Stress urinary incontinence with emphasis on bulking agents

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Impact paragraph
This thesis describes research that was performed after treatment of involuntary leakage of urine or “incontinence” in women. The type of incontinence treated was stress urinary incontinence, which means that leakage of urine happens during moments high abdominal pressure, such as physical exertion, sneezing or coughing.

Different treatments of this condition are mentioned in this thesis, but the most important subject of my research were urethral bulking agents. Urethral bulking agents are substances that are injected near the urethra, to cure stress urinary incontinence. The bulking agent VDPDMS (Urolastic®) had our special interest, because it was newly introduced and had different properties compared to other bulking agents. After injection it becomes a solid implant, whereas other bulking agents become more or less a gel or paste.

Aim of this thesis was to assess the clinical effect and safety of this new procedure, to compare this treatment to other treatments and to other bulking agents and to look at the potential working mechanism. The working mechanism is thought to be based on compression of the urethra from the outside, leading to a higher pressure and resistance to urine flow.

With respect to the clinical effect, we found that after median 12 months follow-up, 85.3% of women treated in a general hospital reported improvement of their symptoms. In a group of largely secondary patients, 76.2% reported improvement. The cure rate was lower and the effect on incontinence gradually declined over time.

We experienced that the procedure with bulking agents was very effective in some patients, but failing in others. A better understanding of the mechanism behind stress urinary incontinence was important to find out more about how bulking agents (and thus VDPDMS) work and more importantly why procedures fail. This was investigated by reviewing the available literature on the pathophysiology of incontinence. By combining existing theories, it was concluded that support of the middle of the urethra was most important in maintaining continence, because it facilitates a reflex closure of the urethra. This conclusion is relevant, because this means that VDPDMS injected around the middle of the urethra, theoretically has the best chance to enhance reflex closure of the urethra. More research is needed to find out whether this is indeed the case.

If a procedure fails, the reason might be that he implants are not positioned at the intended place, around the middle of the urethra. To investigate where the injected material ends up after injection, a study was performed in 20 women with a CT-scan after the procedure. This showed that the material is clearly visible on the scans. The position of the implants is highly variable. The study was too small to draw conclusion about the relation between the position of the implants and clinical success.
From a review of the literature, we learned that bulking agents have a good safety profile, with low risk of severe complications. Our clinical study and literature showed that VDPDMS has a significant chance of complications. The solid implants cause pain in up to 15% of the patients. Erosion or exposure can occur in up to 25% of the patients, but does not always lead to complaints. In 8-26% of women treated, (partial) removal of the implants is necessary, but recurrence of SUI is in that case not imminent.

The results of this thesis are most interesting for patients suffering from stress urinary incontinence. More is now known about the risks and expected effect of VDPDMS as a treatment for this bothersome condition and this might make (shared) clinical decision making easier.