

continue to suffer from incontinence symptoms due to feeling ashamed of their condition or having heard of negative, unfavourable experiences.

- This study also aimed at establishing priority among trans-vaginal, trans-abdominal or combined operations. Our decisions were primarily guided by patients' other gynaecological conditions. Various combinations of operations were opted for if patients had had bleeding abnormalities, myomas, vaginal wall or vaginal stump prolapse as accompanying the incontinence.

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Kimondhatatlan köszönet a *családomnak*, akik nélkül soha nem jutottam volna idáig.

Lower Pelvic Corrective Operations in Females with Urinary Incontinence and their Effect on Quality of Life

Ph.D. Theses

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1. Introduction

Urinary incontinence in females can be considered a public health issue. Research has established that considering the female population urinary incontinence occurs in 5% of patients in their 40s, 10% in women in their 50s and in 25% or more among patients over 60 causing severe complaints. When exactly can we speak about urinary incontinence? *Incontinentia urinae* is the involuntary, objectively demonstrable loss of urine via the urethra resulting in social and hygienic problems.

Several types can be distinguished: the most common is the *stress incontinence* affecting 50% of patients. In this case loss of urine occurs as a result of physical activity or sudden increase in the abdominal pressure (coughing, laughing, stepping up or down stairs, running, physical exercise). Intra-vesical pressure caused by the increased intra-abdominal pressure exceeds the maximal closing pressure of the urethra. The other most common form of urinary incontinence is the so-called *urge incontinence*. This includes approximately 20% of the cases and is characterised by an irrefractable urge to urinate accompanied by loss of urine with normal function of the sphincter muscle in the majority of cases.

The third type is the *mixed incontinence* likewise accounting for 20% of cases combining the symptoms of the two above.

A less frequent type is the so-called *reflex incontinence* which is responsible for 5% of cases and is the result of a neurogenic condition or disease. *Overflow incontinence*, lying in the background of another 5% of cases, is due to an overfilled bladder as a result of lower urinary tract obstruction. Surgery is required in case of stress incontinence if perineal reeducation, pelvic floor muscle exercises, biofeedback and electrical stimulation prove unsuccessful. More than a hundred types of anti-incontinence operations are known which can be put into the following 3 groups:

- trans-vaginal (colpoperineorrhaphy, colporrhaphy ant., Szemesi plasty, TOT etc.)
- trans-abdominal (colposuspension sec Burch, colpopexy and laparoscopic versions of these etc.)

- combined (Gittes, Stamey, Raz,TVT etc.)

These operations can be combined with other types of interventions. On our ward we have most frequently combined abdominal hysterectomy and colposuspension with Burch operation, the Neugebauer- LeFort operation closing the vagina with Gittes' colposuspension operation. We have also combined endoscopic interventions, namely the laparoscopic ventrosuspension with Gittes' colposuspension. In cases of mixed incontinence medication is also recommended besides the above operations in order to eliminate patients' symptoms. Anticholinergic drugs were most often administered in patients with urge incontinence, however, Ca-channel blockers, antidepressants, alpha-adrenoreceptor agonists, beta-adrenoreceptor agonists, vasopressin-analogues, oestrogens etc. may also be considered.

Behavioural therapy, with the cooperation of the patient, also plays a role in conservative treatment involving bladder training for strengthening and coordinating muscles of the bladder and urethra, in order to facilitate the control and delaying of urination.

Electrical stimulation can also prove beneficial by strengthening the muscles of the pelvic floor and reducing the hyperactivity of the detrusor.

2. Aims

At the Department of Obstetrics and Gynaecology of Baranya County Hospital, we have been performing several types of anti-incontinence operations since 1996.

These surgical interventions had the following aims:

- to establish the efficacy and duration of these types of interventions
- to determine complications and how these could be prevented or avoided
- to see if we are able to achieve the same results as published in international literature
- to see which types of operation prove most satisfactory among patients, and how these change their quality of life
- whether trans-abdominal, trans-vaginal or combined techniques yield better results.

3. Patients and Methods

3.1. Patient Examination

We have been performing anti-incontinence operations at our department since 1996. Initially, patients were examined according to the protocol assigned. A *detailed history* was taken in every case including previous gynaecological or obstetric events (e.g. spontaneous or induced abortions, deliveries, surgeries). Thereafter, patients were asked detailed questions about their gynaecological complaints and were asked to fill in a slightly modified *Gaudenz-questionnaire* in order to help us decide the type of incontinence (stress, urge, mixed) the patients were most probably suffering from. Subsequent *gynaecological examinations* revealed if there were anatomical problems present in the background (e.g. cystocele, rectocele, descence, prolapse). Oncocytological smears were taken at this stage if patients had no valid tests.

