New episiotomy: A prospective case series study

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Abstract

Objectives To establish anatomical structures responsible for a resistance force on a fetal head during vaginal delivery; assess the postpartum perception of perineal pain and superficial dyspareunia; develop a new episiotomy. Design A prospective observational case series study. Setting International sites. Population Eighteen pregnant women in labor Methods Small V-shape excision was made on the posterior-lateral vaginal outlet without incising the posterior perineum or vaginal wall. Simple interrupted sutures were used to repair the surgical defect (outlectorrhaphy). Histological examinations were performed on excised specimens. Main Outcome Measures The primary maternal outcome measured postpartum perineal pain; the secondary outcome measured occurrences of superficial dyspareunia, results of Ostrzenski's vaginal outlectomy, and APGAR scores measured the neonatal outcome. Results The small V-shape excision widened the vaginal outlet sufficiently for a vaginal delivery. Outlectorrhaphy required two-three simple interrupted sutures. All subjects were delivered vaginally with median newborns' weight of 3,550 gm ±250gm and median APGAR scores of 9 ±1 at 5 minutes. One patient experienced a grate II extension tear with bleeding heavier than an uncomplicated vaginal outlectomy. Postpartum patients reported no moderate or severe perineal pain and no superficial dyspareunia. Histology showed that the vaginal outlet was deferred from the vaginal walls. Conclusions The vaginal outlet is responsible for resistance force on a fetal head. No moderate or severe perineal pain or dyspareunia occurred in this study group. Ostrzenski's vaginal outlectomy widens the vaginal outlet sufficiently for a fetal vaginal birth, and it is easy to repair.

New episiotomy: A prospective case series study

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Keywords: Vaginal delivery; Episiotomy; Episiotomy tears; Vaginal outlet; Ostrzenski's vaginal outlectomy; Vaginal orifice.

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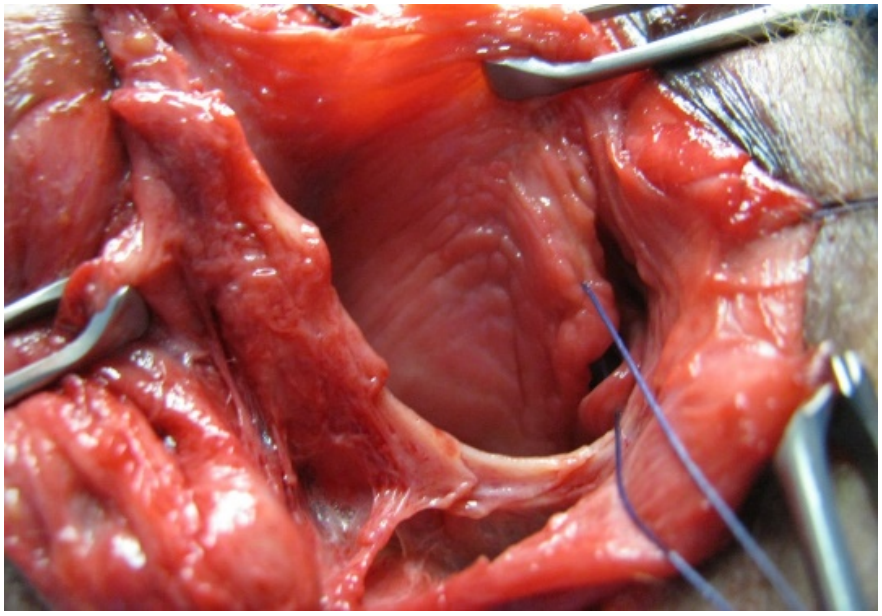
Tweetable abstract

Ostrzenski's vaginal outlectomy reduces postpartum moderate-to-severe perineal pain and eliminates superficial dyspareunia

New episiotomy: A prospective case series study

Graphical Abstract



Introduction

In 1742, Fielding Ouled from Ireland was the first who described episiotomy.[1] Traditional episiotomy is an obstetrical, surgical concept to widen the vaginal canal by incision of the posterior-distal vaginal wall and the posterior perineum. Its purpose is to facilitate the passing a fetus's head during birth. Those women who undergo episiotomy or experience perineal tear(s) suffer from moderate to severe perineal pain that requires pain medication and other forms of therapy. In addition, severe short- and long-term complications from this obstetrical surgical intervention are well-documented in the medical literature. In general, a traditional episiotomy can result in a) moderate or severe perineal pain immediately after delivery; b) blood lost during and post-episiotomy that is compatible with Cesarean section; c) wound infections; d) wound separation; e) long-term postpartum moderate or severe perineal pain; f) urinary or fecal incontinence, or both: g) urogenital and rectovaginal fistulas; h) pelvic floor dysfunction and pelvic organ prolapse; i) persistent superficial dyspareunia.[2-5] The most severe episiotomy complications are associated with an incision extension responsible for the risk of third or fourth degrees of perineal lacerations - obstetrical anal sphincter injuries

(OASIS).[6] It has been postulated that primiparous women from Asia and Sub-Saharan Africa are more predisposed to developed OASI.[7] Additionally, it has been documented that the most common maternal injury during birth is the vaginal outlet.[1]

The concept of Ostrzenski's vaginal outlectomy does not include the posterior perineum or the posterior-distal vaginal wall to avoid postpartum symptoms. Other studies showed that intact posterior perineum does not produce postpartum perineal pain, superficial dyspareunia, or other symptoms.[8, 9] Therefore, the question arises whether the posterior perineum incision is necessary to widen the vaginal opening for vaginal parturition? In addition, does the hymeneal ring and hymeneal plate risk of injuries exist during fetal head delivery? Therefore, the present study will develop the surgical concept of vaginal outlectomy surgical anatomy without including the posterior perineum and posterior-distal vaginal wall.

The hypothesis of the current study is to test whether vaginal outlectomy provides sufficient widening of the vaginal outlet to overcome the tissue resistance force on the fetal head during delivery? Therefore, the objectives were a) to show anatomical structures of the vaginal outlet and resist a fetal head passing through; b) to establish a new gross, topographic, and surgical anatomy of the vaginal outlet; c) assess the postpartum perineal pain perception and superficial dyspareunia; d) to develop a surgical intervention (vaginal outlectomy) to widen the vaginal outlet without incorporating the posterior-distal wall and the posterior perineum and develop a new episiotomy. The primary maternal outcome measures postpartum posterior perineum pain associated with vaginal outlectomy. The secondary outcomes measure a) complication of vaginal outlectomy; b) occurrence of superficial dyspareunia after vaginal outlectomy; c) results of Ostrzenski's vaginal outlectomy; d) neonatal outcome measured by an APGAR score.

Methods

Padua University, Italy, Ethics Committees approved the clinical study's vaginal outlectomy protocol and informed consent (No. 23445/2019). The Warsaw Medical University Bioethics Committee, Poland, approved the experimental anatomical dissections of the urogenital tract on fresh human female adult cadavers and practiced the newly developed vaginal outlectomy procedure (No. AKBE 146/12). The anatomical dissections were conducted at the Forensic Medicine Department, and the author executed all the anatomical macro and micro (3.5 – 4.00 magnifying loupe) dissections. Additionally, he practiced a new vaginal outlectomy surgical intervention. The anatomical dissections were conducted at the Forensic Medicine Department, and the author executed all the anatomical macro and micro (3.5 – 4.0 magnifying loupe) dissections. Additionally, the author practiced a new vaginal outlectomy surgical intervention on female corps.

Eighteen pregnant at term women were recruited, and the case series study was conducted on this cohort subjects. These patients underwent a clinical assessment in the supine position with the legs on stirrups. The posterior-distal vaginal wall, posterior perineum, and anal external and internal sphincters were evaluated by visual inspections and digital vaginal and anal examination.

The most stretch vaginal outlet resistant force on the fetal head at delivery was used as a reference point to determine the small V-shape vaginal outletlectomy excision location. After outlectorrhaphy (V-shape excision's defect repairs), blood loss was subjectively assessed by inspecting the excision site, posterior perineum skin blood smear, and clots.

On the first postpartum day, perineal pain perception levels and at three months postpartum, superficial dyspareunia perception levels were measured using a validated Numeric Rating Scale (NRS).[10] an 11-point scale for patients self-reporting that is based on daily living activities and pain raging 1) no pain - 0; 2) mild pain from 1-3 on the NRS scale (nagging, annoying, and little interfering with activities of daily living; 2) moderate pain from 4-6 on the NRS scale (interferes significantly with activities of daily living); 3) severe pain from 7-10 on the NRS (disabling; unable to perform daily living activities).

Generally accepted indications for traditional episiotomy, Tabl.1, were closely followed and used in the selection process for the present study. This study included singleton fetuses pregnancy in the vertex presentation with occiput anterior and sonographically estimated fetal weight between 2,629gm and 3,999 gm.

Patients who presented with prior episiotomy scar or perineal obstetric - gynecologic surgery or perineal trauma were excluded from the current study. Furthermore, those subjects who reported superficial dyspareunia, dyschezia, or pain in the crotch were also excluded from this study. In addition, abnormal fetal presentations (malpresentation) and breech presentation were excluded from the present study.

The goal of the current research was to develop a new episiotomy procedure that would exclude the posterior perineum. Ostrzenski's vaginal outlectomy first step is identifying the "belt-like" structure embracing the fetal head circumference; a midwife or obstetrician numbs the area between 7 and 8 o'clock with plain lidocaine 1%. At the I-stage of parturition, the lidocaine skin test is performed by placing lidocaine-soaked gauze under the right breast, and the skin reaction is determined one hour later. Next, the V-shape partial excision of the hymeneal membrane, hymeneal ring, and the hymeneal plate is executed (the vaginal outlet). The size of the V-excision is approximately 1.5 cm between the V-arms, and V-shape arms incisions are connected at the bottom. The excision does not incorporate the posterior peritoneum or posterior-distal vaginal wall. Finally, the vaginal outlectomy excised tissue is submitted to the histological, routine examination and is stained with hematoxylin and eosin (H-E), Fig. 1C.

Literature Search

The medical literature was searched electronically and manually for the gross and topographic anatomy of the vaginal introitus, vaginal vestibule, vaginal orifice, and vaginal outlet. In addition, anatomy articles, conference proceedings, and specializing websites were also included. The Medical Subject Headings (MeSH) were applied. The following keywords or phrases were used: vaginal delivery, episiotomy, episiotomy tears, episiotomy extension, episiotomy laceration, vaginal outlet; Ostrzenski's vaginal outlectomy, vaginal orifice, the human vagina, vaginal outlet gross human, vaginal outlet topographic anatomy, human vaginal introitus gross anatomy, human vaginal topographic anatomy, human vaginal orifice gross anatomy, human vaginal orifice topographic anatomy, perineal body location, vaginal posterior-distal laceration, vaginal outlet histology, posterior vaginal colporrhaphy.

Results

The cohort of eighteen pregnant women completed the study and delivered vaginally live neonates with implementing a newly developed Ostrzenski's vaginal outlectomy. All pregnancies were singleton with a fetus in a longitudinal lie, a cephalic presentation, and occiput anterior. A summary of the maternal demographic profile is presented in Tabl. 2, and maternal clinical characteristics summarized in Tabl. 3. Vaginal outlectomy outcome measures are reported in Tabl. 4. The neonatal clinical outcome is encapsulated in Tabl. 5. The neonatal APGAR score at 5 minutes was between 8 and 10 (median 9 $\pm$1), and median birth weight of 3.314 gm $\pm$ 684 gm. Neonatal clinical characteristics are summarized in Tabl. 5.

When a fetal head is crowning, the fragment of the visible belt-like structure of the vaginal outlet can be identified, Fig.1A and Fig. 1B, Fig. 2B, and Fig. 3. A small V-shape excision of the vaginal outlet structure reduced the tissue's resistance force on the fetal head during birth enough. Immediately postpartum, none of the subjects from this study group reported moderate or severe postpartum perineal pain. Additionally, at three months follow up, including the patient who had experienced vaginal outlectomy extension tear, did not report superficial or deep dyspareunia.

The outlectorrhaphy required two or three interrupted absorbable sutures to close the surgical defect. Esthetically, the wound closure resulted in fine scar formation and no complications in wound healing in this study group, Fig. 4. Additionally, the postpartum vaginal opening was not gaping following outlectorrhaphy in every subject of the present study, Fig. 4.

Utilizing the Validated Numerical Pain Rating Scale to record perineal pain intensity on the first postpartum day showed no moderate or severe perineal pain in all subjects who underwent Ostrzenski's vaginal outlectomy. The mild perineal discomfort subsided spontaneously without pain medication on the second and third postpartum days. Furthermore, no woman in this group reported dyspareunia at twelve-week.

One case out of 18 subjects experienced vaginal outlectomy excision tear that included the vulvar skin,

perineal fascia, right bulbospongiosus muscle (the second degree) with the increased amount of bleeding compared to uncomplicated Ostrzenski's vaginal outlectomy, and the neonatal birth weight was 3,390 gm. However, the vaginal wall, corrugator muscle, and external anal sphincter were intact in this case, Fig. 5B. In addition, this pregnant woman presented at full-term being in active labor, and no malpresentation was diagnosed.

Discussion

Main Findings

The present clinical research showed that vaginal outlectomy is a simple obstetrical procedure with a short learning curve, negligible blood loss, mild postpartum perineal discomfort, and no dyspareunia. Approximately 1,5 cm V-shape excision is made on the vaginal outlet (the hymeneal membrane, hymeneal ring, and continued within the hymeneal plate). It was enough to reduce tissue resistance forces on the fetal head at birth. During a fetal head delivery, the perineal muscle would naturally be stretched by the forces of uterine contractions and progressing fetal head that compresses the crotch from inside; therefore, the posterior perineum has limited contribution in widening vaginal outlet and will not require to be included into vaginal outlectomy. Thus, the too-tight vaginal outlet is the cause that inhibits the fetal head from passing through the vaginal outlet and removes this tissue's natural resistance by small excision of the fragment of the transitional skin, hymeneal ring, hymeneal plate without perineal muscles incisions will overcome the resistance force.

Garner et al. developed the injury risk map during parturition and determined that the posterior perineum was at low risk for trauma during fetal head vaginal delivery.[11] Therefore, the posterior perineal incision is not necessary to perform for the birth of a fetus. In addition, not including the posterior perineum in vaginal outlectomy prevents significant bleeding related to episiotomy during parturition, postpartum moderate to severe perineal pain, and, later on, superficial dyspareunia.

The vaginal outlectomy estimated bleeding is minimal, Fig. 5. Furthermore, closing the surgical defect of vaginal outlectomy (outlectorrhaphy) requires only two or three sutures. Compared to episiorrhaphy, Ostrzenski's vaginal outlectomy significantly reduces clinical training and using suturing materials. After healing, the fine-scare, almost invisible, provides a very appealing esthetic look, and the vaginal outlet is not gapping postpartum, Fig. 4. In one case out of eighteen, vaginal outlectomy extension occurred in this study group. The extension included the perineal skin, perineal fascia, right bulbospongiosus muscle (the second degree), Fig. 5 B. However, the vaginal wall, corrugator muscle, and external anal sphincter were intact. Thus, the vaginal outlet extension did not progress towards the anal sphincter. Estimated vaginal outlectomy extension bleeding was heavier when compared to uncomplicated vaginal outlectomy, Fig. 2 and Fig. 5. Additionally, the woman who experienced vaginal outlectomy extension reported moderate postpartum perineal pain that lasted for five days and required pain medication (NRS was 5 pain perception intensity). At three months postpartum follow-up, the subjects did not report superficial dyspareunia. Therefore, this case demonstrates that vaginal outlectomy extension can occur and obstetrical injury of the bulbospongiosus muscle causes heavier bleeding than uncomplicated vaginal outlectomy, Fig. 2 and Fig. 5, and moderate postpartum perineal pain.

Strengths and Limitations

The present study shows that the posterior perineal musculature does not significantly affect the vaginal outlet resistance force on a fetal head during birth. Instead, the most substantial contribution to resistance is the vaginal outlet. Thus, Ostrzenski's vaginal outlectomy eliminates incision of the posterior perineum, decreases post vaginal outlectomy bleeding, reduces using surgical suturing materials, re-establishes the natural esthetic look of vaginal orifice without gapping, eliminates moderate or severe postpartum perineal pain perception, abolishes post-birth superficial dyspareunia, and significantly reduces the length of traditional episiotomy scar. Additionally, the learning curve is short and does not require as intense training as the traditional episiotomy. Esthetically, vaginal outlectomy provides impressive results, creates an almost invisible scar, and eliminates postpartum vaginal gapping. Furthermore, vaginal outlectomy reduces the time of

repairing the excision site and cuts on using surgical suture materials (2-3 stitches are needed).

The current study's limitation is the small number of subjects to draw general conclusions or determine the safety and effectiveness of vaginal outlectomy. Still, this number was sufficient to decide on the clinical implementation of a vaginal outlectomy. Also, the weakness of this clinical investigation is the absence of standardization when a vaginal outlectomy should be performed, and the indication for performing vaginal outlectomy was adopted from the existing practice mode for selective episiotomy and not established for Ostrzenski's vaginal outlectomy, Tabl. 1 Furthermore, this obstetrical procedure was not used at the time of operative vaginal delivery, and whether a vaginal outlectomy will reduce the development of obstetrical anal sphincter injuries - OASIS, particularly in forceps or vacuum delivery, abnormal fetal presentations, or primiparity.

*Interpretation*The vaginal outlectomy eases the passage of a fetal head during vaginal delivery by reducing the vaginal outlet tissue resistance force created by a belt-like structure embracing the fetal skull—the belt-like consists of the transitional vulvar skin, hymeneal ring, and hymeneal plate. V-shaped excision in the most distended belt area is enough for successful fetal head and body delivery.

Histology of the excised vaginal outlet showed no perineal muscle skeletal muscle present in the excised specimens and verified anatomical findings of three distinctive layers: the hymeneal membrane, ring, and plate, Fig. 1C. The absence of the perineal muscle within the excised V-shape tissue helps understand the mechanism of posterior postpartum pain and, later on, superficial dyspareunia. Therefore, the present study shows that the posterior perineal musculature is unnecessary to cut for widening the vaginal outlet to deliver a fetal head.

The surgical concept of Ostrzenski's vaginal outlectomy is how to minimize the "belt-like" tissue resistance force on a fetal head being entrapped by the vaginal outlet and not by the posterior perineum. This procedure is easy to learn and execute with only negligible blood loss and minimal postpartum perineal discomfort and does not produce superficial dyspareunia.

A traditional mediolateral episiotomy incorporates into the incision several anatomical structures: the posterior-distal vaginal, perineal body, hymeneal membrane, hymeneal ring, vaginal plate, inferior labium minus, perineal skin, posterior perineal fascia, superficial transverse perineal muscle, bulbospongiosus muscle, dorsal perineal membrane, urethrovaginal sphincter muscle, the pubovaginalis muscle (the fragment of the levator ani muscle), and superficial external sphincter muscle. A midline episiotomy includes anatomical structures: the posterior-distal vaginal wall, perineal body, vaginal outlet, fossa navicularis, fourchette, posterior perineal skin, perineal fascia, the central point of the posterior perineum, superficial external sphincter muscle, and distal rectovaginal septum.[12] These episiotomy techniques were developed to prevent posterior perineum damages, including anal sphincters, pelvic floor dysfunction, and the fetus from either intracranial hemorrhage or intrauterine asphyxia. None of these suppositions were validated by clinical-scientific studies, and traditional episiotomies are responsible for severe complications.[13] Unfortunately, episiotomy does not prevent damages but does create damages of the posterior perineum in women,

Estimated blood loss associated with traditional episiotomy exceeds the amount observed at cesarean section.[14] The immediate postpartum severe posterior perineal pain followed traditional episiotomy often lasts for several weeks.[15,16]Episiotomy extension to the external and internal anal sphincter causes more pain for several weeks after birth and requires strong pain medication.[17] Additionally, an episiotomy or other obstetrical perineal trauma can cause transient or prolonged, or permanent superficial dyspareunia, which plays a significant role in female sexual dysfunction.[18] Also, episiotomy, particularly midline episiotomy, can lead to debilitating urinary or fecal incontinence, or both due to injuries of the perineal body.[19-23] Furthermore, an obstetrician's or midwife's skill to perform episiorrhaphy is very often inappropriately done. The method of repair techniques increases short- and long-term women morbidity and negatively influences the quality of life, Fig. 4D.[18, 21, 24]

Future Research

The present study's findings showed that vaginal outlectomy has the potential for obstetrical use in everyday practice. However, there is a need for additional clinical-scientific research to assess vaginal outlectomy further since the current study design could not answer the safety and effectiveness of vaginal outlectomy or whether vaginal outlectomy can be applied in the form of a restrictive or routine use. If the restrictive use would be preferable, what are the indications for vaginal outlectomy? In addition, how vaginal outlectomy will assist during vaginal instrumental delivery should also be studied.

Conclusions The vaginal outlet is responsible for resistance force on a fetal head passing through it and not the posterior perineum that only supports the vaginal outlet. Ostrzenski's vaginal outlectomy widens the vaginal outlet sufficiently for a fetal vaginal birth and eliminates postpartum perineal pain and dyspareunia.

Declaration of Competing Interest

The author declares that he has not known competing for financial interest or personal relationships that could have influenced the work reported in this paper.

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Ethical statement

Two independent University Bioethics Committees approved both study's anatomical and clinical protocol before the investigations were commenced.

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Author contributions

The author develops the concept of Ostrzenski's vaginal outlectomy, designs the studys' protocols, collects data, analyses and interprets data, and drafts the manuscript.

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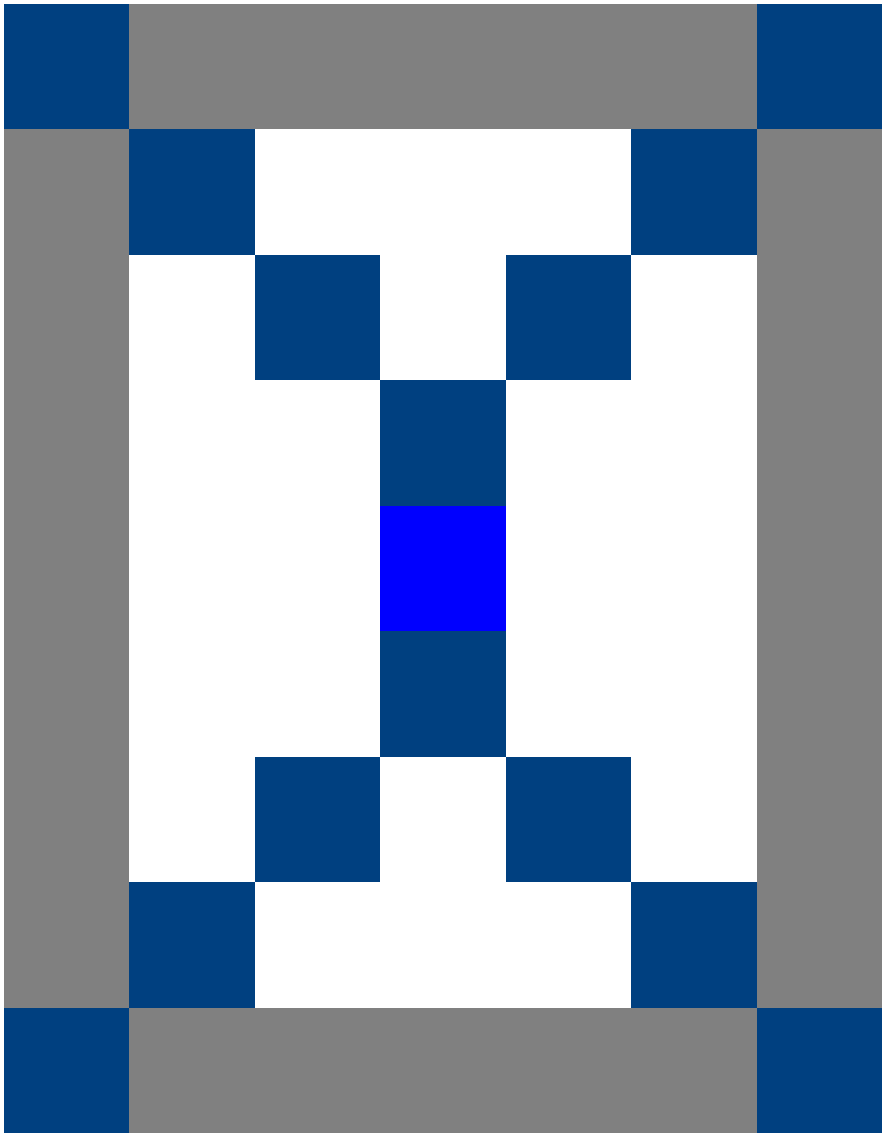

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24. Fernando RJ, Sultan AH, Kettle C, Thakar R, Radley S. Methods of repair for obstetric anal sphincter injury. Cochrane Database of Systematic Reviews 2006, Issue 3. [DOI: 10.1002/14651858.CD002866.pub2]**Figures legends Figure 1.** Discovery of the vaginal outlet anatomy and histology**A.** The yellow arrow represents the hymeneal membrane and its tags. Upon dissecting the hymen membrane, the hymeneal ring is white and indicated by the orange arrow. The low segment of the hymeneal ring fuses with the hymeneal plate, creating the crease and protuberance (the blue arrow).**B.** The excised fragment of the vaginal outlet without posterior perineal muscles. The yellow arrow refers to the hymeneal membrane; the orange denotes the hymeneal ring; the blue arrow

points out the hymeneal plate.**C.** The histology (Hematoxylin & Eosin stained, and 40x magnification) of the vaginal outlet structure consists of the three histological layers: superficial (the green arrow), middle (the orange arrow deep layer (the blue arrow) of the excised strip of the vaginal outlet obtained during parturition. The vaginal outlet consists of the three histological layers: superficial (the green arrow), middle (the orange arrow, and deep layer (the blue arrow). The first histological layer (the hymeneal membrane) is the superficial layer (the green arrow), consisting of multilayer flat squamous cells of the epithelium, loose fibrous connective tissue, collagen fibers, numerous network of capillary blood vessels, and multiple nerve endings. The second or the middle layer (the hymeneal ring) is well-organized, compressed fibers of the collagen fibers, a network of blood vessels of a larger caliber than in the superficial layer, heavily distributed nerve endings more than in the superficial layer (the orange arrow). Finally, the third layer (the hymeneal plate) is less organized and compact collagen fibers than the hymeneal ring (the blue arrow). In this layer, the smooth vaginal muscles fuse with the hymeneal plate, and it is the only connection of the vaginal wall with the vaginal outlet. A significantly smaller number of nerve endings is present in this stratum when compared to the hymeneal ring—none of the microscopic specimens from the V-shape excision shows perineal skeletal muscle.

Figure 2. The implementation of Ostrzenski's vaginal outlectomy at the time of fetal head crowning.**A.** The side of local anesthetic injection before the vaginal outlet excision,**B.** The fragment V-shape excision that includes tissue of the transitional vulvar skin, hymeneal membrane, hymeneal ring, and hymeneal plate,**C.** The minimal amount of bleeding is associated with a vaginal outlectomy.

Figure 3. Crowning of the fetal head through the vaginal outlet ("belt-like") is depicted. The vaginal outlet anatomy consists of a hymeneal membrane (stretched to the point that is almost invisible); the next layer is the hymeneal ring, and under it is the upper crease that separates the next layer of the hymeneal plate, seen as the protuberant configuration. The lower part of the hymeneal plate and the inner surface of the labium minus create a well-visible lower crease.

Figure 4. Post outlectorrhaphy, the suture line (the black arrow) is almost invisible, and the vagina orifice is not gapping.

Figure. 5. Comparison of vaginal outlectomy bleeding with vaginal outlectomy extension and midline episiotomy bleeding**A.** Amount of bleeding associated with vaginal outlectomy,**B.** Vaginal outlectomy extension to the posterior perineum**,** bleeding is heavier than from an uncomplicated vaginal outlectomy,**C.** Midline episiotomy (the black arrow) divides the skin, posterior-distal vaginal wall, the perineal body, posterior perineal fascia, and five surgically separated muscles (1- the bulbospongiosus muscle, 2- the urethrovaginal sphincter muscle, 3- the superficial transverse perineal muscle, 4- superficial external anal sphincter muscle, 5- the perineal body muscle located under the posterior-distal vaginal wall. The white on blue numbers represent the separated posterior perineum musculatures. The white on green no. 5 depicts the perineal body, and no. 6 describes the levator ani defect.

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