REDUCING THE INCIDENCE OF POSTOPERATIVE URINARY RETENTION BY CHANGING THE DEFINITION: A RANDOMIZED TRIAL

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31637

Source
ToetsingOnline

Brief title
INCIDENCE OF POSTOPERATIVE URINARY RETENTION

Condition

- Other condition

Synonym
UNABLE TO VOID SPONTANEOUSLY, URINARY RETENTIE

Health condition

HET IS NIET ECHT EEN AANDOENING= FYSIOLOGISCH PROCES BEÏNVLOEDT DOOR DE OPERATIE

Research involving
Human

Sponsors and support

Primary sponsor: INVESTIGATOR INITIATED
Source(s) of monetary or material Support: VERATHON MEDICAL EUROPE,VERATHON MEDICAL EUROPE;IJSSELSTEIN;WETENSCHAPFONDS MCL

Intervention

Keyword: DEFINITIONPOSTOPERATIVEURINARY RETENTIONINCIDENCE

Outcome measures

Primary outcome

The primary endpoint is the number of urinary catheterizations in each study

group which is expected to be significantly lower in the index group.

Secondary outcome

Secondary endpoints are postoperative micturition problems and possible changes

in voiding pattern after catheterization.

Study description

Background summary

Postoperative urinary retention (POUR) can be defined as *a certain maximal* postoperative bladder volume while being unable to void spontaneously. POUR is considered as a common postoperative complication. Risk factors for POUR are related to the type of operation, to the type of anaesthesia or to the patient (age and history of voiding problems). Another factor that could influence the risk for POUR is an unemptied bladder before the operation. When POUR occurs, bladder catheterization seems imminent. If bladder catheterization is delayed until the bladder volume is well beyond its maximum capacity, bladder damage may occur. The incidence of POUR in the recovery room is varying between 5% to 40%, depending on definition used for POUR. The incidence of POUR at the surgical wards is unknown, because the BladderScan® is more used at the Recovery Room than at the ward. Thanks to the introduction of the BladderScan® the definition for the occurrence of POUR has changed from a time limit (i.e. 6

to even 12 hours postoperatively) into a volume limit. This volume limit for POUR is commonly, though arbitrarily, set at 500 ml. This means that when the bladder volume exceeds the level of 500 ml - as determined by the BladderScan® - catheterization is generally executed. This volume limit of 500 ml is considered as a maximum bladder capacity (MBC) at which, normally, humans have a strong urge to void. The MBC is the bladder volume that a person is able to void spontaneously, after holding up their urine until voiding could not longer be postponed together with the measured residual bladder volume that stays in the bladder after complete emptying. However, there is limited knowledge about the average MBC and it may well vary between individuals. The currently used fixed bladder volume limit of 500 ml to define the presence of POUR and thus the present indication for urinary catheterization, can either be too small or too large compared to the patient*s true MBC. Therefore patients may be catheterized unnecessarily too early, or too late. Bladder catheterization is an unpleasant procedure for the patient involved and can lead to unnecessary complications; such as urethral trauma or urinary tract infections. Also, Bladder catheterization is a time consuming effort for the nursing staff. Preventing unnecessarily urinary catheterizations is improving the quality of patient care.

Study objective

This study aims to investigate whether the definition of a fixed volume limit of 500 ml can be changed to a bladder volume limit adapted to each individual*s own maximum bladder capacity. It is expected that this change in definition will lead to much less urinary catheterizations, which likely reduces the incidence of complications and changes in voiding pattern due to catheterizations postoperatively.

Study design

In this prospective randomized study two surgical patient groups will be studied and compared. The included patients will be randomly assigned in one of the two groups: group one (control group) will receive care as usual, i.e. POUR is defined when, postoperatively, the patient*s bladder volume reaches the 500 ml limit and they are not able to void spontaneously, such that they are catheterized. In the index group, POUR presence will be defined - and catheterization will be executed -when postoperatively the patient*s bladder volume reaches their preoperatively measured MBC and the patient is yet unable to void spontaneously. After Informed Consent (IC) the patient will receive an instruction form, about how to preoperatively measure their MBC at home, together with a measuring bowl. Patients will be asked to measure their Bladder Capacity (BC) 3 times. The measured volumes are recorded by the patient. PEROPERATIVELYAfter arriving at the Operation Centre (OC), the patient returns the instruction form with the 3 measured BC written down. The RA fills in the Case Record Form (CRF). Then randomization will take place. The patient will be

asked whether he/she went to the restroom before arriving at the OC, the time of last voiding, and the bladder will be scanned. The anaesthesia technique and volume infused during the per- and postoperative period is, conform routine care, managed by the responsible anaesthesia team, who are blinded for the group in which the patient is randomized.POSTOPERATIVELYPostoperatively the patient will be scanned by the RA at regular intervals (every hour) until normal voiding happens. The patient is followed after discharge from the Recovery Room to the Surgical Ward, until spontaneous voiding or urinary catheterization has happened. Before spontaneous voiding a Bladderscan will be performed to register the pre-voiding volume. If a patient is not (yet) being able to void spontaneously and the scanned volume is smaller than 500 ml (when randomized to the control group) or than his/her personal MBC (index group), the next scan will be performed the following hour. This procedure will be repeated (if necessary on the wards) until the scanned bladder volume has reached the definition for POUR (depending on the assigned intervention group) and catheterization will be performed. Bladder catheterization will be performed by the nursing staff according to routine care. If the patient was operated under spinal anesthesia the level of regression of the sensory block will be assessed by a routine test (ice cube) at the moment of spontaneous voiding or urinary catheterization.FOLLOW UPOne day, one week and one month after the operation, each included patient will be interviewed for any change in voiding pattern compared to preoperatively, using the same standard questionnaire which has also been used preoperatively (IPSS, see appendix). If the IPSS shows a significant increase, the urologist will be consulted as in routine care.INTERIM ANALYSISAfter 250 included patients an interim analysis will be performed to search for patiënts at risk due to the study protocol.

Intervention

The only intervention is the change in the definition for POUR for half of the study group.

Study burden and risks

There is no associated risk other than the normal procedure.The burden for the patient consist of measuring their bladder capity (BC = maximum voided volume) at home. This can be done by postponing normal voiding until the urge to void can no longer be withheld. Then normal voiding can be performed by voiding in a calibrated bowl, making it possible te read the volume. Measuring the BC have to performed by all patients included in the study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 YEARS OF AGE OR OLDER, NO INDWELLING OR IN/OUT CATHETERISATION PERIOPERATIVELY, ABLE TO MEASURE THEIR MAXIMUM BLADDER CAPACITY AT HOME, GENERAL/SPINAL ANESTHESIA, UNDERSTANDING DUTCH LANGUAGE

Exclusion criteria

YOUNGER THAN 18 YEARS OF AGE, REGIONAL ANAESTHESIA FROM ONE LIMB/EYE, INDWELLING URINARY CATHETER PERIOPERATIVELY, NO UNDERSTANDING OF THE DUTCH LANGUAGE

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2008
Enrollment:	2000
Type:	Actual

Medical products/devices used

Generic name:	BLADDERSCAN
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-05-2008
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21058.099.07