The effects of a catheter clamping protocol on bladder function in neurosurgical patients: A controlled trial

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There is scant evidence-based literature on the best strategies for short-term urinary catheter removal. This clinical trial explored the effects of an early urinary catheter clamping protocol on bladder function in neurosurgical patients. Eligible patients were divided into observation and control groups. Those in the observation group had their catheter clamped postoperatively on return to the ward and unclamped at dedicated intervals. The control group received standard care; the catheter was on free drainage during the entire time in situ.

The mean catheter indwelling time was 2.6 days. Compared with the control group, the observation group experienced shorter time to first postoperative urination, less residual urine volume and better subjective perception during their first postoperative urination. For patients undergoing neurosurgery and associated short-term indwelling urinary catheterization, an early catheter clamping protocol is effective in facilitating bladder function, reducing the rate of dysuria and making patients feel more comfortable after catheter removal.

Key words: bladder dysfunction, catheter clamping, postoperative.

INTRODUCTION
Indwelling urinary catheters (IDCs) are inserted in ≈ 25% of hospitalized patients.1 Due to the frequency of their use, however, health-care professionals can sometimes forget the importance of evidence-based catheter management and that urinary catheters are an invasive medical device that can affect a patient’s physical and psychological well-being.2,3

Common reasons4,5 for IDC insertion include accurate measurement of urine output perioperatively, acute urinary retention and to permit urinary drainage in patients with neurogenic bladder dysfunction. In perioperative patients, IDCs are generally used short term,
defined as a period of 1–14 days. Although IDCs are ideally removed as soon as possible, postoperative voiding impairment and difficulties regaining normal bladder function, also named bladder dysfunction, are frequent in patients after catheter removal.7,8

Background

Extensive literature has been published on IDC insertion and management, but there is scant evidence-based literature on the best strategies for IDC removal.9,10 Nurses play an important role in IDC management, and clinical practice on the removal of urinary catheters is generally based on local preferences and rituals.8 For example, clamping an IDC before removal is a widely implemented practice.8 It was first performed over 70 years ago11 and was reported12 to shorten the time to first void and facilitate the return to normal bladder function after short-term IDC removal.

A recent Cochrane review10 found that evidence on the effectiveness of IDC clamping before removal is inconclusive. The review analysed three trials comparing the effects of IDC clamping before removal with no clamping. Two of the trials showed a statistically significant patient preference and satisfaction toward clamping, whereas the other trial reported no statistically significant difference between clamping and free drainage.10 The review recommended further trials with large samples to investigate the effects of clamping before catheter removal.

It is believed7,9 that clamping an IDC can improve bladder tone and sensation and stimulate normal bladder filling and emptying. Evidence for clamping an IDC before removal is equivocal though and this could be due to the diversity of clamping regimes being compared in clinical trials. Moreover, almost all the regimes in related studies clamped the catheter only immediately prior to removal. The lack of clear and consistent research findings could possibly be because the duration of bladder stimulation training was too short to demonstrate a significant effect.

Due to the current paucity of high level evidence to guide practice, there has recently been a call13 for evidence-based urological guidelines for neurological patients. Timely, effective management of bladder dysfunction is a key treatment component, one in which nurses can have a positive impact for patients with neurologic disorders.14 The prevention of bladder dysfunction is the ideal goal.

AIM AND OBJECTIVE

This study investigated the effects of an early catheter clamping protocol on bladder function in neurosurgical patients with a short-term IDC. The objectives were to determine if an early catheter clamping protocol:

- has an effect on facilitating the return of normal bladder function after IDC removal;
- reduces residual urine volume (RUV) after first void; and
- is clinically preferred by patients.

METHOD

Design and sample

This quasi-experimental study was conducted on a neurosurgical ward in a 1461-bed tertiary hospital in Beijing, China, between February and June 2012. The study was approved by a University Ethics Review Board and Director of Nursing. The research protocol conformed with the provisions of the Declaration of Helsinki (1995).

Patients meeting the inclusion criteria were consecutively recruited. The inclusion criteria were:
1. undergone neurosurgery;
2. an IDC in situ upon return from the operating theatre;
3. planned IDC duration of 1–14 days;
4. aged 18–85 years;
5. willingness to participate in the study; and
6. preoperatively able to urinate without problem and express the intention to urinate.

Exclusion criteria were: IDC in situ preoperatively; history of urinary tract infection, prostatic hyperplasia, urologic problems or sensory disorders; unable to communicate; and signs of cognitive impairment, defined as disorientation to place, time or person, disorganized thinking or agitation.

Patients meeting the inclusion criteria were informed of the purpose and procedures of the study. All participants gave informed consent and signed a consent form. Participants had the right to withdraw from the study at any time. All data were handled confidentially, and patient anonymity was preserved.

Procedure

Consistent with local practice, patients were showered with a skin disinfectant on the ward before transfer to the operating theatre. The operating room nurse inserted the IDC using an aseptic technique, immediately
postoperatively. Postoperatively, the IDC was removed when instructed by the consulting surgeon, consistent with local practice.

The neurosurgical ward has four structural divisions: A, B, C and D. Participants admitted to divisions A and B were in the observation group, and those admitted to C and D, the control group. In the observation group, the IDC was clamped immediately upon return from the operating theatre and unclamped at certain intervals. The intervals were adjusted by the bedside nurse depending on the patient’s input and output volumes, in order to avoid over distension of the bladder. If the patient was receiving intravenous fluids, the IDC was unclamped at 2–3 h intervals for 10 min at a time. If the patient was not receiving intravenous fluids, the IDC was unclamped at 3–4 h intervals.

During catheter clamping periods, patients were told to notify the nurse when they felt the need to urinate and that the nurse would then unclamp the catheter. The duration of each unclamping period was 10 min to allow for complete bladder emptying. For removal, nurses clamped the catheter again and removed it clamped when the patient felt the need to urinate. Patients in the control group received standard care, which was to keep the catheter unclamped during the entire period in situ.

**Outcome measures and data collection**

Participants’ baseline information was collected including: gender, age, body mass index, medical diagnosis and duration of urinary catheterization. Numerous variables were used to assess bladder function after IDC removal. The primary outcome measure was time to first void, defined as the time interval from when the patient first feels the need to urinate to when they actually do so. These data were collected by the primary researcher.

Patients were told to press the call bell when they feel the need to urinate. When they did so, the data collector escorted each patient to the toilet. Once the patient was at the toilet and ready to urinate, time measurement commenced (T1). The data collector waited nearby and noted when urination ceased (T2). Time to first void was noted as the difference between T2 and T1. Patients were instructed to urinate in a urine bottle or bed pan to allow measurement of urine volume.

The primary researcher also performed bladder percussion and palpation within 10 min of the patient’s first void to determine RUV classification. The primary researcher received training on these techniques from a local urological physician. RUV classification is divided into four levels: 15

- level 1: the patient has no discomfort and the percussion note is tympany;
- level 2: the patient feels the need to urinate when their bladder is percussed and palpated; the percussion note is dull;
- level 3: the patient feels their abdomen is distended and the need to urinate when their bladder is percussed and palpated; the percussion note is dull; and
- level 4: the patient feels the need to urinate and the nurse identifies a cystic bladder upon palpation and percussion; the percussion note is dull.

A portable ultrasound device was not used to determine the RUV as its use was not common practice in the study hospital. Each patient’s nurse noted whether the patient had urinary retention or was recatheterized after IDC removal. All nurses collecting data received training on data collection. Baseline data were collected from medical records.

Secondary outcomes included micturition function classification, volume of the first void, recatheterization rate, urinary retention rate and the patient’s symptoms during the first postoperative urination after IDC removal. Symptoms were classified as:

- normal (no discomfort during first void);
- dysuria (the feeling of pain, burning or discomfort on micturition); and
- incomplete voiding (the sensation of still needing to void immediately after urinating).

Urinary retention was defined16 as the need for catheterization within 24 h after catheter removal.

Micturition function classification is divided17 into four levels, depending on the time to first void as defined above:

- level 0: time interval within 1 min;
- level 1: time interval 1 to 30 min;
- level 2: time interval 1 to 30 min and needs assistance such as massage or heat pad; and
- level 3: cannot urinate by self or with other assistance methods and needs catheterization.

Level 0 is regarded as normal micturition function and levels 1–3 as abnormal micturition function. Bladder percussion and palpation were performed to determine RUV after first urination when the IDC was removed.
Pilot study
A pilot study was conducted to determine the feasibility of the study and to explore the reliability of percussion and palpation techniques. Twenty eligible patients meeting the inclusion criteria were recruited and assigned to an observation or control group. In order to explore the reliability of percussion and palpation, a portable ultrasound device (Adara SONOLINE 50643406, Siemens, Bavaria, Germany) with a 3.5 MHz probe was used after bladder percussion and palpation to determine RUV postvoid.

Pilot study data showed the study protocol was feasible. The mean time interval for patients receiving the early bladder function protocol and standard care was 0.46 ± 0.68 and 1.98 ± 1.36 min. No patients experienced urinary retention and needed recatheterization. The RUV determined by the ultrasound device and by percussion and palpation were positively correlated (r = 0.80).

Sample size
Sample size calculation was based on pilot data, as there were no published data relating to the time to first postoperative void in neurosurgical patients. According to the micturition function classification,17 time interval within 1 min is regarded as normal micturition function. A 1 min difference in the time interval between the two study groups was therefore considered to have clinical significance. Sample size calculation indicated 74 patients (37 in each group) were required, assuming a 20% withdrawal rate, to detect a 1 min difference between the two groups (two tailed, α = 0.05, power 80%).

Statistical analyses
Statistical analyses were conducted using SPSS 13 for Windows (SPSS Inc, Chicago, IL, USA) to assess the differences between the two groups. The χ² test was used for categorical data. For continuous data, the Mann–Whitney test was used. Central tendencies were described as median value and the first and third quartiles. Student’s t-test was used for normally distributed data. Spearman analysis was calculated for correlation of subjects’ baseline data and the primary and secondary outcomes. The level of statistical significance was set at P < 0.05.

RESULTS
During the study period, 137 patients were assessed for eligibility (Fig. 1). Of 89 meeting the inclusion criteria, six patients were lost due to transfer to other wards and four patients refused to participate, leaving 79 patients in the final sample. Statistical analyses showed no significant differences between the 10 patients lost to the study and the remaining 79 participants on baseline characteristics.

Of the 79 participants, 40 (15 males and 25 females) were allocated to the observation group and 39 (13 males and 26 females) to the control group. All participants received the allocated intervention. Baseline data did not differ significantly between the two groups (P < 0.05; see Table 1).

Primary and secondary outcomes
No patients experienced urinary retention and needed recatheterization after IDC removal. The time to first void was 0.3 min (Q1 0.17–Q3 0.5) in the observation group, which was significantly shorter than in the control group, 0.67 min (Q1 0.33–Q3 2.0). Only one patient (2.5%) in the observation group had abnormal micturition function, whereas more than half (51.3%) the patients in the control group had abnormal function (P < 0.001). The volume of the first void was also much higher in the observation group (264.5 ± 65.0 mL, 224.9 ± 100.3 mL, P < 0.05).

After first void, the RUV classification of the observation group was significantly lower than the control group. Only one patient (2.5%) in the observation group felt the need to urinate during bladder percussion and palpation. In contrast, eight patients (20.5%) in the control group felt the need to urine when percussion and palpation were performed. Furthermore, 35% of patients in the observation group experienced discomfort during the first micturition, whereas 61.5% of patients reported dysuria or incomplete voiding in the control group. Spearman analysis showed that only duration of urinary catheterization was related to the time to first void (r = 0.335, P = 0.001). Primary and secondary outcomes are presented in Table 2.

DISCUSSION
This study showed that an early IDC clamping protocol can facilitate regaining normal bladder function after catheter removal in postoperative neurosurgical patients. The protocol resulted in shorter time to first void, better micturition function and RUV classification, larger volume of first void, with fewer patients experiencing discomfort during the first void.

In a Cochrane review,10 two trials also reported shorter time to first void after clamp removal. However, a recent
randomized controlled trial\textsuperscript{7} showed neither advantage nor disadvantage with IDC clamping before removal. A possible explanation is that the clamping regimes were different between the studies. In the trial,\textsuperscript{7} IDCs were clamped at 0600 h on postoperative day two and removed when patients needed to urinate. In the current study, IDCs were clamped immediately after patients returned from the operating theatre and unclamped at dedicated intervals.

In the trial\textsuperscript{7} by Nyman et al., normal bladder function was defined as postmicturition residual volume of 150 mL or less. The time required to return to normal bladder function was from the time the IDC was clamped in the control group and in the free drainage group from the time IDC was removed.\textsuperscript{7} In the present study, bladder function was assessed by time to first void, micturition function classification and RUV classification. The use of these different outcome measures might explain the differing conclusions.

Compared with seminal research,\textsuperscript{12,18} time to first void was considerably shorter in the present study. A possible explanation is again differing definitions used. In both seminal studies, time to first void was measured from the time the IDC was clamped to the time the patient urinated after IDC removal. In the present study, time to first void was measured from the time the patient first felt the need to urinate after IDC removal to when the patient actually urinated. This measurement decision was made to exclude extraneous variables influencing the real time to first void. For example, a patient who feels the need to

\textbf{Figure 1.} Number of patients assessed, enrolled and allocated to the study.

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urinate after IDC removal might delay doing so because he/she is using the telephone.

The present study showed the RUV classification of patients who received the IDC clamping protocol was much lower compared with those who did not. Seminal research\(^{12}\) demonstrated no significant difference regarding postvoid RUV between patients who received bladder reconditioning and those who did not. The differences between the results might be due to the postvoid RUV in our study, which was measured by percussion and palpation and classified\(^{15}\) into four levels. In the study\(^{12}\) by Williamson, RUV was measured by straight in-and-out catheterization. Although not significantly different regarding postvoid RUV, Williamson\(^ {12}\) found that the postvoid RUV for patients not receiving bladder reconditioning increased 10-fold over the baseline. This was highlighted as being physiologically abnormal, whereas in the treatment group, RUV increased only 1.3 times over its mean baseline.\(^ {12}\)

In regard to patients’ experience during first void, participants showed a significant preference for the early catheter clamping protocol. This is consistent with other studies\(^ {12,19,20}\) and promotes the clinical uptake of an early bladder function protocol, as patient comfort and satisfaction are important indices of nursing care quality. In the present study, no patients experienced urinary retention and needed recatheterization after IDC removal. In other research,\(^ {7,19}\) no differences between the clamping and free drainage groups were observed regarding the rate of recatheterization.

The present study supports the benefits of an early IDC clamping protocol on bladder function. The results though could be due to the bladder of patients receiving the clamping protocol being more sensitive to urine filling and those of the control group being less sensitive. During micturition, the bladder contracts and pelvic floor muscles and external and internal sphincters relax to allow urine to pass.\(^ {21}\) Tonus, a state of slight contraction and tension in the muscle fibres, is an inherent property in the detrusor muscle and an important factor in maintaining normal micturition.\(^ {12}\) Constant and free drainage of urine by an IDC without clamping keeps the detrusor muscle in a state of continual constriction,\(^ {12}\) which has been demonstrated\(^ {22}\) in animal experiments to influence the muscle tone in the same way that other muscles become weak from lack of exercise.

The goal of the early bladder function protocol of IDC clamping and unclamping is to allow the bladder to store a reasonable volume of urine and empty at an appropriate time interval. This procedure aims to help the bladder muscle maintain tonus by applying stretch intermittently and in turn promote the bladder regaining normal function after IDC removal. Moreover, the finding in the present study that the duration of urinary catheterization was the only factor related to the time to first void, again verifies the above possible mechanism of the effects of the early catheter clamping protocol.

**LIMITATIONS**

The current study was not blinded. This was not actually possible and might have increased the risk of observer bias. The use of objective measures is encouraged\(^ {23}\) to reduce this risk. Time to first void and the volume of first void were therefore assessed with a watch and measuring jug. A portable ultrasound device is argued\(^ {24}\) to be the gold standard in determining RUV. Percussion and palpation were used to determine RUV; this was due to financial limitations as well as to reflect local practices. Percussion and palpation were performed by the same person to ensure consistency, and the pilot study showed

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an acceptable positive linear relationship between RUV classification by percussion and palpation and by ultrasound measurement.

The study was conducted on neurosurgical patients and excluded those with cognitive impairment, urinary tract infection, prostatic hyperplasia or other urologic problems. Caution must be therefore advised in generalizing the results to other surgical patients with short-term IDCs. Furthermore, there is little contemporary research to compare with the results of the present study. Replication studies are therefore recommended to help verify our results.

CONCLUSION

This study demonstrated that an early catheter clamping protocol can facilitate regaining normal bladder function postoperatively. Further trials with larger samples are needed to provide robust evidence of the effects of the early bladder function protocol in patients with a short-term catheter. The impact of the clamping protocol on other surgical patients is also worth exploring.

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