

ONE DAY VERSUS THREE DAY SUPRAPUBIC CATHETERISATION AFTER VAGINAL PROLAPSE SURGERY: A RANDOMIZED CONTROLLED TRIAL.

Hypothesis / aims of study

After vaginal prolapse surgery with anterior colporrhaphy catheterisation of the bladder is common for at least three days. Optimal duration and benefit of this prolonged catheterisation is still unknown. We hypothesize that results of prolonged catheterisation after surgery for only one day or three days are equal.

Study design, materials and methods

All patients undergoing vaginal prolapse surgery with anterior colporrhaphy received a suprapubic catheter and were randomized in two groups. One group starts so called bladder training (clamping of the catheter) on day one after surgery, the other group on day three. Removal of the catheter occurs after successful training defined as twice a post-voiding residual volume of less than 100 ml. Length of catheterisation, completed training within 48 hours, urinary tract infection and duration of hospitalisation were evaluated. With a significance of 0.05 and a power of 80.4% the sample size for this study is 164 patients. An interim analysis (n=64) was performed, the data are expressed as mean \pm SD.

Results

	Mean duration (SD)	% successful training (within 48 hours)	% urinary tract infection	Mean duration of hospitalisation (SD)
Day 1 (n=32)	2,71 (\pm 2,40)	61	7	3,50 (\pm 1,10)
Day 3 (n=32)	4,00 (\pm 3,19)*	86	6	3,55 (\pm 0,96)

* P<0.05

Interpretation of results

Although successful training within 48 hours is lower in the group starting the training on day one, mean duration of prolonged catheterisation is more than one day shorter in this group (p<0.05). No difference was found in percentage of urinary tract infection or duration of hospitalisation between the groups. The latter might reflect the use of a suprapubic catheter which avoids the need of recatheterisation. Whether or not the advantage of shorter duration of catheterisation outweighs the disadvantage of a lower number of successful bladder training remains to be answered after completion of this randomized controlled study.

Concluding message

Starting bladder training at the first day after surgery results in a shorter duration of catheterisation.

Specify source of funding or grant	no funding
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	CCMO (Central Committee on Research inv. Human Subjects), registration number NL18635.075.07 (www.ccmo.nl)
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	METC (Medical Ethics Committee) Isala Klinieken Zwolle
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes