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Comparing clean intermittent catheterisation and transurethral indwelling catheterisation for incomplete voiding after vaginal prolapse surgery: a multicentre randomised trial

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Objective To compare clean intermittent catheterisation with transurethral indwelling catheterisation for the treatment of abnormal post-void residual bladder volume (PVR) following vaginal prolapse surgery.

Design Multicentre randomised controlled trial.

Setting Five teaching hospitals and one non-teaching hospital in the Netherlands.

Population All patients older than 18 years experiencing abnormal PVR following vaginal prolapse surgery, with or without the use of mesh. Exclusion criteria were: any neurological or anxiety disorder, or the need for combined anti-incontinence surgery.

Methods All patients were given an indwelling catheter directly after surgery, which was removed on the first postoperative day. Patients with a PVR of more than 150 ml after their first void were randomised for clean intermittent catheterisation (CIC), performed by nursing staff, or for transurethral indwelling catheterisation (TIC) for 3 days.

Main outcome measure Bacteriuria rate at end of treatment.

Results A total of 87 patients were included in the study. Compared with the TIC group ($n = 42$), there was a lower risk of developing bacteriuria (14 versus 38%; $P = 0.02$) or urinary tract infection (UTI; 12 versus 33%; $P = 0.03$) in the CIC group ($n = 45$); moreover, a shorter period of catheterisation was required (18 hours CIC versus 72 hours TIC; $P < 0.001$). Patient satisfaction was similar in the two groups, and no adverse events occurred.

Conclusion Clean intermittent catheterisation is preferable over indwelling catheterisation for 3 days in the treatment of abnormal PVR following vaginal prolapse surgery.

Keywords Catheterisation, urinary retention, vaginal prolapse surgery.

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Introduction

Incomplete emptying of the bladder is one of the most common unwanted side effects of vaginal prolapse surgery. The incidence varies widely between studies because of differences in definition, but has been shown to vary from 1.4 to as high as 40%.[1–3] When the problem is unrecognised or left untreated, bladder overdistension can occur, which can have negative effects on bladder function in the long term.[4] Although the inability to adequately empty the bladder is generally short lasting, there is a huge variation in the management of this complication, and many physicians still tend to initially catheterise for several days.[2,3,5–9] Based on a Cochrane review studying catheter policies after urogenital surgery, and other recent randomised controlled trials studying catherisation specifically after vaginal

prolapse surgery, there is an ongoing trend to further restrict the duration of this standard prolonged catheterisation.[1–3] However, there is insufficient evidence to tell whether this duration should be 1 day postoperatively or even less.[10] Naturally, patients who experience abnormal post-void residual volumes (PVR) should receive additional treatment. To our knowledge, no evidence exists regarding treatment strategies following vaginal prolapse surgery once abnormal PVR has developed. The absence of such evidence implies that there are risks of practice variation and the unnecessary prolonging of catheterisation, with consequently higher rates of urinary tract infection (UTI).[9,10] Therefore, a randomised controlled trial was designed in which patients who developed abnormal PVR were randomised between 3-day prolongation of transurethral indwelling catheterisation (TIC) and clean intermittent catheterisation (CIC), performed by nursing staff.

Methods

A randomised controlled trial was performed in five teaching hospitals and one non-teaching hospital in the Netherlands. The allocation ratio was 1:1. Approval was obtained from the institutional review boards of all participating centres. All patients older than 18 years of age with symptomatic pelvic organ prolapse experiencing abnormal PVR following vaginal prolapse surgery, with or without the use of mesh, were eligible. We defined abnormal PVR as a post-voiding residual volume exceeding 150 ml, measured by bladder scanning.[9] Exclusion criteria were: any neurological or anxiety disorder, or the need for combined anti-incontinence surgery. Patients were informed about the study preoperatively and written informed consent was obtained. The prolapse was routinely staged according to the pelvic organ prolapse quantification (POPQ) staging system.[11] Surgery was performed by gynaecologists with a special interest in urogynaecology. Although small variations in surgical technique may have occurred, the surgeons had a similar surgical basis.[12]

All patients received prophylactic antibiotics during surgery. A 14 french silicone transurethral indwelling catheter and a vaginal gauze were inserted directly after surgery. The catheter and gauze were removed on the morning of the first postoperative day. Directly after the first attempt to void the residual volume was measured using a bladder-scanning device (Verathon-Diagnostic Ultrasound DxU BVI 3000 or BVI 6100®; BVI, Ijsselstein, the Netherlands), and the voided volume was measured in millilitres.

Catheterisation regimens

Patients with a PVR ≥150 ml as measured by bladder scan on the first postoperative day were randomised for a 3-day trial of TIC or CIC. In the TIC group a 14 french silicone catheter was inserted by nursing staff. In the CIC group a SpeediCath® (Coloplast, Humlebaek, Denmark) catheter was inserted with a maximum interval of 6 hours. Depending on randomisation, patients were allowed to go home with either an indwelling catheter or, when able to self-catheterise, with instructions to perform clean intermittent self-catheterisation. Information on the study was provided by a research nurse, who also enrolled the participants. Computerised block randomisation was performed by the attending residents or gynaecologists. The attending nurse assigned participants to interventions. Because of the obvious dissimilarity of the intervention, blinding of the next treatment allocation was not possible.

In the case of a persistent abnormal PVR after the initial period of 3 days, the surgeon was free to continue treatment by either TIC or CIC.

Outcome measurements

The primary outcome measure was bacteriuria. This outcome measure was chosen because this factor was expected to be least influenced by the design of the study, in which one group received an indwelling catheter for 3 days. Significant bacteriuria was defined as $>10^5$ colony-forming units in a culture. This culture was taken from the first void after PVR had normalised to <150 ml and after either method of catheterisation was finished. Assessments were performed by the microbiology laboratories of the institutions. During the treatment, investigators were not informed about the results of this culture.

Secondary outcome measures included:

1 UTI. Patients meeting the criterion of bacteriuria (culture with more than 10^5 colony forming units) combined with one or more of the following complaints: fever, urinary frequency (more than seven voids a day), dysuria or lower abdominal pain. Patients were asked about the presence of symptoms indicative for the presence of UTI by the principal investigator 1 week after normalisation of abnormal PVR, or earlier when patients reported the aforementioned symptoms themselves. These complaints were combined with the results of the culture to define UTI.
2 Duration of catheterisation until normalisation of PVR occurred.
3 Number of introductions of the catheter.
4 Duration of hospital stay.
5 Pain scores, difficulty with catheter use and patient satisfaction. These factors were assessed using visual analogue scores. Patients were asked to put an 'X' on a 10-cm line, ranging from 0 to 100 between the two extremes, and the distance from the beginning of the line to the 'X' was measured. A score of zero corresponded to 'no difficulty', whereas a score of 100 corresponded to 'maximal difficulty', related to the ease of use of the catheter.

Furthermore, patients were asked to answer whether they would choose the same treatment again (yes or no).

Finally, the post-residual volume was categorised: <300 ml; 300–500 ml; and >500 ml. Then an analysis of variants (ANOVA) was performed to test the differences in duration for normalisation of bladder emptying between these categories for statistical significance. Bonferroni's correction was used to correct for multiple testing.

Power calculation

Studies have shown that the risk on bacteriuria increases by approximately 10% for each additional day of indwelling catheterisation.[1,3] The combined effect of the initial catheter, introduced directly after surgery, and the catheter for the treatment of incomplete voiding on the risk of developing bacteruria was estimated to be around 35%.[1,3] A difference in bacteriuria of more than 20% between both interventions was considered to be clinically relevant. To observe a difference of 35 versus 15% with 90% power, and an alpha of 0.05, 42 patients needed to be included per group.

Statistical analysis

The data were analysed by intention to treat. To examine differences between groups, we used an unpaired Student's *t*-test for continuous variables and a Fisher's exact test for dichotomous variables. A Mann–Whitney *U*-test was performed to test nonparametric outcomes for statistical significance. In the case of multiple group comparisons, an ANOVA was performed and Bonferroni's correction was applied for *post-hoc* tests. Two-sided significance tests were used throughout. $P < 0.05$ was considered to be statistically significant. Statistics were performed using SPSS v16.0 (SPSS Statistics UK, SPSS Inc., Chicago, IL, USA).

Results

From August 2007 until May 2009 a total of 1037 patients underwent vaginal prolapse surgery in the participating centres. Of these patients, 147 (14%) experienced an abnormal PVR, 87 of which were eventually included in the trial (see Figure 1). A total of 45 patients were randomised in the CIC group. In the TIC group, 42 patients were randomised. All patients received the allocated intervention and nobody pulled out of the study. No adverse events occurred.

The baseline characteristics of both groups are shown in in Table 1. All these characteristics were similar for both groups. None of the patients used antibiotics preoperatively, nor were there any patients using medication affecting bladder and bladder outlet, such as anticholinergic or alpha adrenergic agents.

The clinical outcome measures for both interventions are shown in Table 2.

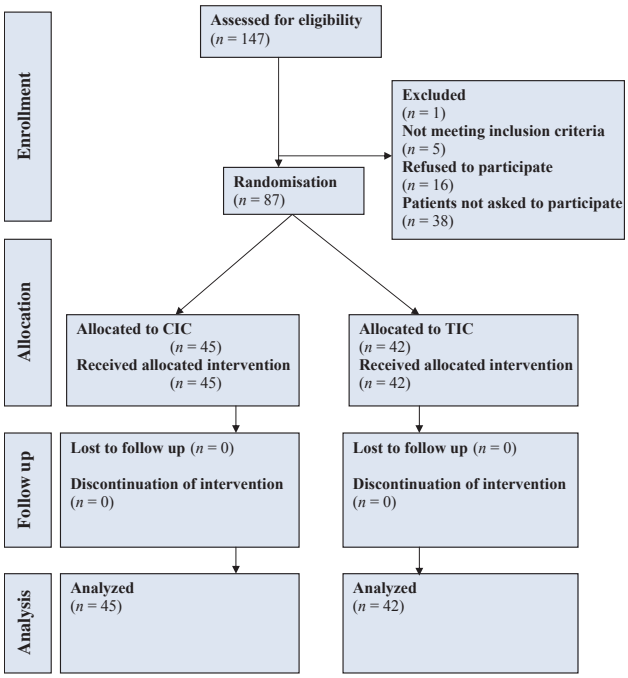

Figure 1. Flow diagram of patients through each part of the study (CONSORT).

A significantly lower risk of bacteriuria and UTI was found in the CIC group (14 versus 38%; $P = 0.02$). The risk of UTI was also significantly lower in the CIC group (12 versus 33%; $P = 0.03$).

Furthermore, a shorter duration of treatment was found in the CIC group.

The normalisation of abnormal PVR occurred 54 hours earlier in the CIC group.

The mean length of time to normalise bladder emptying in patients with a PVR of <300 ml was 22 hours shorter (95% CI 2–42 hours; $P = 0.02$), compared with patients with a PVR of 300–500 ml, and 27 hours shorter (95% CI 4–50 hours; $P = 0.02$), compared with patients with a PVR of >500 ml. The difference in time to normalise bladder emptying between patients with a PVR of 300–500 ml and patients with a PVR > 500 ml was 5 hours, and this was not considered to be statistically significant.

Table 3 shows that pain scores, ease of use of catheter and extent of patient satisfaction were similar.

Discussion

A randomised controlled trial was performed to compare CIC with TIC for patients who experience abnormal PVR after vaginal prolapse surgery. The main findings of this study were that CIC results in a lower risk of bacteriuria and UTI, as well as a faster normalisation of bladder emptying.

The occurrence of a higher risk of bacteriuria and UTI in the TIC group compared with the CIC group was a

Table 1. Patient characteristics

Characteristic	CIC (*n* = 45)	TIC (*n* = 42)
Age (years)	60 (12)	61 (10)
Body mass index (kg/m^2)	26 (1.8)	23 (1.9)
Parity (median, range)	2 (1–5)	3 (1–4)
POP-Q (before surgery)		
Point Ba	0.5 (1.4)	0.8 (1.3)
Point Bp	−1.5 (1.8)	−1.5 (1.7)
Point C	−2.5 (3.2)	−2.0 (3.5)
Repair anterior compartment performed		
Anterior colporrhaphy	42/45 (93)	36/42 (86)
Mesh	2/45 (4)	3/42 (7)
Repair posterior compartment performed		
Posterior colporrhaphy	15/45 (33)	20/42 (48)
Mesh	1/45 (2)	1/42 (2)
Repair middle compartment performed		
Manchester repair	2/45 (4)	5/42 (12)
Sacrospinous ligament fixation	3/45 (7)	4/42 (10)
Vaginal hysterectomy	11/45 (24)	8/42 (19)
Operating time (min)	49 (21)	52 (25)
Blood loss perioperatively (ml)	143 (96)	136 (81)
Height of abnormal PVR postoperatively		
Mean	385 (15)	455 (25)
Median (range 5–95%)	400 (162–647)	400 (167–1000)

Data are presented as means (SDs) or *n* (%), unless otherwise indicated.

Table 2. Comparison of required duration of catheterisation, bacteriuria, number of catheterisations and hospitalisation

	CIC (*n* = 45)	TIC (*n* = 42)	*P*
Bacteriuria	6 (14)	15 (38)	0.02*
Urinary tract infection	5 (12)	13 (33)	0.03*
Duration of catheterisation (hours)	18 (5–112)	72 (72–144)	<0.001**
Number of catheter introductions	3 (1–18)	1 (1–2)	<0.001**
Duration of hospitalisation (days)	2 (1–6)	4 (1–7)	<0.001**

Data are presented as median (range) or *n* (%).
*Mann–Whitney *U*-test.
**Fisher's exact test.

Table 3. Pain score, acceptance and satisfaction with treatment

	CIC (*n* = 45)	TIC (*n* = 42)	*P*
Pain as a result of catherisation*	29 (24)	34 (27)	0.45
Difficulty with catheter use*	28 (25)	36 (32)	0.20
Extent of satisfaction*	80 (22)	76 (24)	0.41
Number of patients that would choose the same treatment again (*n*, %)**	37/38 (97)	33/35 (94)	0.60

*Data are mean scores calculated from a 10-cm visual analogue score 0–100.
**In both the CIC and the TIC groups seven patients were lost to follow-up.

marked difference. We analysed both bacteriuria and UTI in our study, as we think both outcomes are relevant. One could argue that UTI is a more relevant clinical parameter than bacteriuria, and is therefore preferable. However, although there is consensus about suggestive symptoms, UTI could be considered less suitable as its diagnosis is not clearly defined.[13] Moreover, the most frequently applied complaints of urgency, dysuria, frequency or lower abdominal pain appear to be frequently present during and after catheterisation, even in the absence of bacteriuria.[13,14]

During catheterisation, bacteriuria can develop through two mechanisms: direct inoculation from the insertion of the catheter; and colonisation, through bacteria ascending intraluminally and/or extraluminally from the urethral meatus along the catheter.[15,16] The continuing presence of an indwelling catheter with TIC was followed by a higher risk of bacteriuria, which suggests a significant role for colonisation in the development of bacteriuria. Spontaneous clearance of bacteriuria has been described provided that micturition can occur freely, which thus requires the absence of a catheter.[1] Although the repeated introduction of catheters and bacteria with CIC may also induce bacteriuria, we believe that the action of emptying the bladder is advantageous by preventing the pooling of infected urine.

Furthermore, we found a shorter duration of treatment in the CIC group. The essence of CIC is that the intermittent filling and emptying of the bladder possibly trains the bladder to sensate the difference between a filled and emptied status. Such bladder training could be responsible for the quick resumption of voiding, although studies regarding this mechanism after urogynaecological surgery have shown conflicting results.[17–19] Alternatively, the shorter required duration of treatment in the CIC group could arise from a problem in the definitions used. In the absence of an exact cut-off value of pathologic PVR, variation may occur regarding the occurrence and treatment results of abnormal PVR. We followed the most recent survey and used a cut-off value of 150 ml.[9] Treatment of residual volumes below 300 ml took significantly less time to normalise than treatment of PVRs above 300 ml. We hypothesise that the treatment time for patients with initially low abnormal volumes, below 300 ml, was shorter because the natural course of these PVRs are favourable, and are possibly even self-limiting. Hypothetically, the cut-off value of abnormal PVR could be between 150 and 300 ml, but this

can't be exactly defined based on our trial results. Patients' scores for ease of use and satisfaction did not differ, despite the fact that the results clearly indicate the advantages of CIC. One of the reasons for this could be that patients who have actually undergone a certain intervention tend to prefer that particular intervention.[20–22]

Intermittent self-catheterisation has been shown to be a highly acceptable method for patients, with a high degree of freedom and less embarrassment, as opposed to using a suprapubic catheter (SPC), described in one study.[23] When we take this study into account we could expect that the freedom and mobility with CIC would result in a high satisfaction score. Carrying a leg bag with TIC would be expected to result in more embarrassment and an unpleasant feeling of the catheter. However, conversely it is not unthinkable that the TIC group could still reach a high rate of satisfaction because of the single insertion, as opposed to the bother of repeated insertion by CIC. Another factor might have been that in our CIC group catheterisation was performed by nursing staff. Possibly these patients experienced less autonomy and, as a consequence, less satisfaction than they would have in the case of self-catheterisation. In addition, patients were only informed about the protocol of the other option before they decided to participate in the study, but naturally were not informed about the outcomes.

Some issues need to be discussed concerning the study design.

We chose to compare CIC with indwelling catheterisation, and to leave SPC out of the comparison for several reasons. The risk of complications while placing SPCs justifies a reserved attitude towards this technique.[24] This is especially the case after vaginal prolapse surgery, when the duration of initial catheterisation can be reduced to 1 day or even less.[1–3,10] Furthermore, three studies show advantages of CIC over SPC concerning acceptability, duration of treatment and hospitalisation.[23,25,26]

The length of the prolongation period in the TIC group of 3 days might seem arbitrary. This period was chosen to reflect common practice in the Netherlands.[9] Furthermore, the comparison of CIC with an additional period of 3 days of catheterisation (TIC) might have been advantageous for CIC, as the duration of treatment in the TIC group was destined to be 3 days, with the possible consequence of a concurrent rise in the rates of bacteriuria and UTI.[10] However, the mean duration for CIC after prolapse surgery in another randomised study was 5 days.[26] Therefore, this advantage could not have been anticipated beforehand.

Conclusion

This randomised trial compared two of the most frequently applied management strategies for abnormal PVR following prolapse surgery. It was observed that CIC yields a lower risk of bacteriuria and UTI. The study clearly indicates that intermittent catheterisation is a better treatment option than indwelling catheterisation after vaginal prolapse surgery. Future research will be directed towards identifying high- and low-risk subgroups, defining cut-off values and studying patient preferences to further optimise treatment.

Disclosure of interests

None for all authors.

Contribution to authorship

RAH was involved in the conception and design of the study, and made important contributions to critical aspects of the research: recruitment and follow-up of participants; statistical analysis; drafting the article and revising it for important intellectual content; and approving the final version. SDT made important contributions to critical aspects of the research: recruitment and follow-up of participants; drafting the article and revising it for important intellectual content; and approving the final article. FWB, AMB, IMR and MMV made important contributions to critical aspects of the research: recruitment and follow-up of participants; and approving of the final article. MPB was involved in the conception and design of the study, in drafting the article and revising it for important intellectual content, and approving the final version. MHE was involved in the conception and design of the study, drafting the article and revising it for important intellectual content, and approving the final version. JPR was involved in the conception and design of the study, and made important contributions to critical aspects of the research: statistical analysis; drafting the article and revising it for important intellectual content; approving the final version.

Details of ethical approval

IRB Vrije universiteit Amsterdam, date of approval 14 December 2006. Trial registration: NTR1152, www.trialregister.nl.

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