UNIKLINIK KÖLN
Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe

Current Research

Opening symposium launches international URGE I and URGE II studies

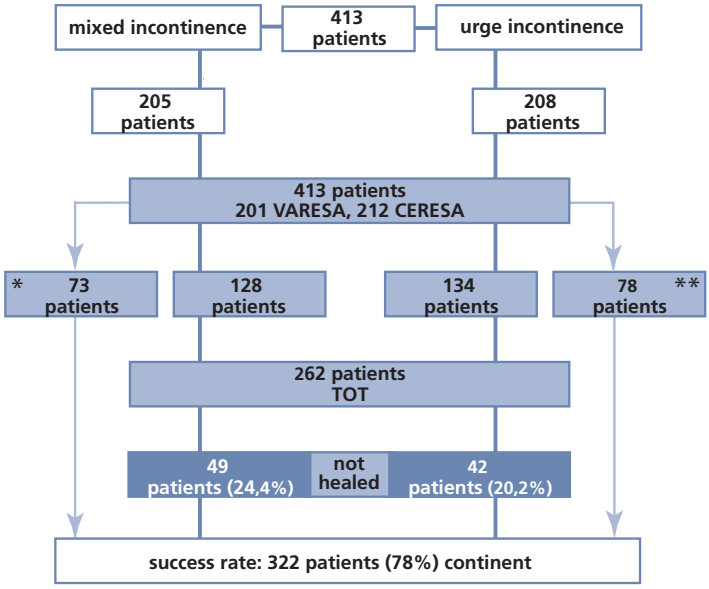
The international URGE I and URGE II studies are the first operative treatment studies looking at urge incontinence in women, which is a completely new treatment approach. As part of an opening symposium on 27 July 2012, background and study design were presented. Professor Dr Peter Mallmann (Director of the Gynaecology Clinic at the Cologne University Hospital) and Professor Dr Wolfram Jäger (Head of Pelvic Floor Surgery and Urogynaecology at the Cologne University Hospital) welcomed Professor Dr Stephen Jeffery (Head of the Department of Urogynaecology and Pelvic Floor Surgery at the Groote Schuur University Hospital in Cape Town) to speak on this issue. A large number of general practitioners and clinical gynaecologists took part in the symposium.

You can find more information on the study and on the inclusion and exclusion criteria on page 4.

Urge incontinence – high healing rate thanks to a new operation

Professor Dr Wolfram Jäger, Head of Pelvic Floor Surgery and Urogynaecology at the Gynaecological Clinic of the Cologne University Hospital

Preliminary investigations on the development of new operative methods to treat urge incontinence in women (VARESA = **VA**gino-**RE**ctal **SA**cropexy and CERESA = **CE**rvico-**RE**ctal **SA**cropexy) began in 2004. Since 2006, 413 patients have undergone this operation as part of the first study (VARESA I, II and III), and a healing rate of 78% (complete continence with no symptoms of urge incontinence) was achieved. The results achieved to date will shortly be published in the Journal of Gynecologic and Obsteric Investigation.



The new operative methods are based on the realisation that the uterosacral ligament (USL) is key to retaining continence and that urge incontinent patients have practically no USL left. In the past few years, technologies have been developed to strengthen or replace the USL. The study first had to determine the length of the ligament, and then the various materials had to be tested. It was particularly important to meet the need for the materials to be radiologically verifiable and to be very dimensionally stable. Conventional products were too adhesive, so the good results achieved post-operatively were unsatisfactory again within a few weeks.

After PVDF (polyvinylidene fluoride) had been identified as a suitable material for the ligament by DynaMesh® (FEG Textiltechnik Aachen / Germany), the method could then be tested in further clinical studies. For this, 413 patients who had not seen successful results using known medications and treatment methods underwent the operation (see diagram). By using simple VARESA (in hysterectomy patients) or CERESA (patients in whom only a part of the uterus is removed), 73 (36.3%*) and 78 (36.8%**) of the women respectively could be healed. The remaining 262 patient developed stress incontinence. In these cases, a TOT was also inserted, as a result further 171 women were healed. In total, 322 out of the 413 patients (78%) were continent and had no symptoms of urge or stress incontinence.

The evaluation of the VARESA studies showed that the routine rectopexy does not have to be performed in the operation (with the exception of faecal incontinence) in VASA / CESA. Additional carefully planned studies should be carried out looking at those patients who were not able to be successfully treated using the new methods. The assumption can be made that female incontinence will be completely curable in a few years.

The aim of the URGE I and URGE II studies is to check and verify the reproducibility of the results. This is done in collaboration with the Gynaecology Clinic at the University of Cape Town (Groote Schuur Hospital). Thereby, the operations are compared with the previous standard methods for treating urge incontinence.

