

Does the Patients Age have an Influence on the Outcome of Cesa (Cervico-Sacropexy) and Vasa (Vagino-Sacropexy) for the Treatment of Urinary Incontinence in Women?

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Abstract

About 40% of all women will develop urinary incontinence during their life, usually starting around the age of 50 years. It usually starts with the spontaneous undesired loss of urine during increased intra-abdominal pressure (coughing or sneezing) and will continue in even shorter time intervals to reach the toilet "just in time". In its ultimate form the patient has no control anymore about her voiding function and is "always wet".

While previously only SUI, the "mild" form of urinary incontinence, could effectively be treated by the replacement of the PUL using suburethral tapes we now have the chance to cure also the moderate and severe forms of urinary incontinence. With the bilateral replacement of the USL by the CESA and VASA operations over 50% of all patients were cured. When the remaining patients received an additional TOT 8/4 the cure rate was increased up to more than 80% of the patients.

We observed that the number of cured patients decreased with increasing age. While patients younger than 60 years have a nearly 90% chance of cure this chance decreases down to 65% for those patients older than 70 years.

The fact that continence could be reestablished by CESA / VASA and a TOT demonstrates that urinary incontinence can be cured through surgery in most patients.

We are not certain which ageing effects were responsible for the diminishing cure rate with increasing age. As all our other calculations did not indicate any responsible factor for this observation, we probably did not measure the responsible factor so far.

Keywords: Urinary Incontinence; Mixed Urinary Incontinence; Urgency Urinary Incontinence; VASA; CESA; Transobturator Tape; TOT; Pelvic Organ Prolapse

Introduction

About 40% of all women will develop urinary incontinence during their life, usually starting around the age of 50 years [1,2]. It usually starts with the spontaneous undesired loss of urine during increased intra-abdominal pressure (coughing or sneezing) and will continue in even shorter time intervals to reach the toilet "just in time". In its ultimate form the patient has no control anymore about her voiding function and is "always wet".

This is a totally debilitating disorder, which massively restricts the social and private life of the affected patient [3]. Every pharmacologic treatment attempts to reduce the urinary incontinence symptoms; however, there was no cure achieved so far [4].

In 1996 Petros and Ulmsten hypothesized that urinary incontinence (UI) in women is caused by the laxity of the anterior vaginal wall [5]. In that respect the pubourethral (PUL) and the uterosacral ligaments (USL) play a major role, as they are a substantial part of the holding

apparatus of the vagina. According to the "bridge allegory" they are the "tows at the pylons which keep the vagina in the correct position" [5,6].

This assumption was supported by the observation that nearly 80% of all women suffering from stress urinary incontinence (SUI) were cured by the replacement of the PUL by suburethral slings [7]. The replacement of the second important ligament—the USL—was not vigorously attempted probably because the operation was considered as to large for an unknown outcome [8].

However, whenever operations, which repaired the posterior part of the "holding apparatus", were performed, also improvements of urgency urinary incontinence were reported – more or less as a surprising side effect [8,9].

We build upon that observation and developed a surgical procedure to replace both (the left and the right) USL and used them in the beginning with patients with genital prolapse (POP-Q stage II to IV) and urinary incontinence (UI) [10,11]. In these CESA (cervicosacropexy) and VASA (vagosacropexy) operations we observed for the first time an absolute cure of UUI in about 70% of these women with UI and genital prolapse. When we performed an additional transobturator tape (TOT) in the remaining patients who were not cured by CESA or VASA alone a cure rate of 90% was

obtained [10]. This high success rate led us to speculate that the replacement of the USL and the PUL could also cure SUI and mixed urinary incontinence (MUI) in patients with less advanced prolapse (POP-Q stage I).

In 2012 we reported about the successful surgical treatment of MUI and urgency urinary incontinence (UUI) using CESA and VASA in these patients [10]. In this study we discussed that 42 patients (32%) of 133 patients with MUI or UUI were cured by these operations. With an additional TOT an overall cure rate of 77% was obtained.

When we started with these operations in 2004 the operations lasted nearly 4 hours and we therefore abstained to operate patients older than 70 years of age and put them on pharmacologic palliative treatment.

However, during the last years the surgical technique was massively changed by giving up routine rectopexy so that the CESA and VASA median operation time was decreased to 90 minutes. Furthermore, when we started using PVDF (polyvinylidene fluoride) tapes, the shrinkage of the polyester tapes, which were used previously, was not observed any longer [12,13].

During the same time period more and more elderly patients were asking for surgical help with their urinary incontinence. We therefore analyzed the outcome of the patients with regard to the group of patients older than 70 years.

Material and Methods

All examinations and surgeries were performed between March 2013 and December 2014 at the Department of Obstetrics and Gynecology at University Hospital of Cologne, Germany. The Age was defined as age at surgery.

Inclusion criteria was an involuntary leakage, accompanied by or immediately preceded by urgency and by mixed urinary incontinence, associated with urgency and also with exertion, effort, sneezing or coughing. Previous urodynamic assessment was not mandatory. All patients had previous pharmacologic treatments and failed success.

Exclusion criteria were stress urinary incontinence (SUI) only, pelvic organ prolapse POP-Q stage \geq II and previous pelvic organ prolapse surgery (sacrospinous fixation, sacrocolpopexy, colposuspension, vaginal or abdominal mesh implantation).

Urinary incontinence – definition and assessment

Urinary incontinence (UI) was classified according to the recommendation of the ICS [14]. Urgency urinary incontinence (UUI) was defined as the complaint of involuntary leakage accompanied by or immediately preceded by urgency, mixed urinary incontinence (MUI) as the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing. Stress urinary incontinence (SUI) was defined as involuntary leakage with exertion, effort, sneezing or coughing.

The assessment of the clinical outcome was obtained 2, 4, 8 and 16 weeks after surgery. All patient examinations were performed at the university hospital.

Cure was defined by the total absence of any urinary incontinence 4 months after surgery. A transobturator tape (TOT 8/4) was indicated when patients were not cured from their urinary incontinence symptoms after CESA or VASA.

Operations

Cervico-sacropexy (CESA) and vagino-sacropexy (VASA)

One day before the surgery the patients had a bowel cleansing as if for a colonoscopy. Before surgery cephalosporin was administered as a single dose injection.

The cervico-sacropexy (CESA) and vagino-sacropexy (VASA) surgical techniques have been described in detail (www.cesa-vasa.com). These are open abdominal surgical treatments described by Jager et al. [10,11]. In brief, specially designed polyvinylidene fluoride (PVDF) tapes (Dynamesh CESA, Dynamesh VASA, FEG Textiltechnik mbH, Aachen, Germany) were used to replace the uterosacral ligaments (USL) (Figure 1).

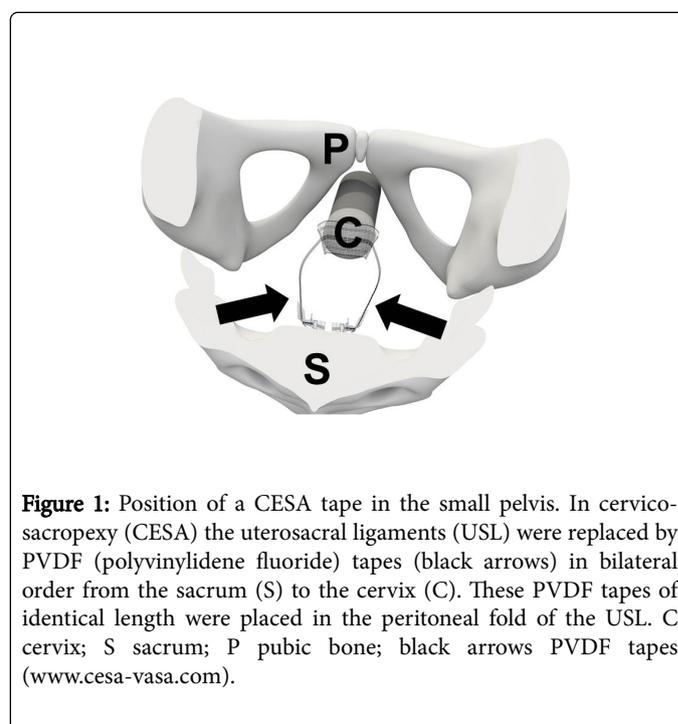


Figure 1: Position of a CESA tape in the small pelvis. In cervico-sacropexy (CESA) the uterosacral ligaments (USL) were replaced by PVDF (polyvinylidene fluoride) tapes (black arrows) in bilateral order from the sacrum (S) to the cervix (C). These PVDF tapes of identical length were placed in the peritoneal fold of the USL. C cervix; S sacrum; P pubic bone; black arrows PVDF tapes (www.cesa-vasa.com).

