726

Zyczynski H[1], Tincello D[2], Gauld J[3], Hinoul P[3], Carey M[4]
1. *Magee-Womens Hospital of the University of Pittsburgh Medical Center, Pittsburg, PA,* ***2.*** *University of Leicester, Leicester, UK,* ***3.*** *Ethicon,* ***4.*** *Royal Women's Hospital, Melbourne, Australia*

A PROPOSAL TO CHARACTERIZE THE MID-VAGINA IN POP-Q.

Hypothesis / aims of study

To demonstrate the inability of the current POP-Q scoring system[1] to describe support of the mid anterior and mid posterior vagina in subjects who have undergone surgical repair of prolapse.

Study design, materials and methods

Women with symptomatic prolapse (POP-Q Stage II-III) were enrolled in this prospective, international, multicenter trial of a trocar-free vaginal pelvic floor repair utilizing a polypropylene mesh (GYNECARE PROSIMA™ Pelvic Floor Repair System, Ethicon, Somerville, NJ). The mesh was inserted into the vesicovaginal and / or rectovaginal planes and extended without fixation over the obturator internus muscles and bilateral sacrospinous ligaments, respectively. The repair was stabilized with a vaginal support device (VSD) for 3 to 4 weeks during initial tissue in-growth. The protocol did not proscribe stabilization of a mobile urethra, stress urinary incontinence or laxity of the genital hiatus in otherwise asymptomatic women. The primary outcome was defined as anatomic success Stage ≤ I, after 12 months, according to the POP-Q scoring system. All investigators were experienced in performing the POP-Q exam and participated in a standardized training session.

At the 6 months interim analysis, we identified that the POP-Q scoring system did not have the ability to discriminate and describe mid vagina support in the presence of compromised distal vaginal support.

For that reason, as a pilot project, the study protocol was modified to assess 2 supplementary points on the vaginal walls that are not standard components of the POP-Q scoring system: point Ma on the midanterior vaginal wall and point Mp on the midposterior vaginal wall. The points M were recorded during a POP-Q exam performed in the dorsal lithotomy position, with women reclined at 45º angle, during maximum straining, with verbal confirmation that the maximum extent of prolapse had been achieved as originally proscribed. Points M were defined as:

- **Ma**, a *fixed point* in the midline of the anterior vaginal wall *5cm* above the external urethral meatus.
- **Mp**, a *fixed point* in the midline of the posterior vaginal wall *5cm* above the plane of the hymenal remnant.

Results

136 women were included, with mean age of 64.3 years (SD 10.5) and mean BMI 28.4 (5.0). At baseline 53.7% were Stage II and 46.3% Stage III; one year postoperatively, 102 (76.7%) of women had POP-Q stage ≤ I, and the leading edge of the vaginal wall was at ≥ 1cm above the hymen in 113 (88.3%) of subjects. Based upon a Patient Global Impression of Change (PGI-C), 73.3% patients reported they were “much better” and an additional 15.3% “a little better” at 1 year. The full results of all outcome parameters regarding this study are reported elsewhere.

Table 1 lists the POP-Q measures from subjects meeting our study criteria for anatomic failure: stage II defined as the leading edge between 1cm proximal and 1cm distal to the level of the hymen. Data for 3 anterior and 1 posterior failures at stage II are missing, as one centre did not record these additional points. The means for point Aa in successful repairs (Stage ≤I) were -2.4 cm (SD 0.5) and -0.6 cm (1.1) in women at Stage II prolapse. Similarly for point Ap the mean scores in successful repairs (Stage ≤I) and failures (Stage II) were -2.8 (0.4) and -2.0 (1.0), respectively.

Interpretation of results

In our study of subjects with stage II prolapse one year after surgery, the mean point Aa score of -0.6 suggests that unaddressed urethroceles or urethral hypermobility provided criteria for the anatomic failures. Points B are co-linear with points A in situations often seen after apical prolapse repair when a distal repair such as perineorrhaphy or urethropexy is not indicated. The current parameters of the POP-Q system permit persistent urethral mobility or relaxation of the genital hiatus to determine the assignment of ordinal staging in some of the cases described above. The inability to describe the position of the mid anterior and posterior vaginal walls is a limitation of POP-Q when studying surgical prolapse interventions. In order to address these limitations we proposed 2 additional measures termed points Ma and Mp.

We recognize that prolapse beyond the hymen is associated with increased pelvic symptoms[2] and should be characterized as a failed outcome after intervention. We propose that M measures be used to assign “stage” of midvaginal prolapse as follows:

Stage 0: -5cm; Stage I: ≤-2cm; Stage II: > -2cm to ≤ 0; Stage III: >0 to <+2cm; Stage IV: complete eversion of the total length of the lower genital tract.

These values take into consideration the definition of points A. As can be derived from table 1, only 4 of the repairs in these 22 patients seem to fail in providing midvaginal support (3 anterior, 1 posterior). When we consider a successful pelvic floor repair as the leading edge (Ba/Bp) ≤0 providing that there is also adequate midvaginal support (Ma/Mp) ≤-2 we would reassign 14 subjects as meeting success criteria and characterize 8 of 22 “stage II’ subjects as true anatomic failures at 1 year after surgery. This could possibly explain the discrepancy between the objective success rate of only 76.7% and the subjective improvement rate in 93.7% of the patients.

Concluding message

We believe that this pilot clinical assessment of 2 points (Ma and Mp), to objectively quantify the position of the midvagina, demonstrates their possible added value to the current POP-Q system. Further debate will weight the benefit of supplementing or substituting points M for B in the POPQ exam. A prospective validation of these midvaginal points and their reliability (e.g. reproducibility of point M results) are required before their use can be recommended.

Table 1: POP-Q points B and M from subjects with Stage II Prolapse*

	Leading edge: Ba/Bp	Point Ma	Point Mp
Anterior Prosima	1	-3	n.a.
	1	-4	

	0	-2	
	-0.5	-2	
	-1	-3	
	-1	-2	
	-1	-3	
Posterior Prosima	0.5	n.a.	-5
	-0.5		-3
	-1		-4
Combined Prosima	1	-1	-4
	0.5	0	-4
	0.5	-2	-4.5
	0	-2	-5
	0	-4	0
	0	-3	-4
	0	0	-5
	0	-2	-4.5
	-0.5	-2.5	-4.5
	-1	-4	-4
	-1	-3	-5
	-1	-4.5	-3.5

*: data on 4 stage 2 failures missing, n.a.: not applicable

References

1. Bump R, et al. Am J Obstet Gynecol 1996;175:10-7
2. Swift S, et al. Am J Obstet Gynecol 2003;189:372-9

Specify source of funding or grant	**This study was fully sponsored by Ethicon.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov; NCT00521066**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Cambridgeshire 1 Research Ethics Committee; Ethics Commission Universitätsklinikum Tübingen; Ethics Committee, Martin-Luther University, Halle; The Research and Ethics Committee, The Royal Women's Hospital, Melbourne; St. Luke's Hospital IRB, Allentown, PA;Oakwood Hospital IRB, Dearborn, MI; Spectrum Health IRB, Grand Rapids, MI; University of Pittsburgh Medical Center/Magee Women's Hospital IRB, Pittsburgh, PA; Western Institutional Review Board (Central IRB)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**