Short profile: Professor Dr Stephen Jeffery

As Head of the Department of Urogynaecology and Pelvic Floor Surgery at the Groote Schuur Hospital in Cape Town, South Africa, Professor Dr Stephen Jeffery is a world renowned expert in the treatment of female urinary incontinence. The focus of his research is new technologies in incontinence surgery, as well as Botulinum toxin and acupuncture in the treatment of urinary disorders. Professor Dr Jeffery's list of publications includes more than 100 publications in international medical journals.

The Groote Schuur Hospital was founded in 1938. The clinic was made famous by the South African doctor Christian Barnard, who carried out the first heart transplant there in 1967. As an academic teaching hospital which is part of the medical faculty of the University of Cape Town, the clinic (with its around 3,700 employees and more than 560,000 referrals per year) has an excellent reputation.

Standard methods of treating female incontinence: a comparison

Professor Dr Stephen Jeffery, Head of the Department of Urogynaecology and Pelvic Floor Surgery at the Groote Schuur Hospital in Cape Town, South Africa

The combination of anticholinergics and pelvic floor training is a common treatment method for incontinence. A number of medications are available on the market, but they almost all have considerable side effects. These side effects are one of the main reasons why less than 20% of patients continue there treatment three months after starting it. According to the results of previous studies, the main reason for stopping treatment is a lack of efficacy. Thirty-two studies determined that the medication had just as little effect as the placebo. A study of 108 incontinent patients carried out at the Groote Schuur Hospital confirmed these results.

Better results are promised through treatment with Botulinum toxin. The nerve poison shuts off neurotransmitters, which means that the walls of the bladder do not receive the instruction to contract. Higher doses show short-term success of 79% within three months, but this success is only seen in 31% after nine months. A complete loss of control of bladder function quickly leads to a large number of patients having to catheterise themselves.

Posterior Tibial Nerve Stimulation (PTNA) and acupuncture have also not shown satisfactory results in the long term. The treatment goals of sacral neuromodulation seem comparatively more easier achievable. Studies have shown a healing rate of 47% after six months, and a significant reduction in loss of urine in a further 29%. However, patients reported pain, technical problems and a lack of comfort, which often necessitated the removal of the neurostimulator.

After intensive work on VASA and CESA, the assumption can be made that the treatment goals of continence can be achieved comparatively easy using these methods.

Development of urge incontinence after a vaginal hysterectomy

Dr Sebastian Ludwig, Gynaecology Clinic at the Cologne University Hospital

Introduction: According to current literature, up to 50% of patients develop urge incontinence following a vaginal hysterectomy.
Method: Retrospective telephone questioning of vaginal hysterectomy patients using a survey on urge incontinence, i.e. frequent urination (>10 times per day) and/or problems retaining urine when there is an urgent need to urinate (<10 minutes).
Results: 48% of the patients we surveyed stated that they had urge incontinence. In 19% of this group, the urge incontinence occurred after the operation, while 29% already suffered from incontinence before the operation. The multivariate analysis showed that the descended uterus, the menopause status (age) and the operation (in pre-menopausal patients) had an effect. While 16% of the patients were urge incontinent without a descended uterus, the percentage of patients with descended uterus was 54%. In pre-menopausal patients, 18% were affected, while in post-menopausal patients this figure was 40%. In this second group, the operation did not lead to any noticeable increase in urge incontinence, but 37% of pre-menopausal patients developed incontinence within three years after a vaginal hysterectomy.
Conclusion: Many patients with a descended uterus also develop urge incontinence at the same time. This cannot be healed with a vaginal hysterectomy. In pre-menopausal women, the vaginal hysterectomy destroys the rear pelvic floor support, which results in the danger of post-operative 'de novo urgency'. Alternative methods such as VASA / CESA can minimise this risk.

VASA and CESA: effects of restored continence

Dagmar Elisabeth Götz, Chair of Geriatric Medicine at the University of Cologne

Introduction: The operative methods VASA and CESA are treatment options for urge incontinence, which has been classified as incurable until now. They lead to continence in 78% of those treated. The positive changes observed post-operatively in cognition and lifestyle need to be determined and documented precisely.
Method: The investigation of the following parameters on 25 continent and 40 pre-operative urge incontinent women: *cognition:* DemTect, *depression:* Geriatric Depression Scale, *lifestyle:* survey on mobility, social activities, sport and exercise. Subsequent to this there was a second test of 25 women with restored continence 16 weeks after VASA / CESA.

