

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

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Registration date 26/08/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/02/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 anesthetic, 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 than 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 measure

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

Secondary outcome measures

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

Overall study start date

14/05/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Total number of patients 1839

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

Leeuwarden

Netherlands

8901 BR

Sponsor information

Organisation

Verathon Medical Europe BV (Netherlands)

Sponsor details

Boerhaaveweg 1

IJsselstein

Netherlands

3401 MN

Sponsor type

Industry

Website

http:\\www.verathon.eu

ROR

https://ror.org/00b75tt95

Funder(s)

Funder type

Industry

Funder Name

Verathon Europe™ (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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