

# **Evaluation of surgical methods for treatment of female stress urinary incontinence**

## **Akademisk avhandling**

Som för avläggande av medicine doktorexamen vid Göteborgs Universitet kommer  
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av

**Maud Ankardal**  
Leg. Läkare

Fakultetsopponent  
Docent Margareta Hammarström  
Institutionen för kvinnors och barns hälsa, Karolinska Institutet  
Kvinnokliniken, Södersjukhuset, Stockholm

Avhandlingen baseras på följande delarbeten:

- I. **A randomised trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence.**  
Ankardal M, Ekerydh A, Crafoord K, Milsom I, Stjerndahl J-H, Ellström Engh M.  
BJOG. 2004 Sep;111(9):974-81.
- II. **A three-armed randomised trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using sutures and laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence.**  
Ankardal M, Milsom I, Stjerndahl J-H, Ellström Engh M.  
Acta Obstet Gynecol Scand. 2005;84(8):773-779.
- III. **Short and long term results of the tension-free vaginal tape procedure in the treatment of female urinary incontinence.**  
Ankardal M, Heiwall B, Lausten Thomsen N, Carnelid J, Milsom I.  
Submitted
- IV. **Comparison of health care costs for open Burch colposuspension, laparoscopic colposuspension and tension-free vaginal tape in the treatment of female urinary incontinence.**  
Ankardal M, Järbrink K, Milsom I, Heiwall B, Lausten Thomsen N, Ellström Engh M.  
Submitted

## Evaluation of surgical methods for treatment of female stress urinary incontinence

Maud Ankardal, MD, Department of Obstetrics and Gynecology  
Sahlgrenska Academy at Göteborg University, Göteborg, Sweden

**Aims:** *Paper I & II:* To compare the subjective and objective results of open Burch colposuspension and laparoscopic colposuspension using sutures or mesh and staples in randomised trials. *Paper III:* To assess the short and long term results of the Tension-free Vaginal Tape (TVT)-procedure in a large observational study and to identify factors predictive of successful outcome. *Paper IV:* To compare direct health care costs for incontinence surgery in Sweden using four different surgical procedures and to relate health care costs to subjective cure thus creating a simple cost effectiveness ratio.

**Patients and methods:** *Papers I & II:* Women with stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) with a predominant stress component were included. *Paper I:* Multicenter Randomised Controlled Trial comparing open Burch colposuspension (n = 120) to laparoscopic colposuspension with mesh and staples (n = 120). *Paper II:* Three-armed Randomised Trial comparing open Burch colposuspension (n = 79), laparoscopic colposuspension using sutures (n = 53) and laparoscopic colposuspension using mesh and staples (n = 79). *Papers I & II* Evaluation one year after surgery included subjective cure, quality of life assessed by a visual analogue scale, leakage in a 48-hour pad-test and in *Paper II* a standardised stress test. *Paper III:* Prospective observational trial of 707 consecutive women with SUI (n = 396) or MUI (n = 311) treated with the TVT-procedure. Subjective cure after 1, 2 and 5 years was evaluated by a postal questionnaire. A sub-sample of 59 women was objectively evaluated 5 years after surgery. Factors influencing the cure rate were analysed using a stepwise multiple regression analysis. *Paper IV:* A model was constructed representing a hospital with standardised surgical equipment, staff and average unit costs in 2003 value. Clinical data collected from the studies in Paper I, II and III and hospital cost data were put into the model to create the different cost elements.

**Results:** *Paper I & II:* Objective cure 1 year after surgery was higher after open colposuspension and laparoscopic suspension using sutures compared to laparoscopic colposuspension using mesh and staples. Subjective findings were in concordance with the objective results. Performing an open colposuspension was less time consuming than performing a laparoscopic colposuspension but resulted in more blood loss than both the laparoscopic methods. Patients in the laparoscopic colposuspension group using mesh and staples had a shorter duration of catheter use and hospital stay. *Paper III:* Subjective cure rate was 83% after 1 year and 73% after 5 years. Objective cure rate was 83% in the subgroup after 5 years. In patients with MUI the cure rate was lower than in patients with SUI (after 5 years 55% vs 81%). Type of incontinence was the only independent variable found to influence surgical outcome. *Paper IV:* The total cost per individual, showed a lower cost for TVT compared to the other three methods. The direct costs for a TVT were only 56% of the costs for an open colposuspension and 59% of the costs for a laparoscopic colposuspension using sutures. The TVT procedure was more cost-effective, in costs per subjectively cured patient, compared to all other three methods.

**Conclusions:** Open colposuspension had a higher objective and subjective cure rate 1 year after surgery, but with a greater blood loss, greater risk of urinary retention and a longer hospital stay than laparoscopic colposuspension using mesh and staples. The use of sutures, irrespective of whether the surgical approach was laparoscopic or open surgery, was superior to the laparoscopic mesh and staples technique. The TVT-procedure, performed in over 700 women at a single unit, was found to be safe and efficient. Type of incontinence was the only independent variable found to predict for outcome of surgery. When using an economic model and comparing health care costs for surgical treatment of female stress urinary incontinence in Sweden, the TVT-procedure generated a lower direct cost and cost per subjectively cured patient.

**Keywords:** *urinary incontinence, female, surgery, colposuspension, laparoscopic, laparoscopy, tension-free vaginal tape, stress urinary incontinence, mixed urinary incontinence, quality of life, long term results, health care costs, cost analyses, health priorities, vaginal surgery, Sweden*