

OPTIMAL MANAGEMENT OF BLADDER RETENTION FOLLOWING VAGINAL PROLAPSE SURGERY: A RANDOMIZED CONTROLLED TRIAL COMPARING CLEAN INTERMITTENT CATHETERIZATION (CIC) AND TRANSURETHRAL INDWELLING CATHETERISATION (TIC)

Hypothesis / aims of study

Abnormal post voiding residual bladder volume (PVR) is one of the most common complications of vaginal prolapse surgery. Often management is either clean intermittent catheterization (CIC) or transurethral indwelling catheterisation (TIC). As there is no evidence and thus no consensus about the optimal management, we randomly compared both interventions to investigate which of these modalities yields the shortest time to normalize bladder emptying, which modality has the lowest morbidity and which modality is preferred most by patients.

Study design, materials and methods

Multi-centre randomized controlled trial in 5 teaching hospitals and 1 non teaching hospital in the Netherlands from August 2007 till May 2009. All patients older than 18 years who underwent vaginal prolapse surgery were eligible. Exclusion criteria were any neurological or anxiety disorder or the need of combined anti-incontinence surgery. All patients initially received an indwelling catheter which was removed on the first postoperative day. After removal of this catheter PVR was measured using an abdominal bladder scan. In case of abnormal PVR (defined as a residual volume of more than 150 ml) patients were randomized by a computer to either CIC or TIC during 72 hours. As primary outcome we selected the duration of catheterization (in hours) until PVR normalized. Secondary outcomes included bacteriuria and UTI at the moment of normalized PVR, number of performed catheterizations and duration of hospitalization. The trial was powered to detect a decrease of 12 hours in required duration of catheterization between both groups (power 90%, alpha = 0.05, assumed standard deviation = 0.6 days). We planned to recruit 74 patients assuming a loss to follow-up of 15%. An intention to treat analysis was performed.

Alongside this randomized trial a patient preference study was performed to evaluate how patients trade the risk on urinary tract infections to the risk of longer duration of treatment until PVR normalizes. This was done by taking a face to face interview using written treatment scenarios. In the initial scenario the duration of treatment and the risk of urinary tract infections (UTI) was set at 3 days and 30%, respectively, for both treatment options. After expressing a preference for one of the treatment options, the duration of treatment and the risk of UTI after CIC were systematically varied to measure at which scenario patients switched from their initial preference.

Results

In the RCT a total of 87 patients were randomized of which 45 patients were included in the CIC group and 42 patients in the TIC group. No patients were lost to follow up. Patient characteristics, pre-operative prolapse staging (POP-Q), surgery time and preoperative blood loss were similar between groups (data not shown). In the CIC group a significantly shorter duration of catheterization was observed (18 hours in the CIC group versus 72 hours in the TIC group, $p < 0.001$) together with a lower risk to develop bacteriuria or UTI (14 vs 38%, $p=0.02$ respectively 12 vs 33%, $p=0.02$) and shorter hospitalization (2 vs 4 days, $p < 0.001$) (see table). No adverse events related to the catheterization occurred in the two groups.

In figure 1 preferences for 3 possible durations of CIC are shown. Combining these scenarios with a hypothetical difference in UTI risk between both interventions generates several combinations of duration of CIC and difference in UTI risk. For each of these combinations patients have expressed their preference for CIC relative to TIC (Y-axis). The combination as observed in our RCT corresponded to a preference for CIC over TIC in 99% of the patients.

Interpretation of results

CIC results in a shorter duration of treatment and lower risk of bacteriuria and UTI than TIC during 72 hours. Given these conditions 99% of the patients prefer CIC over TIC. We hypothesize that repetitive filling and emptying of the bladder trains the bladder in filling sensation and adequate responding to this sensation whereas in case of TIC this learning effect is not present. The lower bacteriuria risk in the CIC group may be explained by a shorter overall exposure to a catheter and the rinsing of the bladder that results in more adequate clearance of bacteriuria than continued drainage.

