

## Title

Stress urinary incontinence treatment—surgery first?

## Authors

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## Standfirst

A randomized trial involving 460 women with stress urinary incontinence compared physiotherapy with mid-urethral-sling surgery. We question whether the results, showing higher rates of improvement and cure for surgery than for physiotherapy, should change best practice and clinical practice guideline recommendations.

## Text

Labrie *et al.*<sup>1</sup> conducted a randomized controlled trial (RCT) comparing pelvic-floor muscle training (PFMT) with mid-urethral-sling surgery using sub-urethral tape for treatment of stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) in which SUI predominates. 230 women were assigned to each treatment group, and outcomes were assessed 12 months after the onset of treatment. As the primary endpoint, subjective improvement was reported by 90.8% of women with initial surgical treatment, and by 64.4% of the physiotherapy group. Higher rates of subjective cure (85.2% versus 53.4%) and objective cure (76.5% versus 58.8%) were also seen for initial surgery compared with physiotherapy. Labrie *et al.* used a posthoc per-protocol analysis to address crossover between treatment groups, finding similar outcomes in women initially assigned to surgery and with crossover to surgery.”]

Most guidelines recommend PFMT as the first-line treatment for SUI.<sup>2-4</sup> However, both PFMT and sub-urethral tape have been shown to be efficient in the treatment of SUI and MUI, although previously these two interventions had not been directly compared. Results from the trial conducted by Labrie *et al.*<sup>1</sup> indicate a higher rate of both subjective and objective improvements in the mid-urethral-sling surgery group at 1 year. The question therefore arises of whether the results of this study should be used to change best practice and clinical practice guideline recommendations.

Notwithstanding the results, we have some concerns about the application of clinical equipoise in the trial. Before a trial begins, there should exist no decisive evidence that the intervention being tested (in this case, surgery) will be superior to an existing conventional intervention (PFMT) in the identified time period (here, 1 year after the onset of treatment). However, as an RCT progresses, the findings may provide sufficient evidence to convince the investigators of the superiority of one intervention over another. Once this threshold of evidence is passed and there is no longer genuine uncertainty about which treatment is most beneficial, then there is an ethical imperative for the investigator to provide the superior intervention to all participants.

Participants in the study by Labrie *et al.*<sup>1</sup> were allowed to cross over from physiotherapy to surgery before either had been definitively identified as being superior. The crossover rate was particularly high (almost 50%), which makes us wonder if the women included in the physiotherapy group received a real and comprehensive attempt at physiotherapy treatment before being allowed to cross over. According to the results, the women in the physiotherapy group seem to have crossed over at a very early stage, on average after only  $7.4 \pm 4.4$  treatment sessions. This period of time is extremely short and is inadequate in terms of maximizing the effect of PFMT, as it is not considered long enough to address muscle hypertrophy,<sup>5</sup> and it is shorter than the effective PFMT duration as recommended in a Cochrane review on PFMT.<sup>6</sup> Moreover, allowing women to cross over too early could ultimately have undermined both the individuals' commitment levels and their internal belief systems. A belief in one's ability to achieve or attain a result, such as a cure, can negatively or positively affect a person's actual ability. Self-efficacy has been identified as a strong predictor of PFMT effectiveness.<sup>7,8</sup> It is also unclear whether the women were taught how PFMT works, were informed of the required commitment it entailed, or were apprised as to what point during the treatment they could expect to see improvement (after how many treatment sessions or weeks of exercise). Thus, it is possible that women crossed over to the surgical intervention because they did not have enough knowledge about how PFMT works, and this might have ultimately biased the results of this study.<sup>1</sup>

The authors recorded short-term adverse events, all of which were associated with surgical treatment. A more detailed description and exploration of the short-term and long-term consequences of surgery would have been useful, including factors such as individual costs to the patient (such as work days lost and losses to physical and social mobility that are crucial to quality of life and continued health) and costs to the health-care system (such as complications and ensuing medical interventions, costs of re-operating or providing corrective surgery, and resource implication).

The results of Labrie *et al.*<sup>1</sup> suggest that PFMT might not be as effective as a surgical option in all women with SUI or MUI. However, we need to be able to identify which women are better-served by physiotherapy and which are better-served by surgery as an initial intervention. For example, type of urinary incontinence, circumstances of leakage, severity of urinary incontinence, or pelvic floor morphological deficits or dysfunction might be predictors of the likelihood of successful treatment and therefore serve to clarify the respective indications of physiotherapy and surgery.<sup>9,10</sup> We would therefore recommend that future studies include parameters that would enable identification and reporting of the predictors of effectiveness of PFMT or surgery. Further, the cost of each intervention must also inform recommendations as to the best treatment option, specifically with regard to financially overburdened medical health-care systems and the cost to uninsured women in countries where adequate health-care coverage (private or public) is problematic. Otherwise, patients could be directed to the more

expensive and invasive surgical option when conservative PFMT interventions are just as effective.

National and international clinical practice guidelines recommend physiotherapy as a first-line treatment to SUI. The results of this study alone should not change present clinical practice. More studies are needed comparing these two interventions in respect to cost-effectiveness are needed. Women should be given informed choices supported by evidence for both treatment options.

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### Competing interests

The authors declare no competing interests.

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