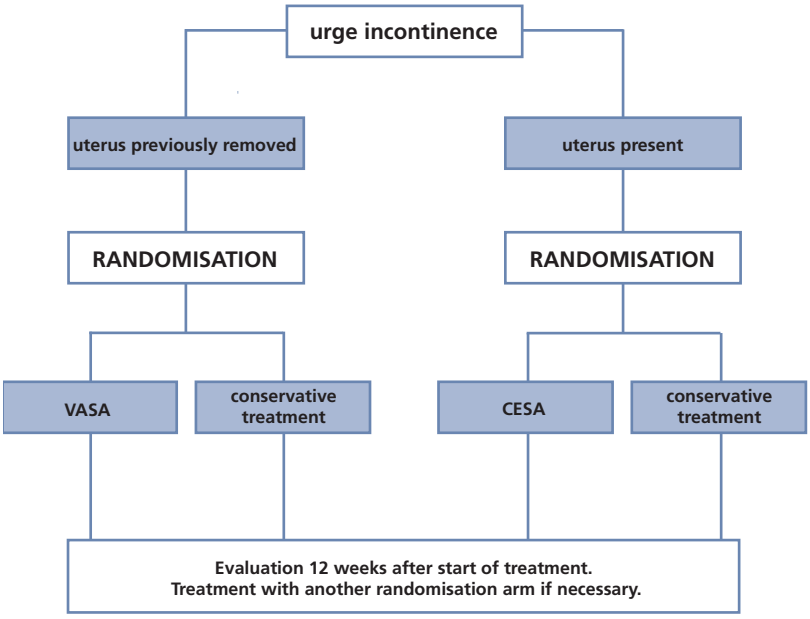
Results:

	pre OP	4 Month post op	control group
mobility	8%	64%	60%
activities	8%	72%	76%
sport + exercise	4%	28%	20%
average depression	48%	12%	16%
cognition appropriate	4%	64%	52%

Conclusion: VASA and CESA induce positive changes in mobility, social activities and depression. An above average occurrence of mild cognitive impairments before the operation decreased later, and made way for age-appropriate cognitive abilities.

Study Design

URGE I



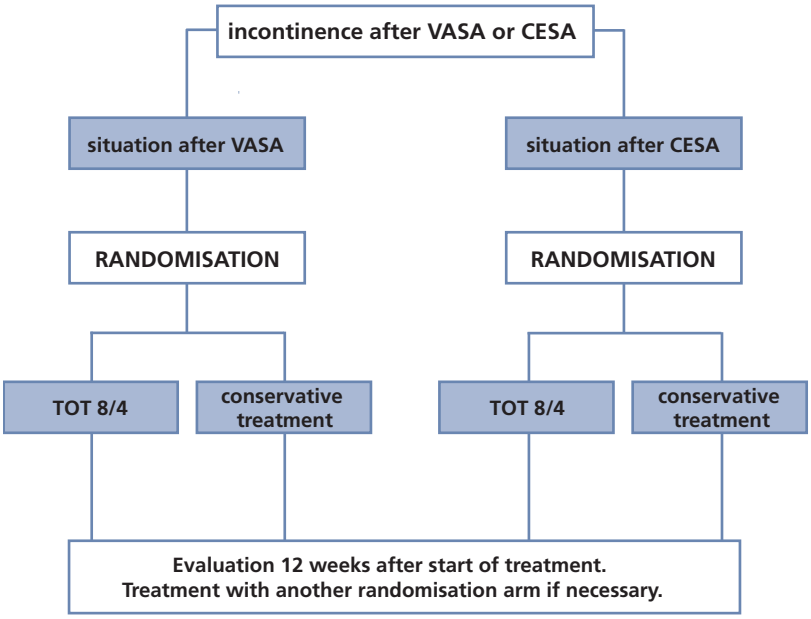
Inclusion criteria

- going to the toilet more than ten times in a day (less than four times a night)
- able to refrain from urinating for less than 10 minutes with an urgent need to urinate

Exclusion criteria

- simple stress incontinence (no symptoms of urge incontinence)
- polynocturia (going to the toilet more than four times a night)
- morbid obesity (> 100 kg)
- neurological/psychological effects of incontinence
- an "active" diagnosis of cancer
- pregnancy
- previous urogynaelogical operations (e.g. inserting mesh, TVT, TOT)

URGE II



Inclusion criteria

- condition according to VASA or CESA
- continued incontinence

Exclusion criteria

- polynocturia (going to the toilet more than four times a night)
- morbid obesity (> 100 kg)
- neurological/psychological effects of incontinence
- an "active" diagnosis of cancer
- pregnancy
- previous urogynaelogical operations (e.g. inserting mesh, TVT, TOT)

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