CESA was performed in patients with a uterus. After supra-cervical hysterectomy two PVDF tapes, with a length of 8.8 cm, were placed in the peritoneal fold of the USL, in bilateral order from the rectum [15]. The tapes were attached distally on the cervical stump and proximally to the presacral fascia in front of the S1 / S2 sacral vertebra by non-absorbable 2-0 sutures (Figure 2).

In patients with previous total hysterectomy, VASA were performed using two PVDF tapes of 9.3 cm length. These were placed at the vaginal stump on top of the vaginal cuff scar.

Transobturator tape (TOT 8/4)

The transobturator tape (TOT) was placed outside-in, following the method of Delorme [16]. In order to standardize the suburethral placement a Hegar dilator size 8 mm was placed in the urethra and a Hegar dilator size 4 mm was placed between the tape and the urethra (TOT 8/4) [17]. Thereafter, the transobturator tape was pulled tight; the Hegar dilators were removed just before the last stitch when the anterior vaginal wall was sutured. Ethical approval for this study was obtained.

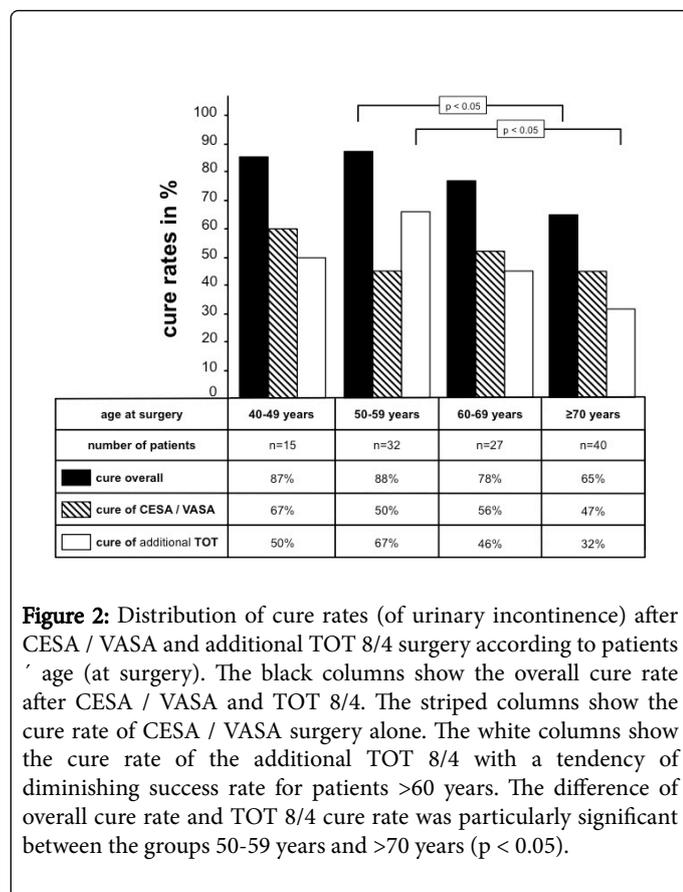


Figure 2: Distribution of cure rates (of urinary incontinence) after CESA / VASA and additional TOT 8/4 surgery according to patients' age (at surgery). The black columns show the overall cure rate after CESA / VASA and TOT 8/4. The striped columns show the cure rate of CESA / VASA surgery alone. The white columns show the cure rate of the additional TOT 8/4 with a tendency of diminishing success rate for patients >60 years. The difference of overall cure rate and TOT 8/4 cure rate was particularly significant between the groups 50-59 years and >70 years ($p < 0.05$).

Statistical Analysis

According comparisons were done by U-Mann-Whitney-test or Chi-square-test. Significance level was set at 5%, analyses were executed with IBM SPSS Statistics version 22 (SAS Institute Inc., Cary, NC, USA).