Inserting a graded Foley catheter into the bladder allowed us to *measure the length of the urethra* which normally is around 4 cm. Subsequently, the *Bonney and Valsava stress tests* were performed. In case the Bonney test proved positive patients were asked to cough upon which urine leakage ceased when bladder neck was lifted with fingers.

The Valsava test was considered positive if the vatta-tupfer positioned in the urethra moved 30° from the horizontal baseline position when the patient started to push.

Thereafter, an *ultrasound* was carried out (Siemens SI 450, 3.5 MHz with convex head) during which the patients were asked to press resulting in a 3 cm sinking of the bladder base in a pathological case.

Finally, we asked for a *bacteriological urinalysis* and started the patients on a course of antibiotics if results were positive.

Patients were administered 3x1 mg estriol (Ovestin) daily for 2 weeks before and after the operation. *Urodynamic examination*, i.e. the functional examination of the lower urinary tract, was performed if incontinence recurred or a TVT operation had been planned.

3.2. Surgery

Colpoperineorrhaphy

Between 1996-2007, 345 colpoperineorrhaphies (vaginoplasty) were performed at the Department of Obstetrics and Gynaecology of Baranya County Hospital. The average age of patients was 62 years (the youngest 42, the oldest 81). Operations were performed in 334 cases (97%) under laryngeal-mask anaesthesia and in 11 cases (3%) under spinal anaesthesia. Indications were cysto-rectocele and accompanying stress incontinence.

Gittes' Operation

The Gittes operation was performed in 42 cases at our department, out of which 13 were combined with laparoscopic ventrosuspension and 15 with Neugebauer-LeFort. The average age of patients was 59 (the youngest 45, the oldest 76). 27 (64%) patients underwent the operation under spinal anaesthesia and 15 (36%) under intra-tracheal narcosis. The Gittes operation alone sufficed in patients having had previous vaginoplasty but recurrent symptoms and ongoing incontinence.

Gittes and Neugebauer-LeFort Operations

The combination of the two surgical interventions was performed in 15 patients under spinal anaesthesia. Patients had uterine prolapse of 3rd or 4th grade – had no active sexual life – but insisted on retaining their uteri. In these cases previous curettage was carried out and the operations were performed if cytology proved negative. Firstly, the previously mentioned Gittes operation was performed followed by the Neugebauer LeFort technique.

Laparoscopic Ventrosuspension and Gittes' Operation

The two techniques together were indicated in 13 cases, in patients having uterine prolapse of 3rd or 4th grade but insisting on retaining their uteri. All interventions were performed under intra-tracheal narcosis.

Burch Operation

Burch's colposuspension has been carried out in 65 cases at our department since 1997, out of which 36 were combined with abdominal hysterectomy (due to hypermenorrhoea, dysmenorrhoea or myomas) and 17 with vaginal stump fixation. Vaginal hysterectomy had been performed in 10 cases and abdominal hysterectomy in 7 cases prior to the development of vaginal stump prolapse. The condition resulted from inadequate fixation of the vaginal stump or connective tissue weakness accompanied by stress incontinence. The average age of patients was 55 years (the youngest 46, the oldest 63). Burch operation alone was carried out in patients whose stress incontinence was caused by -as tests verified- hypermobility of the urethra. All operations were performed under intra-tracheal narcosis.

Abdominal Hysterectomy and Burch Operation

The 36 operations performed so far have all been carried out under intra-tracheal narcosis. This was indicated by recurrent bleeding abnormalities and myomas in the uterus beside stress incontinence.

Vaginal Stump Suspension and Burch Operation

The combination of these two procedures was performed in 17 patients under intra-tracheal narcosis, where patients had developed prolapse of the vaginal stump and incontinence. In 7 cases abdominal in 10 cases vaginal hysterectomy had previously

been carried out and the condition resulted from inadequate fixation of the vaginal stump or connective tissue weakness.

TVT (Tension-free Vaginal Tape) Operation

Due to insufficient financial support from the OEP in the recent years we could only perform 20 TVT operations at the department. Patients having had recurrent stress incontinence as verified by previous urodynaemic tests, and bladder neck failure underwent the procedure under spinal anaesthesia. The average age of patients was 62 years (the youngest 55, the oldest 73). Gynacare TVT is a tension-free tape with a net-like structure which is surgically inserted via the vaginal wall in order to provide support for the bladder neck and the urethra.

4. Results

At our department 345 *colpoperineorrhaphies* have been performed since 1996, which account for 73% of all anti-incontinence operations. The most common post-operative complication was the development of cystitis in 62 cases (18%). The second most common complication, in 40 cases (11.5%), was difficulty voiding urine in the post-operative period. In order to exclude the presence of lower urinary tract obstruction, cystoscopy was performed which revealed narrowing of the urethra in 4 cases. Consequently, Stoeckel-stitches in the anterior wall of the vagina had to be removed. Administering 60mg pyridostigmine (Mestinon) 3 times daily successfully resolved symptoms of dysuria of the other 36 patients.

- Patients complained of no incontinence on the control examination after 4 weeks.
- We could collect sufficient data only from 269 (78%) patients on the 12-month control. 71.7% (193) of patients were able to control their bladder well. 28.3% (76) patients developed incontinence to various degrees. Anatomical changes (cystocele) developed in 41% (31) of these patients. Only 14 patients agreed to undergoing the

recommended anti-incontinence operations. Gittes operation was performed in 5, TVT in 5 and Burch in 4 cases.

- 45% (155) of the originally operated patients appeared on the 5-year control examination. 57% (88) of them had no symptoms. Mild, moderate or severe incontinence developed in 43% (67) of patients repeatedly. Subsequently, 32 patients (48%) volunteered to have another operation, primarily those who were suffering from moderate or severe recurrent incontinence. Following detailed examinations and preparation we performed different anti-incontinence interventions: Gittes in 9, Burch in 8 and TVT in 15 cases.

During the period under investigation 42 *Gittes operations* were carried out on our ward. Bladder injury occurred in 4 cases (9.5%) upon inserting the needles during the procedure which were detected during control cystoscopy. Inflammation around the symphysis developed in 3 occasions (7.1%) in the early post-operative stage. In these cases 3x625mg Amoxicillin, Clavulanic acid (Augmentin) and 3x25mg Diclofenac (Voltaren) were administered, consequently symptoms ceased. In this period, as a result of catheterisations and cystoscopies during the operations acute cystitis developed in 5 (12%) cases. On the day after surgery, following the removal of the catheter (Lolcy) 2 (4.7%) patients developed anuria. Cystoscopy performed to exclude lower urinary tract infection proved negative. Since medication therapy (3x60mg pyridostigmine [Mestinon]) could not resolve the problem, a suprapubic drain had to be inserted. The drain remained in the bladder for 2 days until residual volume was below 50 ml. Thereafter, patients regained normal urinary functioning.

- On the 1-month control examination the 12 patients who had had Gittes' operations had no complaints of incontinence. Three patients complained of mild abdominal pain due to the tense 'hook-stitches'. Pain management (3x500 mg Metamizole sodium [Panalgorin]) proved effective.
- Out of the 13 patients who had had operations combined with ventrosuspension 5 (38.5%) complained of abdominal pain. This number is also due to suspension stitches put in during the laparoscopic procedure.

- Out of the 15 patients having undergone Gittes colposuspension combined with the Neugebauer-LeFort operation 5 (33.3%) complained of lower abdominal pain on the control examination 1 month after surgery. Complaints ceased as a result of the above analgesic therapy.

- 39 patients came for the 12- month control. By this time 6 patients (15.3%) complained of incontinence symptoms. They reported weight loss of more than 10 kg during the past year which could cause the symptoms since suspension stitches could loosen as a result of a thinner abdominal wall. Patients who had had Gittes operations combined with ventrosuspension (13) had a well-positioned uterus on palpation and did not complain of pain or incontinence.

- We could register the data of only 30 (71%) patients on the 60-month control examination. 21 (70%) of them did not have any complaints of incontinence. 30% (9) patients complained of incontinence symptoms but refrained from having further surgery due to the mild stage of incontinence and bad internal medical condition.

Since 1997, 65 *Burch operations* have been performed at our department. During these operations bladder injury appeared twice (3%) which were immediately noticed and treated with multi-layer stitches. In the post-operative stage 10 (15.3%) patients developed acute cystitis which was successfully eliminated by targeted antibiotic therapy. Temporary urge incontinence occurred in 3 (4.6%) patients in the early post-operative stage which was eliminated by the administration of anticholinergic medication (3x4.5 mg Oxybutinin [Uroxal]).

- On the 1-month control examination 5 (7.6%) patients complained of lower abdominal pain due to colposuspension stitches. Complaints ceased upon the administration of non-steroidal anti-inflammatory medication (3x25mg Diclofenac [Voltaren]). On palpation the anterior wall of the uterus was in a well-fixed position, the operation area was healed per primam.

- 59 patients came for the 12- month control. Only 6 (10.1%) patients complained of occasional mild incontinence upon heavier physical exercise.

- We could register the data of 45 (69%) patients on the 60-month control examination after the operations. Incontinence recurred in 9 (20%) cases out of which

6 were mild and 3 were in a moderate stage. In case of patients with a mild incontinence the uterus or the vaginal stump were well in position and provided a sufficient support for the bladder base. The development of rectocele could already be observed in 5 (11.1%) patients among those who appeared on the examination, in these cases the Moschowitz operation was performed.

