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## **SURGERY FOR CONCOMITANT PELVIC ORGAN PROLAPSE AND URINARY STRESS INCONTINENCE.**

### **A MULTICENTER PROSPECTIVE RANDOMIZED TRIAL TO COMPARE THE RESULTS OF AN INCONTINENCE PROCEDURE PERFORMED AT THE TIME OF PROLAPSE REPAIR OR 3 MONTHS AFTER.**

#### Hypothesis / aims of study

Stress urinary incontinence (SUI) is often present in women with pelvic organ prolapse (POP). No consensus exists to the surgical management of these women. We wanted to compare the result of an incontinence procedure performed at the time of prolapse repair and the same procedure performed 3 months after the surgery for prolapse.

#### Study design, materials and methods

Women suffering from both POP and SUI were randomized to have the incontinence procedure (TVT (Tension-free Vaginal Tape from Johnsen and Johnsen)<sup>TM</sup>) simultaneously with the prolapse repair (group I) or 3 months later (group II). All women had the symptom and sign of SUI. Women in group II were evaluated after the prolapse repair to see whether SUI was still present. All women were also evaluated one year after the last surgery for the presence of SUI. All kinds of prolapse surgery were included but no dissection was done under the urethra and no Kelly plication performed. We were interested in a difference greater than 20% in order to demonstrate a clinically important difference between the groups. Power calculations indicated that 140 women (70 in each group) were needed to have a power of 80%. Major endpoint was frequency of postoperative SUI (defined as any leakage on a stress test). Secondary endpoints were preoperative grade and type of prolapse and components of POPQ score in cured compared to not cured patients.

#### Results

Ninetyfive were randomized to group I and 99 to group II, 8 and 5 were lost to follow-up respectively, leaving 87 in group I and 94 in group II for intention to treat analysis. But 3 months after prolapse surgery, 27 in group II were continent and therefore no TVT was performed, another 14 had a minimal leakage and did not want a TVT, leaving 87 and 53 for on treatment analysis. This resulted in a power of 75% in finding at least 20% difference between the groups. No differences were found in demographic variables (age, parity weight previous surgery, use of estrogens and general health) between the two groups. We found no difference in grade of prolapse, type of prolapse or procedure performed between the two randomization groups nor any differences in the POPQ scores. Only the severity of leakage (gram of leakage performing a stress test) turned out to be different preoperatively in the two groups (mean 35g (0-200) in group I and 67g (2-270) in group II,  $p=0.003$ ). In group I 95% (83/87) were cured from SUI compared to 89% (47/53) in group II ( $p=0.2$ ). In an intention to treat analysis the result was still 95% cure in group I and 77% (72/94) in group II ( $p=0.0003$ ). Sixty-nine % of cured women had a predominantly anterior or midcompartment prolapse and 80% of those not cured ( $p=0.5$ ). Large prolapses (grade III and IV) were found in 43% of those cured and 50% of those with remaining SUI ( $p=0.5$ ). There was no difference in type of prolapsed procedures performed.

#### Interpretation of results

We were interested in a difference of 20% in cure of SUI in order to choose one of the treatment strategies for women presenting with combined POP and SUI. No difference was found between the groups if a TVT was performed concomitantly or 3 months after the prolapsed procedure. Even on intention to treat analysis that included 14 women in group II that were known to have SUI after the prolapse surgery but declined incontinence surgery as planned, the difference between the groups did not reach 20%. The fact that women in group II had more severe incontinence could explain a slightly poorer result in group II. No clinical variable in the preoperative evaluation seems to influence the results.

#### Concluding message

The result of TVT as an incontinence procedure in women with both POP and SUI give the same good result regardless of being performed simultaneously with the prolapse surgery or 3 month later. As much as 29% of women were cured from SUI after only prolapse surgery and after one year 27% were still continent.

These results should be useful to counsel women with both POP and SUI prior to surgery on the possibility of different treatment strategies

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<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	Clinical Trials.gov NCT 00308009
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Regional Committee for Medical Research Ethics, Eastern Norway
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes