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INTRAPARTUM PELVIC FLOOR AND PERINEAL INJURIES - risk factors and prevention

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THESIS SUMMARY
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The dissertation contains 116 standard typed pages and is illustrated with 28 figures, 5 tables, and 4 appendices.
The references include 215 titles, of which 5 in Cyrillic and 210 in Latin script.
Figures and tables in the abstract do not correspond to the numbering in the dissertation.

The author is a doctoral student in full-time study at the Department of Obstetrics and Gynecology, Faculty of Medicine, Medical University – Varna, and enrolled under order P-109-553/12.12.2023.
He works as an obstetrician-gynecologist and head of the IVF sector at "Vita" Hospital – Sofia.

In connection with this dissertation, 4 original full-text publications and 2 conference presentations have been achieved.
The dissertation has been discussed, accepted, and proposed for public defense at the Department Council of the Department of Obstetrics and Gynecology, Faculty of Medicine, at the Medical University "Prof. D-r Paraskev Stoyanov" – Varna, held on 04.07.2025.

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All materials related to the defence are available at the Scientific Department and are published on the website of the Medical University – Varna.

CONTENTS

I. Introduction

Tears of the perineum during childbirth are a problem affecting millions of women worldwide each year. The frequency of perineal injuries depends on differences in obstetric practice, including the rate and type of performed episiotomies, which vary not only between countries but also among individual practitioners within a hospital.

In the Netherlands, the episiotomy rate is 8%, compared to 14% in the United Kingdom, 50% in the USA, and 99% in some Eastern European countries. These rates also differ among hospitals within a country— for example, in the USA, the episiotomy rate ranges between 20% and 70% across different clinics.

The overall risk of intrapartum injury to the anal sphincter (ИУАС) is approximately 1% of all vaginal deliveries. Additionally, "occult" injuries to the anal sphincter (defects detected only through endoanal ultrasound) occur in about 33% of first-time mothers after vaginal birth.

The most plausible explanation for these so-called "occult" injuries is that they are either missed, recognized but not documented in the patient’s records, or incorrectly classified as less severe tears.

Due to the training of obstetricians and increased awareness of this issue, there is a trend toward better recognition of anal sphincter injuries.

The morbidity associated with perineal trauma depends on the extent of the injury, the techniques and materials used for stitching, and the skills of the operator. It is crucial that obstetricians ensure routine procedures, such as perineal repairs after delivery, are based on evidence from clinical studies to provide the most effective, proper, and cost-efficient treatment for patients.

II. GOAL AND TASKS

The goal of this research is:

To determine the actual frequency and severity of intrapartum injuries to the pelvic floor, the risk factors for their occurrence, and methods for their prevention and treatment.

In relation to this goal, the following tasks are formulated:

1. To establish the true frequency of intrapartum injuries to the anal sphincter using imaging methods for early diagnosis (endoanal ultrasound examination).

2. To formulate the problem of intrapartum injuries to the pelvic floor as a cause of the commonly encountered fecal incontinence among women in the older age group.

3. To assess the influence of the most common risk factors and their degree of severity on the development of occult intrapartum injuries of the anal sphincter.

4. To identify changes in the duration of the second stage of labor as an independent risk factor for pelvic floor rupture in clinical practice, following the application of a medical device – obstetric gel.

5. To develop an algorithm for prevention, diagnosis, timely treatment, and follow-up of intrapartum injuries to the pelvic floor.

III. CLINICAL MATERIAL, RESEARCH METHODS, AND STATISTICAL ANALYSIS OF RESULTS

3.1 Clinical Material

The data for the patients included in this dissertation were collected between 2009 and 2014 from four hospitals: UMHAT "Dr. Georgi Stranski" – Pleven, Bulgaria, "Nadezhda" Maternity Hospital – Sofia, Bulgaria, University Clinical Center, Labor and Delivery Department – Ljubljana, Slovenia and Gynecology-Obstetrics Department, General Hospital – Trbovlje, Slovenia.

The clinical material from the two international hospitals was personally collected and examined by the doctoral candidate within the framework of the ERASMUS exchange program for doctoral students between MU – Pleven and UKC – Ljubljana, Slovenia, during 2008/2009 and 2010/2011, and from January to June 2012 at the Gynecology-Obstetrics Department of the General Hospital – Trbovlje, Slovenia, in his capacity as a licensed specialist.

Final analysis was performed on data from 203 patients examined during studies related to this scientific research. To solve the tasks and achieve the research goals, working groups were formed from all included patients, carefully defined and monitored across the specific studies.

