

## PDF hosted at the Radboud Repository of the Radboud University Nijmegen

The following full text is a publisher's version.

For additional information about this publication click this link.

<http://hdl.handle.net/2066/109642>

Please be advised that this information was generated on 2020-09-29 and may be subject to change.

## Surgery for cystocele I—questions

Mariella Withagen · Alfredo Milani · Mark Vierhout · Mickey Karram

Received: 1 December 2011 / Accepted: 6 December 2011 / Published online: 27 January 2012  
© The Author(s) 2012. This article is published with open access at Springerlink.com

In May 2011, an important article on the surgical correction of cystocele was published in the *New England Journal of Medicine*: “Anterior colporrhaphy versus transvaginal mesh for pelvic organ prolapse” [1]. In this multicenter randomized controlled trial, the use of a trocar-guided, transvaginal polypropylene-mesh repair kit was compared with traditional colporrhaphy in 389 women with prolapse of the anterior vaginal wall. The primary outcome was a composite of objective anatomical pelvic organ prolapse (POP) stage 0 or I [2] and the subjective absence of symptoms of vaginal bulging 12 months after surgery. As compared with anterior colporrhaphy, use of a standardized, trocar-guided mesh kit for cystocele repair resulted in higher (60.8% versus 34.5%) short-term rates of successful treatment. Surgical reintervention to correct mesh exposure during follow-up occurred in 3.2% of patients in the mesh-repair group.

---

Further articles in this debate can be found at DOI [10.1007/s00192-011-1626-6](https://doi.org/10.1007/s00192-011-1626-6) and DOI [10.1007/s00192-011-1627-5](https://doi.org/10.1007/s00192-011-1627-5).

---

M. Withagen (✉) · M. Vierhout  
Department of Obstetrics and Gynaecology,  
Radboud University Nijmegen Medical Centre,  
Huispost 791, Route 791, PO Box 9101, 6500 HB, Nijmegen,  
the Netherlands  
e-mail: m.withagen@obgyn.umcn.nl

A. Milani  
Department of Obstetrics and Gynaecology,  
Reinier de Graaf Group,  
Delft, the Netherlands

M. Karram  
Division of Urogynecology,  
The Christ Hospital & University of Cincinnati,  
Cincinnati, Ohio, USA

We congratulate the authors on publishing a multicenter randomized trial on a very controversial subject using internationally accepted validated outcome instruments. However, we have the following concerns about the study set-up and the way the data were presented.

For anatomic outcomes the authors used the POP-Q system which clearly states:

“Point Aa: a point located in the midline of the anterior vaginal wall 3 cm proximal to the external urethral meatus, corresponding to the approximate location of the ‘urethrovesical crease,’ a visible landmark of variable prominence that is obliterated in many patients. By definition, the range of position of point Aa relative to the hymen is  $-3$  to  $+3$  cm.

Point Ba: a point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to point Aa. By definition, point Ba is at  $-3$  cm in the absence of prolapse and would have a positive value equal to the position of the cuff in women with total post hysterectomy vaginal eversion”.<sup>2</sup>

The authors present POP-Q values as median with ranges in Table 1 in the Supplementary Appendix (original version, before 23th of June). Ranges for point Aa vary from  $-4$  to  $5$ , which, as noted above, is, by definition, not possible. The same applies to values of point Ba which range from  $-8$  to  $7$ . Also, the authors state a value for point D of  $-13$  which is also not possible, since the maximal tvl (total vaginal length) in the same table is  $12$ . This would seem to indicate that the POP-Q measurements were not performed according to ICS standards. Since there are 21 ‘non-existing’ values in Table 1 (of the Supplementary Appendix), we

have serious doubts about the anatomic outcomes the authors' report.

Apparently, the authors updated the Appendix on June 23, and a number of incorrect values were omitted in Table 1B. They state that “the incorrect values were omitted before final analysis, while treatment assignment was still blinded.” We wonder how many data or cases exactly were excluded as no numbers are given in the table for crude or corrected data. Furthermore, there is no recognition in the flow chart (Fig. 1) of these patients that have been excluded at this point.

The surgical procedure the patients received was either an anterior tension-free vaginal mesh or an anterior colporrhaphy. No concomitant surgery was permitted. How did the specific study sites counsel their patients regarding the fact that a portion of their prolapse would not be addressed, as in patients in which the descending point of the posterior wall was 4 cm beyond the hymen (Bp=4, Table 1 Supplementary Appendix) or if the cervix or vaginal apex was 4 or 6 cm beyond the hymen (C=4 and D=6, Table 1 Supplementary Appendix). Are we to assume that these segments of the pelvic floor were ignored even though the prolapse extended well beyond the hymen?

Finally, we were surprised that the authors only reported on surgical reinterventions for mesh exposure (3.2%) and did not report the total number of mesh exposures. Mesh exposure is the most significant complication of transvaginal mesh surgery for pelvic organ prolapse. The total percentage of mesh exposure is presented by virtually all

comparable papers and not presenting these data makes comparison of this study with previous literature impossible. Furthermore, only reporting on reinterventions of mesh exposure is subject to considerable bias. The optimal indications and timing of reintervention is ultimately the decision of the individual surgeon, thus, potential bias such as not to reintervene or to delay the reintervention until after the study period is a real possibility.

**Conflicts of interest** Milani has a consultancy agreement with Ethicon Women's Health & Urology. Withagen, Vierhout and Milani are on the Speaker's Bureau of Ethicon WH&U. Withagen and Vierhout received an unrestricted educational grant from Ethicon WH&U. Karram is on the Speaker's Bureau of Ethicon WH&U and American Medical Systems.

**Open Access** This article is distributed under the terms of the Creative Commons Attribution Noncommercial License which permits any noncommercial use, distribution, and reproduction in any medium, provided the original author(s) and source are credited.

## References

1. Altman D, Väyrynen T, Ellström Engh M (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. *N Engl J Med* 361:1826–36
2. Bump RC, Mattiasson A, Bo K et al (1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 175:10–17