Concluding message

For the treatment of abnormal post void residuals after vaginal prolapse surgery, clean intermittent catheterization is preferable above transurethral indwelling catheterization.

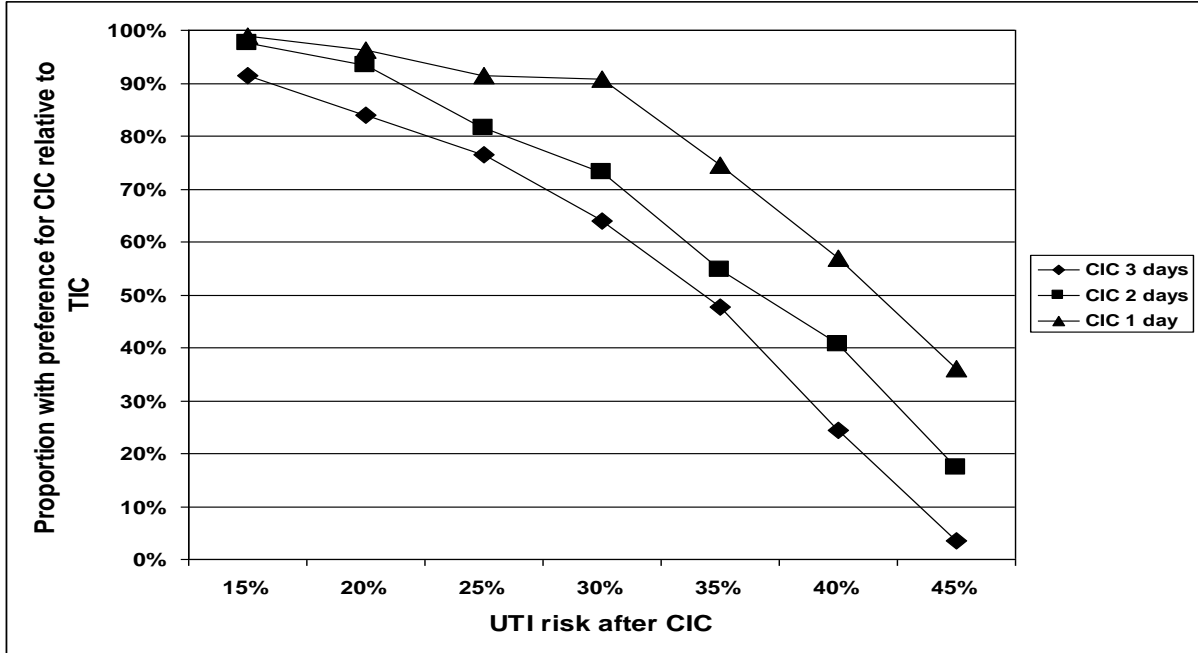
Table 1. Comparison of required duration of catheterization, bacteriuria, number of catheterizations and hospitalization

	CIC (n=45)	TIC (n=42)	P-value
Mean duration of catheterization	18 (5 – 112)	72 (72 – 144)	< 0.001
Significant bacteriuria at end of treatment	6/43 (14)	15/40 (38)	0.02
Number of catheter introductions	3 (1-18)	1 (1-2)	< 0.001

Urinary tract infection [#]	5/43 (12)	13/40 (33)	0.02
Mean hospitalization (days)	2 (1-6)	4 (1-5)	< 0.001
Mean duration of catheterization	18 (5 – 112)	72 (72 – 144)	< 0.001

*Data are presented as mean (range) or n, (%)

Figure 1: patient preferences for CIC relative to TIC



CIC= clean intermittent catheterization
 UTI= urinary tract infection
 TIC= transurethral indwelling catheterization

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	Netherlands Trial Register Identifier: NTR1152
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Free University Medical Center, Amsterdam, Ethical Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes