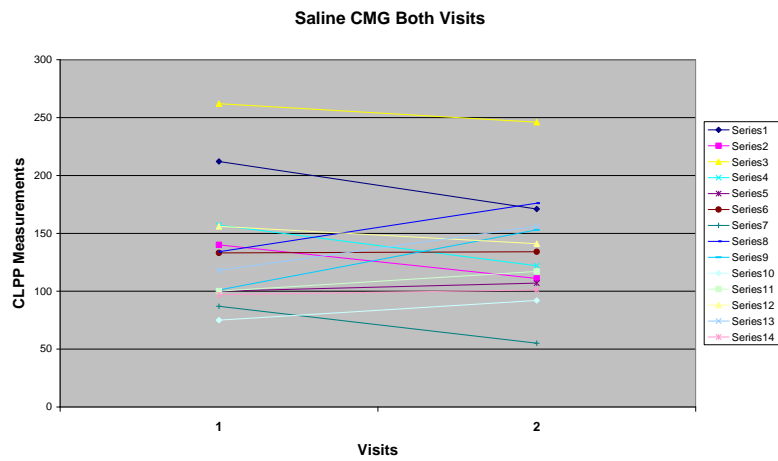


Figure 1: Cough Leak Point Pressure measurements with Saline CMG both visit.

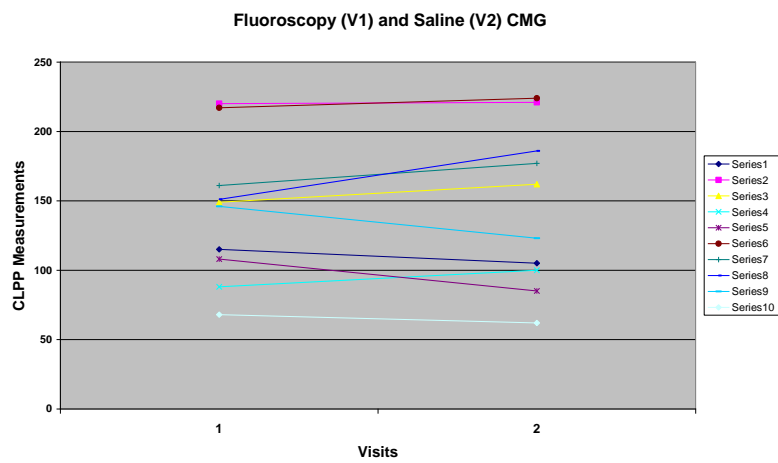


Figure 2 Cough Leak Point Pressure measurements with Fluoroscopic CMG 1<sup>st</sup> visit and Saline CMG 2nd visit.

#### Interpretation of results

The Wilcoxon-signed rank test shows that there is no significant between the two visits in each group. Although, the mean of difference was less in fluoroscopic CMG group, Mann-Whitney test failed to show significance beyond 0.05 level.

#### Concluding message

This is the first known study comparing fluoroscopic and direct visualisation of leak point pressure. The data in this study found no significant difference between the two methods of testing for cough leak point pressure in the same subject.

<b><i>Specify source of funding or grant</i></b>	<b>Pfizer Ltd.</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Research and Development Department</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>