

Comment on Schiøtz et al.: Ten-year follow-up after conservative treatment of stress urinary incontinence

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It is with great surprise that we have read Schiøtz et al.'s article [1] with 10-year follow-up of some of the participants in our randomized controlled trial [2]. There are major concerns about this study:

1. The original data belonged to the project leader and her institution as contracted by the Norwegian Research Council, The Data Inspectorate and Regional Ethics Committee. No permission was given to store data after the project period. Schiøtz was, among five urologists/gynecologists, paid to recruit and assess patients in this multicenter study, and was not part of the project group.
2. Schiøtz et al. have reported 10-year follow-up data on only 35 of 107 participants coming from one site only. In his application for ethics approval, the author he claimed to have had 54 participants. However, in the published paper he has left out 19 women.
3. Of the 33 women who were originally in the different groups, Schiøtz et al. do not report how many were originally cured and how many of them were long-term responders. In the original study, PFMT was the only group that showed significant effect over the control group, and PFMT was significantly more effective than electrical stimulation and vaginal cones in a variety of outcome measures. Hence, long-term results from the

different groups should be reported separately. Since they have only 33 patients altogether, they can at most have 8 from the original PFMT group in their study.

4. Schiøtz et al. claim that all patients had intensive PFMT after cessation of the RCT. "Intensive PFMT" in our project was defined as individual assessment and motivation once a month with a physical therapist, 3×8–12 PFM contractions per day, and participation in a weekly exercise class led by a physical therapist for 6 months. Schiøtz et al. provide no data on how many had 6 months of "intensive training" or to what degree the women who had already been in either the control, electrical stimulation, or cone group adhered to such a training course. On the contrary, they report that only 18 of 33 women continued to use any form of "conservative treatment".
5. There may well be selection bias to surgery. Interestingly, given the limitations of the underpowered study, Schiøtz's findings support our previously reported 10-year follow-up of another RCT, showing no difference in quality of life between those who had surgery and those who did not [3].

References

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