European Journal of Obstetrics & Gynecology and Reproductive Biology 159 (2011) 449–452

Contents lists available at SciVerse ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

The first clinical classification of vaginal introital defects

Adam Ostrzenski *

The Institute of Gynecology, Inc. St. Petersburg, FL, USA

ARTICLE INFO

Article history:
Received 16 June 2011
Received in revised form 11 August 2011

Accepted 18 September 2011

Keywords:
Vaginal rejuvenation
Cosmetic gynecology
Vaginal introitus
Vaginal introital defect classification
Vaginal introitoplasty
Wide vagina
Smooth vagina

ABSTRACT

Objectives: To develop a new clinical classification of vaginal introital defects. A literature search failed to show any previous classification or medical nomenclature related to vaginal introital defects.
Study design: A prospective comparison cohort clinical trial was conducted at the Institute of Gynecology, Inc., St. Petersburg, FL, USA. Group I (study group) included 128 women who presented with an acquired sensation of a wide vagina. Group II (control) consists of 31 healthy subjects. Main outcome measures were to document the presence or absence of vaginal introital site-specific defects, their location within the introitus and their potential contribution to decreased female sexual function. At the initial visit, sexual function was evaluated in heterosexual subjects in both groups with the Pelvic Organ Prolapse/Urinary Incontinence/Sexual Function Short Form Questionnaire (PISQ-12) and answers were assessed on a 5-point Likert scale. The data were reported as mean results. Both groups were evaluated for well-being, depression, somatization, anxiety and hostility with the Symptom Questionnaire (SQ). Chi-square and Fisher exact test were utilized to compare demographics. Statistical significance was considered for $P < 0.05$. The paired "*t* test" with 0.05 two-sided significance was used.
Results: Locations of vaginal introital defects were multiple in 78 subjects; lateral in 29 and anterior in 18, and an isolated posterior vaginal introital defect was found in 3 subjects. A posterior introital defect associated with an anal sphincter defect was found in one subject. In Group I the mean PISQ-12 at baseline was 29.6 (SD ± 6.3) and in Group II the mean PISQ-12 was 41.8 (SD ± 5.6). The sexual function score determined by PISQ-12 was statistically different in subjects with vaginal introital defects compared to controls ($P < 0.001$).
Conclusions: A new vaginal introital defect clinical classification based upon location of anatomical defects within the vaginal introitus encompasses: Category I (anterior), Category II (lateral), Category III (posterior) and Category IV (multiple locations).
Evidence-based medicine: Level II-1.

1. Introduction

This author is proposing a new term of "vaginal introital defect", since the introital anatomy and its suspensions differ significantly from the vaginal anatomy and its suspensions [1–3]. The vaginal wall structures incorporate the vaginal epithelium, sub-epithelium, muscular layers (circular and longitudinal muscles) and the pubocervical fascia. However, the anterior compartment of the vaginal introitus incorporates the pelvic arch ligament, the ventral perineal membrane, the compressor urethral muscle, the urethrovaginal sphincter muscle, the upper part of the bulbocavernosus muscle, the upper part of pubocervical fascia, the urethral meatus, and upper part of hymeneal plate [4–9]. The presence of anterior vaginal introitus defect(s) can not only indicate anatomical distortion(s) of the compressor urethral muscle and/or the urethrovaginal sphincter muscle but also indicate different structures. The lateral vaginal introitus encompasses the dorsal perineal membrane, the lateral middle part of urethrovaginal sphincter muscle, middle part of the bulbocavernosus muscle, the dorsal perineal muscle, the lateral pubocervical fascia, and the lateral part of hymeneal pate [4–9]. Lateral vaginal introital defects can result from separation in three potential areas: (1) the dorsal perineal membrane at the attachment to the lateral vaginal pubocervical fascia, (2) the attachment of the dorsal perineal membrane to the ischiopubic rami, and (3) the attachment of the low-lateral vaginal introitus to the superficial transverse perineal muscle. The posterior vaginal introitus includes the dorsal perineal membrane, the posterior urethrovaginal sphincter muscle, the dorsal perineal muscle, the lower part of the bulbocavernosus muscle, the dorsal perineal muscle, the perineal body, and the distal Denonvillier's fascia and the lower part of hymeneal plate [4–9].

Therefore, the vaginal introitus is not a simple extension of the vaginal wall structure, but distinguishes itself independently from

* Correspondence address: Institute of Gynecology, Inc. St. Petersburg, FL 33710, USA. Tel.: +1 727 458 6060; fax: +1 727 341 0121.
E-mail address: ao@baymedical.com.

0301-2115/$ – see front matter © 2011 Published by Elsevier Ireland Ltd.
doi:10.1016/j.ejogrb.2011.09.033

vaginal anatomical structures. A defect can develop in any of these structures and can present as the flattening posterior perineum (decreased the perineal body measurement), partial or complete absence of the hymeneal plate, different sizes of perineocele, distal vaginal wall prolapse (distal rectocele) and anal sphincter defect causing widening of the vaginal introitus. Also, the posterior vaginal introitus can drop downwards and can rest on the fossa navicularis. The objective of this study was to develop a new clinical classification based upon symptoms (including female sexual function) and signs of vaginal introitus defects associated with an acquired sensation of a wide vaginal introitus.

2. Materials and methods

An extensive literature search was carried out on the subject of vaginal introital defects from 1900 to May 2011. Medical Subject Headings (MeSH) were selected and used in a search on ISI Web of Science (including conference proceedings); 1950 PubMed, ACOG-NET, ProQuest, OVID, Cochrane Collection, the Lancet on Line Collection, MDConsultant, New England Journal of Medicine, American College of Physician on Line Resources, Highwire Journal, and Citation Index Reference. Also, a manual search was conducted.

The proposed vaginal introital classification was based on the location of the defects. The vaginal introitus was divided into three segments: anterior, lateral, and posterior. The different locations of vaginal introital defects created different clinical characteristics (symptoms and signs) of an acquired sensation of wide vagina.

This study was a part of a comprehensive research on wide/smooth vagina conditions and was approved by the institutional review board. The clinical trial was conducted at the Institute of Gynecology, Inc., St. Petersburg, FL, USA, between January 2006 and January 2010 and included two groups. Group I encompassed 128 subjects (out of 192 women) who met the study's inclusion criteria. The control group II included 31 consecutive women who requested a routine annual check-up without any gynecologic complaint and without a sensation of a wide vaginal introitus. Main outcome measures were to document the presence or absence of vaginal introital site-specific defects, their location within the vaginal introitus and their potential contribution to decreased female sexual functions.

The inclusion criteria accepted women who presented with an acquired sensation of wide vaginal introitus (diminished or absence sensation of vaginal insertion of the penis). Subjects were able to give informed consent and were sexually active with a male partner at the onset of the clinical trial. At the time of the initial visit, written informed consent was obtained from each participant and the subject's signature was verified by a witness. Subjects were advised that all information was strictly confidential and would be utilized for research and education purposes. All subjects in both groups completed a short form of the Pelvic Organ Prolapse/Urinary Incontinence/Sexual Questionnaire (PISQ-12) at the initial visit [10]. Only subjects with BMI < 30 kg/m^2 were included in this study [11,12].

The following exclusion criteria were applied: lower genital tract or pelvic infections, pregnancy, previous vaginal, perineal or anal surgery, and the presence of neurological condition. Subjects who tested positively for depression with Symptom Questionnaire (SQ) [13] or body mass index was higher than 30 (BMI ≥ 30 kg/m^2) were excluded.

The author developed and scientifically validated questions pertinent to the wide vaginal introitus which were used to obtain a medical history related to a wide vaginal introitus [10]: (1) Do you feel that your vaginal opening is too wide? (2) When did you first notice a sensation of wide vaginal opening? (3) Had you felt fullness and/or pressure in your vaginal opening from penile penetration before identifying a sensation of wide vaginal opening? (4) Do you experience that your vaginal opening is too wide for having meaningful vaginal sexual intercourse?

The examination of the vaginal introitus was performed in the lithotomy position. A visual inspection for symmetry, shape, descent, gaping, or sagginess and by palpation for size, site-specific defect(s), squeezing force, and for discomfort were recorded. The width (the transverse measurement obtained between 5 and 7o'clock) of the vaginal introitus was measured between its most lateral points in the lateral–posterior vaginal introitus and attempt was made to insert 2, 3, or 4 examiner's fingers. A subjective squeezing strength of the vaginal introitus was determined by inserting the examiner's index finger to the vaginal introitus and asking patient to squeeze the finger. The following quantification of a subjective squeezing strength was established and used: (a) the absence, (b) mild, (c) moderate, (d) significant squeezing strength. Also, any discomfort reported by a woman that occurred during examination or during coitus was recorded. The vaginal orifice edge was placed between the examiner's right hand thumb and the index finger and palpation was initiated on the right side of the vaginal introitus, starting in the posterior midline and continuing to the anterior midline vaginal introitus, then the examiner changed the hand from the right to left and continued evaluation of the left side of the vaginal introitus. Any palpable abnormality was recorded and analyzed. The urethral meatus location, shape, closed versus gaping, urethral relationship to the anterior vaginal introitus and the hymeneal plate (ring) were assessed. The clitoral frenulum, prepuce, body, glans and root were examined.

Laterally, visual inspection was conducted with gentle, manual separation of the labia minora and followed by a speculum evaluation (a free, double-blade vaginal speculum was used) to rule-in or to rule-out the presence of a lateral vaginal introital defect. Palpation was applied along the ischiopubic ramus to determine the attachment integrity of the dorsal perineal membrane to the bone. The attachment of the superficial transverse perineal muscle was evaluated at the level of ischial tuberosity. Also, the lateral pubocervical fascia and the lateral hymeneal plate were examined and recorded.

Posteriorly, the superficial transverse perineal muscles, the bulbospongiosus muscles, the anal sphincter muscle, the recto-vaginal fascia, the pubocervical fascia, and the posterior aspect of the dorsal perineal membrane were evaluated. Site-specific defects of the distal posterior vagina and the posterior perineum were record. The external and internal sphincter muscle integrity was evaluated. The coccyx bone and the anococcygeal body and its attachment to the coccyx bone were assessed.

At the initial visit, sexual function was evaluated in heterosexual subjects in both groups with the Pelvic Organ Prolapse/Urinary Incontinence/Sexual Function Short Form Questionnaire (PISQ-12) and answers assessed on a 5-point Likert scale [10]. Data were reported as mean results. Subjects in both groups were evaluated for well-being, depression, somatization, anxiety and hostility with the Symptom Questionnaire (SQ) [13]. Chi-square and Fisher exact test were utilized to compare demographics. Statistical significance was considered as $P < 0.05$. On a priori sample size calculation for the external validation and responsiveness portion of the study, a sample size of 30 subjects in Group II provided 80% power to detect an effect size of 0.50 using paired "t test" with 0.05 two-sided significance.

3. Results

Out of 192 subjects, 128 subjects met the inclusion criteria. Demographic and general health characteristics were closely matched between both groups. In Group I, the age of subjects ranged from 19 to 66 years (mean 39 years); with 116 Caucasian women, 7 Latino and 5 Black women. Vaginal deliveries were

identified in 107 women (median, 2 deliveries) and cesarean section deliveries were documented in 18. Three were nulliparous. Among the 128 subjects, 102 were married and 26 were single. All subjects were sexually active. In Group II, the age of subjects ranged from 21 to 62 years old (mean 37 years, SD ± 25). There were 22 Caucasian, 7 Latino and 2 Black women. Among the 31 subjects, 24 delivered vaginally and 7 by cesarean section. Seven had undergone hysterectomy for benign conditions. Twenty-one women were married and 10 were single. All subjects were sexually active.

There was 100% correlation between initial medical history related to a wide vaginal introitus and anatomical vaginal introital defects. Subjects described symptoms as "sensation of wide vagina", "not feeling penile insertion", "feeling like an empty hole", and "decrease sensation of penile penetration". Superficial dyspareunia was reported in 18 cases. A mild form of the wide vaginal introitus (transverse measurement > 3.5 cm) was identified in 19 out of 128 subjects; a moderate form of the wide vaginal introitus (5.5–7 cm) was documented in 84 subjects; a severe form of the wide vaginal introitus (>7 cm) was established in 25 subjects. There was no correlation between vaginal introital transverse measurements and symptoms of an acquired sensation of wide/smooth vagina.

A vaginal introitus subjective squeezing strength test established the absence of squeezing strength among 25 subjects in whom severe enlargement of the vaginal introitus was also diagnosed. All subjects associated with a moderate wide vaginal introitus presented with mild squeezing strength.

Anterior vaginal introital defects were identified in 18 women where asymmetry, gaping and distorted anatomy of the vaginal introitus were observed. In addition, the urethral meatus and its surroundings exhibited abnormal clinical characteristics when compared to the control group. Urethral orifices presented in different shapes, symmetry, dropping downwards, gaping, deviating from the natural midline location, and with irregular edges. Also, anatomical distortion either in the form of hypotrophy or hypertrophy was present, in some cases, in the distal urethral–vaginal fusion associated with vaginal introital defects.

Lateral vaginal introital defects were identified in 29 subjects. Bilateral defects were the most common among lateral defects (18 out of 29 subjects). Unilateral defects were present in remaining 11 women. Lateral vaginal introital defects manifested in different degrees of bulging into the vaginal pool.

An isolated posterior vaginal introital defect was rare occurrence. It was identified in 3 subjects out of 128 subjects and 78 subjects presented with multiple (anterior, lateral, and posterior) vaginal introitus defects. One subject out of 78 presented with posterior introitus defect associated with an anal sphincter defect.

Based upon the presence of anatomical characteristics associated with vaginal introital defects, four distinct locations were established in the following domains: Category I: anterior vaginal introitus defects; Category II: lateral vaginal introitus defects; Category III: posterior vaginal introitus defects; Category IV: multiple locations of vaginal introitus defects (anterior, lateral, and posterior) (Table 1).

Table 1
A new classification of vaginal introital defects.

A. Ostrzenski: Vaginal introital classification and its management		
Category	Characteristics	Management
I	Anterior vaginal introitus defects	Anterior vaginal introital defect(s) reconstruction
II	Lateral vaginal introitus defects	Lateral vaginal introital defect(s) reconstruction
III	Posterior vaginal introitus defects	Posterior vaginal introital defect(s) reconstruction
IV	Multiple location of vaginal introitus defects	Reconstruction of multiple introital vaginal defects

In Group I, the mean PISQ-12 at baseline was 29.6 (SD ± 6.3) and in control group II, the mean PISQ-12 was 41.8 (SD ± 5.6). The sexual function score, determined by PISQ-12 instrument, was statistically significantly lower in Group I ($P < 0.001$) than in Group II.

4. Comments

The vaginal introital classification was established for diagnostic and research purposes, based upon location of anatomical defects within the vaginal introitus. The new classification encompasses: Category I (anterior), Category II (lateral), Category III (posterior), and Category IV (multiple locations). These anatomical changes in diverse vaginal introital locations led to developing new and specific surgical interventions for the treatment of vaginal introital defects. The clinical classification of vaginal introital defects is important in clinical practice by means of changing the clinical diagnosis and management of this new medical entity.

This author defines the wide vaginal introitus as the presence of site-specific defect(s) within the vaginal orifice whose changes cause symptoms of a wide vagina. Vaginal introital defect is a new term and a new medical entity, since the extensive literature search has not yielded a single article in the scientific medical literature or scientific conference proceedings. Also, the vaginal introital classification is a new clinical system which was not designed to establish differences in clinical severity of vaginal introital defects.

The results of PISQ-12 established a statistically significant difference in sexual function between the study group and the control group ($P < 0.001$). However, the PISQ-12 cannot identify the subscale which has the highest effect on women sexual activities.

Currently, there are no adequate surgical procedures to address vaginal introital defects associated with an acquired sensation of wide vaginal introitus. An application of traditional colpoperineoplasty, one-procedure-fits-all is not a solution for these abnormalities. Therefore, new surgical techniques should be developed to correct the existing vaginal introital defects associated with an acquired sensation of a wide vaginal introitus.

Results of this clinical research translate into the clinical practice of an acquired sensation of wide vaginal introitus on multiple levels. *First*, specific symptoms and signs were identified associated with a vaginal introital defect(s). *Second*, vaginal introital defects will qualify for surgical interventions, since this entity is affiliated with symptoms and signs. The presence of symptoms and signs fulfill ACOG's requirements for vaginal surgical intervention [14]. *Third*, vaginal introital defect(s) causing an acquired sensation of a wide vaginal introitus is a symptomatic medical condition; therefore, requiring clinical management. *Fourth*, performing a one-procedure-fits-all such as colpoperineoplasty with or without paravaginal repair or just a colpoperineoplasty is not an adequate clinical management of an acquired sensation of a wide vaginal introitus due to the presence of diversified site-specific defects of the vaginal introitus [15]. *Fifth*, new surgical techniques will be needed to address adequately site-specific defect restorations of the vaginal introitus.

There were a number of strengths of this study. The relationship between anatomical defects of the vaginal introitus and the symptoms of an acquired sensation of a wide vagina has been established. One-procedure-fits-all surgical intervention to rectify a sensation of wide vaginal introitus is not enough and the need for diversified surgical interventions is in order.

There were several limitations of the study. The single most important limitation was undetermined extension of vaginal introital site-specific defects to the vaginal wall. A single physician-evaluator represents more bias than multiple evaluators

and also, the study was executed in one site. The trial has not evaluated the timing of a wide vagina event in relation to symptom occurrences. Also, the correlation between the degree of the vaginal introital defects and their effect on symptoms was not evaluated. Additionally, the correlation between the transverse measurements of the vaginal introitus and severity of symptoms was not examined. Also, it is possible that the number of the subject population enrolled was not representative of all potential abnormalities. Nevertheless, the results of this preliminary clinical trial suggest that further studies should be considered necessary to advance our knowledge and clinical understanding of this new entity.

References

[1] Berglas B, Rubin IC. Histologic study of the pelvic connective tissue. Surg Gynecol Obstet 1953;97:277–89.
[2] DeLancey JO. Correlative study of paraurethral anatomy. Obstet Gynecol 1986;68(1):91–7.
[3] Otcenasek M, Baca V, Krofta L, Feyereisl J. Endopelvic fascia in women: shape and relation to parietal pelvic structures. Obstet Gynecol 2008;111(3):622–33.
[4] Brandon CJ, Lewicky-Gaupp C, Larson K, DeLancey JO. Anatomy of the perineal membrane as seen in magnetic resonance images of nulliparous women. Am J Obstet Gynecol 2009;200(5):583.e1–6.
[5] Stein TA, Delancey JO. Structure of the perineal membrane in females: gross and microscopic anatomy. Obstet Gynecol 2008;111(3):686–93.
[6] DeLancy JO. Structural anatomy of the posterior compartment as it relates to rectocele. Am J Obstet Gynecol 1999;180(4):815–23.
[7] Oh C, Kark AE. Anatomy of the perineal body. Dis Colon Rectum 1973;16(6):444–54.
[8] Leffler KS, Thompson JR, Cundiff GW, Buller JL, Burrows LJ, Schon Ybarra MA. Attachment of the rectovaginal septum to the pelvis sidewall. Am J Obstet Gynecol 2001;185(1):41–3.
[9] Matsubara KMA, Murakami GAS, Usui IYT. Female perineal membrane: a study using pelvic floor semiserlia sections from elderly nulliparous and multiparous women. Int Urogynecol J Pelvic Floor Dysfunct 2008;19(12):1663–70.
[10] Rogers RG, Coats KW, Kammerer-Doak, Khalsa S, Qualls C. A short form of the Pelvic Organ Prolapse/Urinary Incontinence/Sexual Questionnaire (PISQ-12). Int Urogynecol J 2003;14:164–8.
[11] Kolotkin RL, Binks M, Crosby RD, Ostbye T, Gress RE, Adams TD. Obesity and sexual quality of life. Obesity 2006;14:472–9.
[12] Esposito K, Ciotola M, Giulgliano F, et al. Association of body weight with sexual function in women. Int J Impot Res 2007;19(4):353–7.
[13] Creti L, Fichten CS, Brender W. In: Davis CM, Yaber WH, Bauserman R, Schreer G, Davis SL, editors. Handbook of sexuality-related measures. 2nd ed., Thousand Oaks: Sage; 1991. p. 261–7.
[14] The American College of Obstetricians and Gynecologists. Vaginal rejuvenation and cosmetic vaginal procedures. ACOG committee opinion no. 378. Washington, DC: The American College of Obstetricians and Gynecologists; September 2007.
[15] Pardo JS, Sola VD, Riccia PA, Guiloff EF, Freundlich OK. Colpoperineoplasty in women with a sensation of a wide vagina. Act Obstet Gynecol Scand 2006;85(9):1125–7.