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Preventing bladder catheterization after an operation under general or spinal anesthesia by using the patient's own maximal bladder capacity as a limit for maximum bladder volume

Submission date
18/07/2011

Recruitment status
No longer recruiting

Registration date
26/08/2011

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
After almost any operation the patient may be unable to spontaneously urinate. This can result in the bladder enlarging beyond its maximum capacity and may lead to permanent bladder damage requiring lifelong use of a catheter (tube) to drain the bladder. Portable bedside ultrasonography can be used to determine bladder volumes after the operation to prevent overfilling of the bladder. This device measures the bladder volume by ultrasound, which is a non-invasive patient-friendly method and gives fast and accurate results. Bladder volumes between 400 and 600 ml are commonly used as thresholds for bladder catheterization. Surprisingly, there is no evidence as to what constitutes a ‘safe’ maximum bladder volume in surgical patients, but is it likely to be variable between patients depending on their maximum bladder capacity. A previous study has found that maximum bladder volumes can vary between 200 and 1600 ml. Therefore we think that many surgical patients are catheterized ‘too early’ when arbitrary but commonly accepted limits for a maximum bladder volume are used, instead of the patient’s own maximum bladder capacity. Knowledge of a patient’s MBC combined with ultrasound measurements of their actual bladder volume could result in a more selective use of bladder catheterization after an operation. Such a practice potentially reduces both overtreatment (unnecessary catheterizations and its attendant risk) and undertreatment (late catheterization with the risk of an over-distended bladder). The aim of this study is to find out whether using the patient’s maximum bladder capacity as a threshold for bladder catheterization lowers the use of bladder catheterization compared to using a fixed volume of 500 ml.

Who can participate?
Patients aged 18 or older undergoing surgery under general or spinal anesthestic, without the anticipated need for a bladder catheter during the operation.

What does the study involve?
Participants are asked to measure their maximum bladder capacity at home. After surgery

patients are randomly allocated into two groups. In one group the patients who are unable to void are catheterized when their bladder volume reached 500 ml (the current standard treatment). In the other group the patients who are unable to void are catheterized when their own maximum bladder capacity is reached.

What are the possible benefits and risks of participating?
Bladder catheterization after an operation is a common procedure and we only changed the bladder volume at which the bladder was catheterized. Because the bladder was measured every hour after the operation, long-term bladder distention did not occur and so there were no additional risks compared to the standard treatment.

Where is the study run from?
The study took place in the Medical Center in Leeuwarden, Netherlands.

When is the study starting and how long is it expected to run for?
May 2008 to June 2009.

Who is funding the study?
Verathon Europe (Netherlands).

Who is the main contact?
Dr Tammo Allie Brouwer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
TPO 523; NL 21058.099.07

Study information

Scientific Title
Effect of using Individual bladder capacity on the incidence of postoperative bladder catheterization in surgical patients

Study objectives

We hypothesized that many surgical patients are catheterized too early when arbitrary, but commonly accepted limits for a maximum bladder volume are used, instead of the patients individual MBC. Knowledge of a surgical patients individual MBC combined with postoperative serial ultrasound measurements of actual bladder volume could reduce the incidence of POUR and result in a more selective use of perioperative bladder catheterization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Local Medical Ethical Committee of the MCL (METC/RTPO=Regionale Toetsingscommissie Patiëntgebonden Onderzoek), 13/05/2008, ref: 523
2. Dutch Center for research involving human beings (CCMO: www.ccmmo.nl), 02/05/2008, ref: NL 21058.099.07

Study design
Single-centre single-blinded observational randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postoperative bladder catheterization if spontaneous voiding was impossible and the volume for the randomized group was reached in surgical patients operated in the Medical Center Leeuwarden

Interventions
1. Bladder catheterization when the measured bladder volume measured by ultrasound was larger the the limit for the group the patient was randomized (500 ml group = control group or the maximum bladder capacity group (MBC) = index group)
2. Postoperatively, after arriving at the recovery room, the patients bladder was scanned by the research assistant. If the patient was not able to void spontaneously or had no urge to void and the scanned bladder volume was less than the volume limit for the group the patient was randomized, a subsequent scan was performed after one hour
3. The patients bladder was scanned every hour at the recovery room and on to the surgical ward
4. If the patient was able to void spontaneously before the volume limit was reached, pre-voiding volume and subsequently the residual volume was measured
5. When the scanned bladder volume was larger than the volume limit, POUR was diagnosed and patients were encouraged to void spontaneously
6. If spontaneous voiding was not possible bladder in-and-out catheterization was performed, regardless if the patient expressed sensation of urge

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. The incidence of bladder catheterization in each treatment group
2. Pre-planned subgroup analyses were the influence of gender and the influence of the anesthesia technique - general versus spinal - on the incidence of bladder catheterization

Key secondary outcome(s))
1. The number of patients in whom catheterization could have been avoided, which could retrospectively only be determined in the control group. Avoidable catheterization was defined as catheterization in the presence of a measured bladder volume larger than 500ml, but smaller than the patients individual MBC
2. Those patients would not have been catheterized if they were randomized in the index group where their MBC was used as threshold instead of 500ml
3. IPSS and QoL scores, specially focused on LUTS, were also compared

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. All consecutive patients who visited the preanesthesia assessment clinic (PAC) at the Medical Center Leeuwarden, the Netherlands were invited to participate in this study
2. Eligible patients were 18 years or older, were planned for surgical intervention under general or spinal anesthesia, without the anticipated need for an indwelling catheter peroperatively
3. All participating patients gave informed consent (at the PAC) to follow the instructions to measure their individual MBC at home, to be randomized to one of the two study arms and to complete the questionnaires as required in the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
936

Key exclusion criteria
1. All patients operated under local anesthesia, or operations where an indwelling bladder catheter was obliged
2. Patients younger than 18 years of age

Date of first enrolment
14/05/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Henri Dunantweg 2
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Sponsor information

Organisation
Verathon Medical Europe BV (Netherlands)

ROR
https://ror.org/00b75tt95

Funder(s)

Funder type
Industry

Funder Name
Verathon Europe™ (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/01/2021	12/02/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes