

**UNIVERSITY OF MEDICINE
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ABSTRACT

**TRANSVAGINAL COLPO LIGAMENT SUSPENSION WITH
ALLOPLASTIC IMPLANT MATERIALS IN THE
TREATMENT OF FEMALE GENITAL PROLAPSE**

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Summarized contents of the thesis

- Introduction Objectives
- Chapter I – Genital static disorders
 - Comparative anatomy notions
 - Genito-pelvic topographical anatomy and the pelvic-perineal plancher
 - Stato-dynamic consequences of the functional and lesional abnormalities
 - Clinical Aspects
- Chapter II – Techniques and surgical procedures more frequently used to treat utero-vaginal prolapse
 - The fold under the cervical urethra
 - Anterior coporrhaphy
 - Colpoperineorrhaphy with high myorrhaphy of the anal lifters
 - Anterior fold of the parameters (Crossen)
 - Triple operation from Manchester (the procedure Fothergill)
 - Spalding-Richardson combined operation
 - Vesicoureteral vaginal interposition of the uterus (the procedure Watkins-Wertheim-Schauta)
- Chapter III – Total vaginal hysterectomy
- Chapter IV – Other types of surgery for utero-vaginal prolapse
 - Modern endoscopic methods/HTV laparoscopic assisted
 - Colpocleisis
 - Vaginal stump prolapse
 - Hypertrophic elongation of the cervix
 - Old perineal tears
- Special part – Personal contributions
- Chapter V – Material and Method
- Chapter VI – Results
- Chapter VII – Discussions
- Chapter VIII – Conclusions
- Bibliography

Introduction

Objectives

The descent of the uterus into the vagina and outside the axis is accompanied by the movement in the same direction of the vagina walls, adjacent portion of the bladder and rectum, defines the uterine-vaginal prolapse.

The pathology is an attribute of multiparous women and occurs predominantly in the third age groups.

My research focused on the reevaluation of utero-vaginal prolapse cases hospitalized in two clinics of obstetrics and gynecology in Germany, St. Marien of Borcken in 2012-2013, 156 cases and Santa Barbara in Attendorn, current Helios in 2009-2013, 367 cases; studying a total of 523 cases.

There are described three degrees of utero-vaginal prolapse, according to the uterine descent. For the correct classification of prolapse it is assessed the situation of the uterus in upright and gynecologic position. It is important to detect the association of stress urinary incontinence, pathology which can be masked by the utero-vaginal prolapse. It is also important to detect the association or coexistence with other pelvic-genital lesions (cervical dysplasia, cervical cancer, hypertrophic endometrial lesions, adenocarcinoma of the endometrium, single or multiple uterine fibromyomas, benign or malignant ovarian herd).

Their presence precludes simple surgery, being required complex, particular treatments.

Are taken into account the eventual general diseases associated in order to establish the anesthetic and operational risks: cardiopathies, hypertensive disease, respiratory disorders, renal disease, obesity, coagulopathy, diabetes, collagen diseases, spinal injuries, coxarthroses.

Most cases operated were classified in grade III - total genital prolapse.

In the USA 1/3 women and in the UK 1/5 women have in antecedents hysterectomy practiced before the age of 60 years. In the Netherlands 1/3 women have throughout the life hysterectomy.

Since the period 2002-2008, Schaffer noted in the USA 23% total vaginal hysterectomies, 65% total abdominal hysterectomies, 10% laparoscopic assisted hysterectomies, 2% total hysterectomies.

In Britain after 1990 to about 200 total hysterectomies practiced annually in a specialized department, 12-14% are total vaginal hysterectomies. (7.12)

In all studies predominates abdominal hysterectomy compared with vaginal hysterectomy, total hysterectomy compared to subtotal hysterectomy. In both ways of approach the main problem remains the innervation interception which is affected before reaching the detrusor bladder on the occasion of the vesicouterine fold takeoff. Paravaginal excessive tissue dissection affects the vascularization and area innervation. This was one of the reasons that determined the promotion of laparoscopic-assisted hysterectomy or robotic surgery.

For the prophylaxis prolapse of the vaginal stump are schools that have introduced the systematic use of meshes alloplastic (polypropylene) substances for vaginal colpo - sacral - ligamento – pexy, the main objective of my dissertation paper.

Material and Method

The operative technique - transvaginal colpo-ligamento-suspension with alloplastic implant materials

1. Anterior Vaginal Wall Incision
 - If desired, inject local anesthetic/vasoactive solution;
 - Make a 2-3 cm midline incision on anterior wall starting from bladder neck moving toward the apex.
2. Anterior Wall Dissection
 - Dissect underneath the pubo-cervical fascia utilizing full-thickness dissection technique up to the level of the apex ensuring that the vagina is completely dissected off of the bladder to minimize the likelihood of ureter kinking or obstruction;
 - Utilize blunt dissection to maintain dissection in the same plane;
 - Dissect toward ischial spine and palpate with index finger bilaterally.
3. Clearing the Sacrospinous Ligament
 - Sweep medially approximately 2 cm from the ischial spine along the sacrospinous ligament;
 - Perform technique for both patient right and left sides.
4. Loading the Anterior Fixation Tips
 - Holding the anterior fixation tip for stability, load the anterior fixation tip onto the pink handled anterior needle.
 - Ensure the anterior fixation tip is seated and aligned on the needle.
5. Inserting the Anterior Fixation Tips
 - Aim the anterior needle tip towards the obturator foramen approximately 1 cm medial to the ischiopubic ramus while holding the needle curve against the index finger. The needle trajectory / alignment should be such that it is horizontal to the bladder neck;
 - Using a lateral arcing motion, guide the anterior needle around the backside of the ischiopubic ramus. Once beyond the ischiopubic ramus, pivot the handle such that it passes through the saggital and midsaggital planes to ensure the anterior fixation tip approaches perpendicular placement into the obturator internus muscle. Advance the needle until the blue midline marker is aligned with the vaginal incision. The handle should move towards the patient's contralateral leg. A tactile sensation may be felt as the interior fixation tip penetrates the obturator internus muscle.
6. Mesh Trimming and Suture Placement
 - Trim the apical end of the mesh body to the desired length based on the patient's anatomy. Ensure the mesh lays flat and covers the entire defect;
 - Place sutures at the vaginal apex leaving suture ends on the patient's abdomen for later attachment to the mesh.
7. Loading the Apical Fixation Arms and Sheath
 - Insert the apical needle into the self-fixating tip on an apical fixation arm ensuring that the tip of the needle is visible through the end of the self-fixating tip;
 - Insert the apical needle with apical fixation arm attached into the plastic sheath with the small window closest to the handle. Ensure the entire fixation arm is covered by the sheath;

- Slide the plastic sheath down the apical needle until a click is heard or the sheath is locked to the needle;
 - Verify the plastic sheath is secure and the needle tip does not protrude from distal end of sheath.
8. Positioning Apical Needle
- Locate the sacrospinous ligament by palpation;
 - While keeping palpating finger on the sacrospinous ligament, guide the tip of loaded apical needle and sheath alongside and lateral to the finger towards sacrospinous ligament;
 - For patient left, hold the apical needle in the 5 o'clock position and for patient right, hold the needle in the 7 o'clock position.
9. Inserting the Apical Fixation Arms
- Place tip of the plastic sheath at the base of the palpating finger such that it is perpendicular and on the caudal side of the sacrospinous ligament 2 cm from the ischial spine. Hold the handle at the level of the clitoris (parallel to the floor or slightly higher to ensure correct placement). With your index finger, press the release mechanism on handle of the apical needle. Keeping the release mechanism pressed, drive the apical needle and apical fixation tip into the sacrospinous ligament. Finger palpation may be used to confirm correct placement of the apical fixation tip in the sacrospinous ligament.
10. Removing Sheath and Needle
- Remove the apical needle and sheath by pulling back gently on the needle until it disengages from apical fixation tip;
 - Pull gently on apical fixation arm to ensure that arm is securely fixed in the sacrospinous ligament;
 - Press the release mechanism on the handle of the apical needle and disengage sheath;
 - Repeat on contralateral side switching to contralateral side for all directional instructions;
 - If desired, you may perform cystoscopy at this time to inspect for bladder damage or perforation and verify ureter function.
11. Sliding Mesh over Fixation Arms
- Locate one of the loose eyelets on the mesh body and slide the apical fixation arm anchored on the same side through the center of the eyelet. From the top side of the mesh, gently pull the apical fixation arm through the eyelet. Repeat on contralateral side;
 - Locate one of the loose eyelets on the mesh body and slide the apical fixation arm anchored on the same side through the center of the eyelet. From the top side of the mesh, gently pull the apical fixation arm through the eyelet. Repeat on contralateral side.
12. Position and Adjust Mesh
- Insert the end of either apical fixation arm through tip of the adjustment tool;
 - Hold the apical fixation arm medially within the introitus and slide adjustment tool down the apical fixation arm toward the mesh pushing into the pelvic cavity;
 - Slide the mesh body down the apical fixation arms until desired position is obtained;
 - Check for desired tension on mesh;
 - To loosen the mesh, grab the center mesh and pull towards introitus.
13. Deploying the Locking Eyelets

- Once final mesh placement has been achieved, attach the female end of eyelet applicator into the end of either apical fixation arm;
 - Slide one locking eyelet onto an apical fixation arm at least 2 cm and disengage eyelet applicator;
 - Load locking eyelet on other apical fixation arm.
14. Final Tensioning
- Using the adjustment tool and alternating sides throughout the process, slide the locking eyelets down the apical fixation arms into the pelvic cavity while maintaining medial positioning within introitus;
 - Continue advancing the locking eyelets down apical fixation arms until they reach the mesh;
 - Palpate to verify locking eyelets are resting against the surface of the mesh and desired tension has been achieved. If not, readjust with the adjustment tool;
 - Perform a vaginal exam to ensure that the mesh is appropriately tension free.
15. Trim Fixation Arms
- Trim apical fixation arms so at least 1 cm of mesh extends past the locking eyelet;
 - Verify that discarded portion of the apical fixation arm contains mesh on the end. If not, locate and trim remaining stem while maintaining required length of mesh.
16. Anterior Wall Management
- Completely close vaginal incision with your choice of suture;
 - Insert vaginal packing;
 - If cystoscopy has not been performed, using cystoscopy, inspect for bladder damage or perforation and verify ureter function.

Results

The 523 cases operated in two state hospitals in Germany have enjoyed excellent conditions and medical conduct. I mention that I spoke with most of these patients, both in terms of historical data and on other issues concerning their family life, moral, economic and social. Many of these women over 71 years (129 cases between 71-80 years old, 55 between 81-90 years old, 5 cases of patients aged over 91 years, a total of 189 cases or 36.4% of all cases studied), were born or were contemporary to the Second World War. I had and participated in the surgery of several patients from Koln which recounted that during the Allied bombing, especially American and British, the city was almost razed to the ground, the only building left intact being the famous Catholic Cathedral, monument belonging to the UNESCO heritage, otherwise superb visited by hundreds of thousands of tourists from all over the world, the third world importance and splendor after the famous Westminster Cathedral in London and the Cathedral of Saint Mary of the Sea in Sevilla, Spain.

The evolution of post - operative operated cases was good and very good, without bleeding complications, thromboembolic, or infectious patients being discharged after 72 hours in most cases. Postoperative treatment consisted of early mobilization, normo-protein diet, normo-caloric, water-soluble, selective antibiotic therapy, anti-inflammatory, anticoagulant treatment.

On the groups analyzed by me on both clinical departments (199 cases of HTV with transvaginal and perineal mesh setting, 38.06% of total cases) positive diagnosis for which it was intervened surgically was the utero-vaginal prolapse, grades II and III.

The three degrees of utero-vaginal prolapse are:

- a. Grade I - the cervix remains endo-vaginal, above the vulvo-vaginal orifice;
- b. Grade II - the cervix externalizes outside the vulvo-vaginal ring;
- c. Grade III - the uterus descends entirely outside the vulvo-vaginal orifice and hangs between the thighs of the patient as a "clapper", this degree is always accompanied by the vaginal prolapse being also called total genital prolapse.

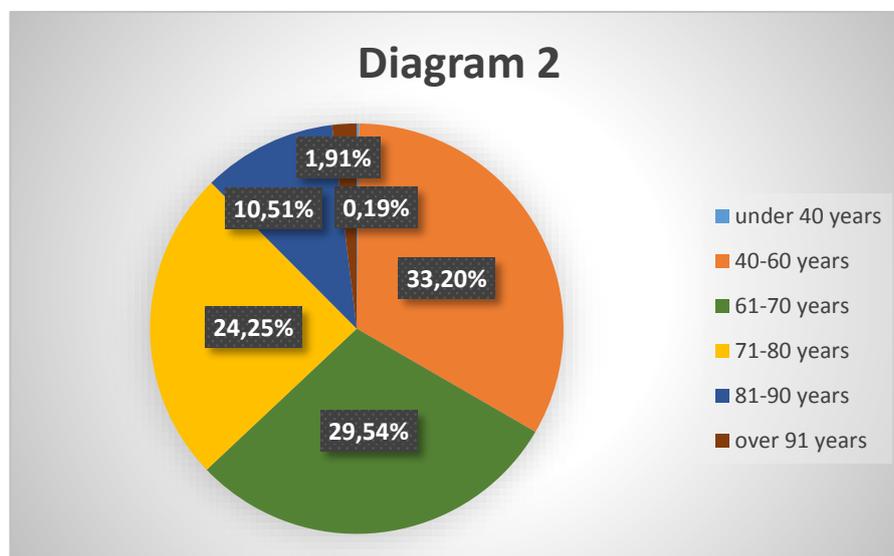
The cases studied were analyzed from the medical records and procedure protocols during two years in the Borken Hospital and five years in the Santa Barbara Hospital from Attendorn.

Obstetric antecedents are the most important in the etiopathogenesis of the utero-vaginal prolapse. For this purpose 482 cases respectively 92.2% of total had a previous history of between 1 and 3 births, 27 cases respectively 5.1% had a history between 4-5 births, 14 cases respectively 2.7% of the total submitted a history of over six births.

With one previous caesarean section we recorded 89 cases or 17.1% of the total, with two caesarean sections we studied 42 cases, respectively 7.9% of all cases.

By age we found a patient under 40 years of age respectively 0,19% of the total cases which was hospitalized and underwent surgery for RVP, cystoectocele, SUI.

Surgery for RVP, cystoectocele, uterine descent grade I, II and III were performed on a number of 177 cases respectively 33.20% of the total, patients with ages between 40-60 years; 156 cases respectively 29.54% of the total patients with ages between 61-70 years; 129 cases respectively 24.65% of the total patients with ages between 71-80 years; 55 cases respectively 10.51% of the total patients ages of 81 - 90 years; 5 cases respectively 1.91% of total patients aged over 90 years. (Diagram 2)



It is noted the particularly high proportion of patients aged over 70, 189 cases or 36.3% of the total of which 55 patients aged between 81-90 years and 5 patients aged over 91 years. This aspect is particularly relevant in resolving procedure cases in 3rd age patients in the context of a major medical specialty from the western countries of Europe and the US, like geronto-surgery.

Patients were well investigated in preoperative and interdisciplinary checkups otherwise anteriorly mentioned. The surgical procedure applied by HTV was standard and the

application of polypropylene mesh was made according to the procedures described in Material and Method section.

There were no reported incidents, anesthetics accidents, intra procedural or significant postoperative complications. Patients were discharged after 72 hours of surgery, with the specific recommendations. The vital and functional, immediate and late prognosis was very good.

Discussions

In the etiopathogenesis utero-vaginal prolapse may be incriminated many causes. Some are related to the biological quality of the patient tissue, respectively anatomical and histological quality of the pelvic- perineal plancher, conjunctival tissue - muscle, implicitly of the collagen found in their constitution, essentially the individual genetic constellation, he degree of civilization and education, traditions and customs of the respective population.

I was impressed by the high level of civilization, education and knowledge of women in Germany, which alone, after the disaster to the Second World War, had to rebuild the country, most able-bodied men being dead or prisoners of war.

Other causes are related to the number of births, obstetric care quality, absence or presence of post - partum complications and appropriate treatment used in solving them.

The decreasing number of classic obstetrical interventions like the application of forceps and the proper guidance of labor, epidural analgesia usage, have led to the increased number of vaginal births and decreased number of caesarean sections to less than 15% and to the frequency reduction of utero - vaginal prolapse.

No less true it is that not all women with multiple births after a certain age suffer from prolapse utero-vaginal.

I have encountered patients with 10 to 16 natural births in antecedents who had no utero-vaginal prolapse and women which presented uterine descent of grade II and III after previous caesarean operation. As communicated in the specialized literature, cases of utero-vaginal prolapse in little girls and virgins, it's true rare cases, but which come to confirm the practical reality, respectively the importance of genetic constellation, heredity, deficient biological quality, of the conjunctive-muscle perineal and genital tissues of each individual. Over time many surgeons and gynecologists in the world brought their personal technical contributions in the treatment of genital static disorders, in the surgical treatment of utero-vaginal prolapse, in the practice of total vaginal hysterectomy.

We must not forget that caesarean section was not introduced into the obstetrical practice until the beginning of XX century (segmento – cross caesarean Fuchs - Dörfler in the period 1904-1908, segmento - longitudinal caesarean Kronig - Beck in the period 1910 – 1912, the protagonists being German).

Natural birth being the rule of many more children is understandable that the incidence of total genital prolapse was much higher then, compared to the current period when the incidence of caesarean operations exceeds 60% in some centers in the world.

At this rate future surgeons and gynecologists will no longer encounter cases of total genital prolapse will practice less HTV and thus less and less will know the standard procedure.

For them and in homage to the predecessors I decided to bring into discussion other procedures used in practice, with certain technical artifices added to the standard procedure described:

1. The process Muller – Quenu, hemisection and uterus morsellation in the uterine poly-fibromatosis.
2. The procedure Doyen, hemisection of the anterior uterus wall.
3. The procedure Doderlein, hemisection of the posterior uterus wall.
4. The procedure Pean, uterus morsellation through layered cuts to the sides on the cervix, isthmus and body, up to the fundal of uterus.
5. The procedure J.L. Faure, total anterior - posterior hemisection.
6. The procedure Peham- Amreich, morsellation for the poly-fibroid uterus.
7. The procedure D.R. Cruikshank, utero – sacral and cardinal ligament fixation to the vaginal wall before uterus removal, after removal proceed setting up a peritoneal pouch starting at 12 o'clock though the bladder peritoneum, including the cardinal ligaments, utero - sacral ligaments, the front face of the rectal peritoneum at 3-4 cm above the reflection area of the Douglas pouch; tighten the pouch, the long left thread ends are passed through the vaginal wall and the cardinal ligaments, vaginal suture with separate Vicryl threads, knotting them above the vagina, the pouch wire ends.
8. The procedure Lorincz, the utero - sacral pedicles, the cardinal ligaments and ligaments round are ligated with Nylon threads or thread kept long on the indications, up to the removal of the uterus; the stumps of these pedicles are fixed with Vicryl to the vaginal walls; the right semi-circumference includes the bladder peritoneum, cardinal ligament, round ligament, paravesical peritoneum, utero - sacral ligament, pre - rectal peritoneum; the same on the left side; tighten the two juxtaposed pouches insert a mesh between them up to the peritoneal cavity, the vaginal walls are sutured transversely, leaving a larger space for the mesh; the mesh is maintained 3-4 days achieving with the fixed stumps a scar consolidation that will ensure a proper suspension of the vaginal vault.
9. The procedure Rouhier, is practiced when the woman is no longer interested in sex life, shall be cut in "horseshoe" or in inverted "U" the anterior vaginal wall, then the posterior one, is excised a front and rear flap on the pattern of the cuts outlined before; further it is practiced in the standard procedural steps as in the HTV procedure.
10. Laparoscopic assisted HTV, allows in the abdominal step also the annexes removal.
11. HTV and colpo-sacro-ligamento-pxy laparoscopic assisted, is practiced HTV and fixing meshes to the vaginal stump; laparoscopic the two polypropylene meshes are secured retro - or intra - peritoneal by the anterior face of the pouch.
12. HTV and the fixing mesh to the sacro - sciatic ligaments, the practiced and described technique by us by the colpo - sacro - ligamento pxy with alloplastic implant materials.

In the last two years I have noticed in some clinics in Germany a tendency to use for solving stump cervical prolapse after subtotal hysterectomy of the cervical sacro pxy (CESA) by traditional abdominal and laparoscopic ways.

The same trend I noticed it also with the occasion of vaginal vault suspension (VASA) after total hysterectomy.

Another trend I noticed it in the technique shown (BSC) using alloplastic implant materials with minimized dimensions (like the TOT and TVT strip).

Another current technique starting more frequently to be applied is the installation of polypropylene mesh in vaginal or cervical stump by vaginal way, suspended at the sacrum level by laparoscopy, mixt vaginal-abdominal.

By abdominal way the polypropylene mesh can be fixed at some cases with normal uterus left in place (histero-sacro pxy), fixing the mesh only on the cervical stump after subtotal hysterectomy or fixing the mesh on the vaginal stump after total hysterectomy.

What is discussed in this chapter is the incontinence of urine on exertion, "often disguised by the female genital prolapse".

After some vaginal intervention for SUI the procedure erosion is found in a relatively short time (6-12 months in the Kelly-Marion procedure of anterior colporrhaphy with urethra recalibration) after three years other techniques for correcting SUI, after 6-8 years in the Burch surgery and 4-6 years operation Lapidus.

"The golden standard" in correcting SUI was until recently the procedure Burch of more than 120 other procedures communicated in the world literature, it being actually outdated by the suburethral polypropylene sling.

I recalled this aspect because I met in Germany clinics where I worked the following aspect. Both BSC technique (bilateral colpo ligament suspension by vaginal way) researched technique applied by me and described in the paper and also CESA and VASA techniques are not followed by incontinence of urine on exertion and if it occurs later, in rare cases what is right, we can proceed to TOT-O or TVT.

We must not forget that suburethral sling was first introduced in 1910 following a "shadow cone" of about 75-80 years, after which "exploded" unexpectedly as method of choice in the treatment of SUI regardless of age, as first procedure or later after other procedures failed.

Conclusions

- I practiced Colpo - sacro - ligamento pexy with alloplastic materials (polypropylene mesh) in 199 cases of HTV for utero - vaginal prolapse out of 523 interventions by vaginal way made by us in two hospitals in Germany, Borken Hospital and the Hospital Santa Barbara in Attendorn - incidence of procedure 38.03%.
- By age groups from 39 to 96 years, the distribution was as follows:
 - Under 40 years - 1 patient - 0.19%
 - 40-60 years - 177 cases - 33,20%
 - 71-80 years - 129 cases - 26.65%
 - 81-90 years - 55 cases - 10.51%
 - Over 90 years - 5 cases - 1.91%.
- It is noticed the particularly high proportion of patients aged over 70 years - 189 cases, 36.3%. This aspect is particularly important in terms of solving free procedures to the 3rd age cases, in the context of a country with high economic - social and medical standards, in which the geronto surgery practice, as in many developed countries from Europe, USA, Canada, Asia, South America, it became an everyday reality.
- The level of economic-social development, the high degree of education and civilization in Germany has allowed these patients, fully insured to be operated in excellent conditions until the age of 96 years.
- In addition to the 199 cases of HTV with a polypropylene mesh there were also practiced for the old perineal tear, cystocele, SUI, anterior colporrhaphy with urethra recalibration, posterior colpoperineorrhaphy with high myorrhaphy of the anal lifters, analysts, sling with suburethral polypropylene strip TOT – O.
- All cases were thoroughly investigated preoperative anesthesia was predominant general with IOT and spinal, loco - regional.
- There were no reported incidents, anesthetic or intraoperative accidents, complications intra - or post - procedure. Vital and functional prognosis, immediate and late were good or very good.

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