Results

Within this study period 114 patients have been operated by CESA or VASA. We separated these patients into 4 groups according to their age: 40-49 years, 50-59 years, 60-69 years and older than 70 years (≥ 70 years) (Figure 2).

The overall cure rates between the age groups were decreasing with age. While close to 90% (40-49 years $n=13$; 50-59 years $n=28$) of the patients <60 years were cured, the respective percentages decreased down to 65% ($n=26$) of the patients ≥ 70 years. This difference reached the level of statistical significance (Figure 2).

The number of patients <70 years cured by CESA and VASA alone were between 50% and 67% (40-49 years $n=10$; 50-59 years $n=16$; 60-69 years $n=15$). Out of the group of patient ≥ 70 years, 47% ($n=19$) were cured after CESA and VASA (Figure 2).

The limited number of patients who received an additional TOT 8/4 were cured in between 32% and 67% (40-49 years $n=3$; 50-59 years $n=12$; 60-69 years $n=6$; ≥ 70 years $n=7$), with a tendency of diminishing success rate for patients >60 years. According to the statistical analysis

the difference was significant between the patients <60 years and the patients >70 years (Figure 2).

Discussion

While previously only SUI, the "mild" form of UI, could effectively be treated by the replacement of the PUL using suburethral slings we now have the chance to cure also the moderate and severe forms of UI. With the bilateral replacement of the USL by the CESA and VASA operations over 50% of all patients were cured. When the remaining patients received an additional TOT 8/4 the cure rate was increased up to more than 80% of the patients.

However, we observed that the number of cured patients decreased with increasing age. While patients younger than 60 years have a nearly 90% chance of cure this chance decreases down to 65% for those patients older than 70 years. According to the statistical analysis this difference was probably not caused by chance; however, because of the still limited number of patients we consider this not to be the final result but rather a tendency.

When we asked ourselves for an interpretation of this result we mainly came up with two assumptions:

Firstly, this overall decrease in clinical success rate was observed in CESA and VASA as well as in TOT 8/4. The statistical difference in the overall cure rate was mainly caused by a diminished success rate of the TOT in the elderly.

We knew that the standard TOT placement resulted in distances between urethra and tape between 1 and 10 mm [18].

Therefore we had developed a surgical technique to get a standardized distance between tape and urethra. Using this TOT 8/4 procedure 83% of all tapes were placed in a distance between 3 and 5 mm [17].

The fact that all patients were operated with defined surgical procedures – identical lengths of USL tapes and defined distance between suburethral tape and urethra - led to the assumption that the difference in outcome did not depend on the surgical treatment itself.

Secondly, the analysis of all our documented data could not delineate the responsible factor(s) for the different clinical outcome. Hence, we assume that other aspects, that have not been observed so far, must be responsible for the outcome.

We have to take into consideration that with the depletion of circulating estrogens with increasing age the internal genitalia shrink remarkably. In that respect it was interesting to note that most of the cured elderly women at the age of 70 years had hormone replace therapy (HRT) until the age of 65 years. We therefore hypothesize that estrogens have an important "side"-effect in that respect.

Furthermore, our telephone interviews with these patients, which we performed on an annually basis after surgery revealed that several of the elderly patients who could not be cured by CESA or VASA and TOT 8/4 had developed dementia within this short time period after surgery. Therefore, central neurogenic aspects of incontinence may play an important role for these patients. We therefore decided to perform a mini-mental state examination in all patients before surgery.

Our results demonstrated that also moderate and severe forms of urinary incontinence can be cured through surgery. The fact that continence could be reestablished by CESA / VASA and a TOT

demonstrates that urinary incontinence can be cured through surgery in most patients.

We are not certain which ageing effects were responsible for the diminishing cure rate with increasing age. As all our other calculations did not indicate any responsible factor for this observation, we probably did not measure the responsible factor.

The advantage of the CESA and VASA operation techniques as well as the TOT 8/4 is the standardization of every surgical step. This will offer pelvic surgeons the chance to repeat these operations and thereby prove our findings. Beside the cure of patients the then achieved absolute comparability of all studies using the same concept will definitively improve our knowledge about ageing and the development of urinary incontinence and help us to further improve cure rates.

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