Following the 20 *TVT (tension-free vaginal tape) operations* one patient developed post-operative incontinence. As described above, cystoscopy was carried out in order to exclude lower urinary tract obstruction. Since the problem could be eliminated by the administration of 3x60mg Pyridostigmine (Mestinon) the condition was not the result of the excessively tense and tight implantation of the TVT tape. The most common complication was acute cystitis.

It occurred in 3 (15%) out of the 20 cases and was eliminated by targeted antibiotic therapy.

Urgent incontinence following colposuspension was less frequent, we had 2 (10%) such cases postoperatively. Complaints of these patients could be eliminated by the administration of 3x4.5 mg Oxybutinin (Uroxal) for a couple of days.

- On the one-month control examination we had 3 (15%) patients complaining of lower abdominal pain. They had no other complaints, reported no recurrent incontinence, fever or cystitis.

- On the one-year control examination only 2 (10.5%) patients out of the participating 19 mentioned mild occasional incontinence upon strenuous physical activity.

- We have not had any patients coming for the 60-month control since this period of time has not been over yet. Therefore, it is not yet possible to report about the efficacy and success of the TVT operation after a 5-year interval.

5. Effects of Treatment on Quality of Life

One year after the operation 76.6% of patients, five years after the operation 63% of patients reported as having experienced positive changes in their quality of life due to successful surgery. This meant that they did not have complaints of incontinence,

were passing urine 3-4 hourly and the urge to void urine did not wake them up during the night. After a year 386 patients presented on the control examinations 39 of them (10.1%) reported as having symptoms of mild incontinence. Nevertheless, since the condition of these patients had also improved considerably as compared to the preoperative state, they also reported positive changes in their quality of life.

On the 12-month control examination 51 (13.2%) patients complained of having moderate or severe incontinence. They were experiencing leakage upon sneezing, laughing or coughing and had to wear incontinence pads continuously. Fourteen of them agreed to undergo different anti-incontinence treatment (5 Gittes, 4 Burch, 5 TVT operations). The other 37 patients (9.5%) refrained from further surgery. Unless contraindicated, Ovestin (3x1 mg estiol daily) was prescribed for them that helped eliminate complaints.

We were able to collect and analyse the data of 230 patients on the 5-year control examination, out of them 85 (37%) complained of symptoms of incontinence. Twenty (8.7%) mentioned having mild incontinence, experiencing symptoms of leakage upon strenuous physical activity. They did not have urinary frequency during the night, did not need incontinence pads constantly and 75-85% of them considered surgery successful.

Further anti-incontinence operations were performed on 32 (13.9%) patients, these were: 9 Gittes, 8 Burch and 15 TVT operations. Thirty-three (14.3%) patients decided against repeated surgery upon reasons like ongoing other conditions and fear of another unsuccessful procedure. These patients considered the interventions unsuccessful, their incontinence prevailed and had to wear pads constantly. On the whole, we may conclude that successful or mostly successful surgical interventions resulted in positive changes in patients' quality of life in 72-82% of cases.

6. Conclusion

Regarding the aims of the study the following conclusions can be drawn concerning the anti-incontinence operations performed:

- The effectiveness of colporrhaphy at our department after 1 year was 71.8%, after 5 years 57%. This result corresponds to that achieved by others with the same therapy. The most frequent complications were acute cystitis and incontinence the occurrence of which we were not able to prevent, but could solve with adequate medication or the removal of Stoeckel stitches.

- Gittes operations showed a 84.7% effectiveness after one year and a 70% effectiveness after 5 years which is significantly higher than data published in international literature. Bergman and Kondo reported 35-43% effectiveness after a 5-year follow-up. The above significant difference can be attributed to us placing the hook-stitches into the fascia of the m.recti abdominis thereby providing a more stable suspension for the anterior wall of the uterus. The most common complications during or after surgery, were the development of cystitis, bladder injury, periostitis around the symphysis and lower abdominal pain later on. However, timely diagnosis and adequate medication therapy helped us eliminate the complaints soon.

- The most up-to-date and efficacious types of anti-incontinence operation at present are the Burch and TVT operations, the outstanding effectiveness of which we could also experience. Our results, namely the 89.9% and 89.5% effectiveness after one year, further support this claim. In case of the Burch operation, the effectiveness after a five-year follow-up was 80%. A 60-month control result cannot yet be reported on since the required time has not been over. We can mention however, the development of a small number of complications such as lower abdominal pain, temporary post-operative urge incontinence, which could be treated by conservative therapy.

- Regarding changes in patients' quality of life, based on control interviews, we can assume that patients whose incontinence did not recur – 76.6% after a year and 63% after 5 years – and complaints ceased have been satisfied with their much improved quality of life. Even patients who redeveloped mild post-operative incontinence and have to wear pads consider their post-operative life quality as much better. These patients widely supported anti-incontinence operations among friends and relations. Unfortunately, however, the majority of patients avoid visiting a specialist and