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REPRODUCIBILITY OF COLPO-CYSTODEFECOGRAPHY AND CORRELATIONS TO CLINICAL EXAMINATION

Hypothesis / aims of study

The aim of this study was to determine reproducibility of interpretation of ColpoCystoDefecography (CCD) images and the correlation between clinical and radiological findings for the assessment of pelvic organ prolapse.

Study design, materials and methods

Eligible were consecutive patients reporting to our pelvic floor unit with prolapse. Clinical assessment was done by an experienced gynaecologist and for quantification of prolapse both the Baden Walker staging system and International Continence Society (ICS) Pelvic Organ Prolapse Quantification system (POPQ) were used. CCD was performed as previously described [1]. The clinical assessment could be up to three weeks apart from the CCD. In a second stage, an off-line analysis was done on stored images. All measurements were made by two independent examiners who were blinded to each other's findings and the clinical findings. All CCD's were scored twice, first with a categorical classification system with the hymenal ring as a point of reference at maximal strain. It provides four values, the most distal migrating point of the anterior, central and posterior compartment, but does not provide information on vaginal length or length of the perineal body. The second scoring system provides more comprehensive information, using continuous variables in which eleven points were measured on two selected CCD images (maximal strain and strain at defecation with empty bladder), and most are referenced to the pubo-coccygeal line. Clinical findings were described by the Baden Walker categorical staging systems and using POP-Q system for continuous variables.

We first assessed the *inter-observer agreement* between a senior and junior assessor. Further we determined the *agreement between clinical and radiological* findings. Statistical analysis was done with JMP®7.0 (SAS Institute Inc, Heverlee, Belgium). Inter-observer agreements were done with contingency tables and presented as Kappa levels of agreement. Correlations between clinical and radiological staging are shown as Spearman correlations coefficients. Bi-variate linear fits with Pearson pair-wise correlations followed by Bland Altman analysis of matched pairs to assess the possible bias between two methods were used for correlations of POPQ and CCD exact measurements. Because of the multiple correlations, a $p<0.01$ was considered as significant. For both Spearman and Pearson correlations we assumed that a ρ coefficient between 0-0.3 indicated no correlation; 0.3-0.5 a weak correlation; 0.5-0.7 strong and 0.7-1.0 very strong correlation between different examiners.

Results

Forty nine women (mean age 63.8 years; range 47–79 years) were enrolled. *Inter-observer* agreements between senior and junior assessors, using a *staged classification* system were in general very good. The correlation for different compartments by the two operators ranged from 0.66 to 0.87. We did not find any absolute disagreement (i.e. for three stages) between assessors for any of the comparisons for different scoring points. For the description with *continuous variables*, the agreement between assessors was good with very strong correlations in the anterior and central compartment, e.g. bladder neck, most distal part of the bladder and position of vaginal top (0.83, 0.93 and 0.90 respectively). A strong correlation was found for the position of the anorectal junction (0.65) and very strong for detection of rectocele (0.86) and enterocele (0.90), but a weak correlation for the position of the most distal posterior vaginal wall (0.46). Correlations for vaginal length and perineal body were 0.54 and 0.31 respectively.

The *categorical* clinical and radiologic staging findings were strongly correlated for the anterior compartment (0.63), while no correlation was found for the central and posterior compartments. When findings were expressed with *continuous* variables, the agreements between specific POP-Q clinical points and the correlating points on CCD images were in general poor. The best correlations were found for bladder descent (0.44) and extent of enterocele (0.41). No correlation was found for the position of the bladder neck, the anorectal junction (irrespective of bladder filling), and the measurements of perineal body and vaginal length. Bland Altman analysis of the findings using continuous variables revealed for example a bias for anterior, posterior compartment and enterocele of 1.1cm, 3.6cm resp. 2.4cm.

Interpretation of results

CCD is currently the standard imaging technique, and often used for the assessment of posterior compartment prolapse. The technique is bothersome and not highly appreciated by the patients as it requires contrast administration into different hollow organs, and they may feel inhibited when they are asked to strain, void and defecate while this "functional" imaging is performed. There is neither a generally accepted classification system of findings. Furthermore, compared to the clinical examination, CCD overestimates the posterior compartment descent [2]. For these reasons we investigated several possibilities for interpretation of the CCD results in attempt to recognize and define the objective value of the method in daily clinical practice.

First, there was a comparable and good agreement for both ways our assessor's describing CCD findings. Also, assessors reported that it was more difficult to read CCD images using the categorical classification system. The correlation between clinical and radiologic examinations was in general poor, irrespective of the quantification system used. Best agreements were for the most distal anterior vaginal wall. For quantifying the degree of enterocele there was no good correlation for the categorical classification. Conversely this was better when using continuous variables. Apart from the above, reference lines for CCD and clinical assessment are not the same. The way to overcome this problem is to determine the "bias", which can serve as a correction factor. We identified these in our study, but this obviously means one has to use continuous variables.

Concluding message

Reading colpocystodefecograms is reproducible, using both reporting systems. Using continuous variables has several advantages such as comprehensiveness, precision, and the potential for correction when correlating to clinical measurement.

However it is more time-consuming. The leading problem is that CCD findings were discrepant from clinical findings, with the best, but still relatively poor, correlations for anterior compartment descent and the extent of enterocele. Perhaps this could be optimized by defining better reference points or lines, a better understanding between clinicians and radiologists what to score for. At this moment, our study points to the many questions about the benefit of medical imaging techniques in clinical practice. A study like this cannot determine the ultimate value of CCD in a clinical setting, as it would involve looking at outcomes following interventions for the clinical problem. Any such study would require prior agreement on standardization of reading, and agree on what is the gold standard. Given the invasiveness of CCD, it might be worth while exploring other imaging techniques such as ultrasound, in a research setting.

Table 1: Specific points used for correlations between clinical and CCD examination

image:	CCD	POPQ	ρ	Bias (cm)	p value
Full bladder	bladder neck	Aa	0.26	1.9	<0.0001
	most distal anterior wall	Ba	0.44	1.1	0.02
	vagina top	C	0.32	0.3	0.61
	anorectal junction	Bp	-0.05	0.6	0.13
	vaginal length	TVL	-0.16	0.6	0.35
	perineal body	Pb	0.29	0.7	0.019
	rectocele	Bp	0.33	0.02	0.95
Empty bladder	vagina top	C	0.28	0.6	0.21
	most distal posterior wall	Bp	0.34	3.6	<0.0001
	enterocele	Bp	0.41	2.4	<0.0001
	anorectal junction	Bp	0.01	1	0.006

References

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Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Retrospective audit study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**