Definition of some examined parameters:

For the parturient (woman):

-Parity – the order of birth, according to the Bulgarian Standard in Obstetrics and Gynecology: gestational age of the fetus over 26 weeks and weight over 800 grams.

-Weight – the patient’s weight, measured in kilograms.

-Height – the patient’s height, measured in centimeters.

-Age – the patient’s age, recorded in years.

-Gestational age – the duration of pregnancy calculated from the first day of the last regular menstrual cycle, expressed in days or weeks depending on the study’s purpose.

For the fetus:

-Weight – measured within 10 minutes after birth, in grams.

-Length – measured within 10 minutes after birth, in centimeters.

-Head circumference – circumference at the level of the occipitofrontal circumference, within 10 minutes after birth, in centimeters.

-Presentation – the lowest part of the fetus in the pelvic inlet.

For labor progression:

-Induction and stimulation – administration of prostaglandins or oxytocics to induce or strengthen clinically evident uterine contractions.

-Intrapartum injury to the anal sphincter (IUS) – damaged anatomical integrity of the perineum and/or pelvic floor, classified according to the International Classification of ICS.

-Duration of the second stage of labor – the time from full cervical dilation to delivery, measured in minutes.

3.2 Diagnostic Methods

3.2.1 Anamnestic Data

All data related to each study were recorded in a specially created research protocol, which included the main information about the course of labor.

Information for each patient was duly collected from the available official medical documentation — the "Birth Disease History" (form from the Ministry of Health of Bulgaria) and "Porodni zapisnik" (form №4 from the Ministry of Health of Slovenia). Different data were gathered and recorded from the medical documentation depending on the purpose of each study.

For the parturient: parity, weight, height, age, gestational age in days or weeks.

For the fetus: sex, weight, length, head circumference, presentation.

For the labor process: anesthesia, induction and stimulation, pain relief, intrapartum injury to the anal sphincter (ТД), tissue repair — technique and suturing material.

At the end of each protocol, there is a section for the patient's informed consent, confirming that she agrees to the use of her data regarding labor course, treatment, and follow-up for clinical research and publications.

3.3 Clinical Methods

3.3.1 Methods for Imaging Diagnosis – Ultrasound Examination

Endoanal Ultrasound (EAU)

The endosonographic images and corresponding anatomical structures at high, middle, and low levels can be seen in figure 14.

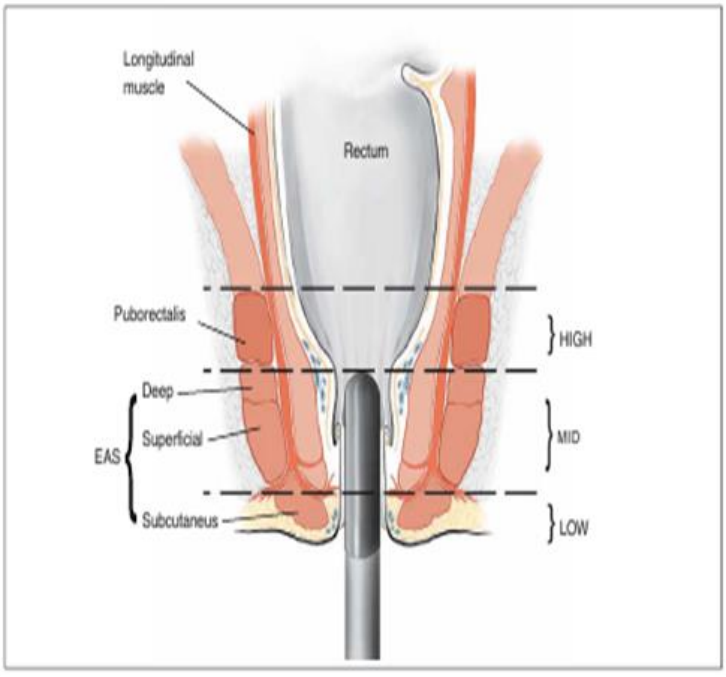


Figure 1 Schematic ultrasound scan of endoanal ultrasound

In the endosonographic image, orienting according to the clock face, 3 o'clock represents the left side of the patient, 6 o'clock is posterior, and 9 o'clock is the right side of the patient when the examination is performed in the lithotomy position. Some authors prefer the left lateral position, which is not preferred by gynecologists due to the orientation of structures. The endoscopic probe creates two bright images in the center.

Three acoustic images are visualized:

Anal mucosa / anal submucosa. The mucosa itself is not visualized. The lamina muscularis submucosae ani can be seen as a thin, hypoechoic ring with the superficial subepithelium. Large vascular bundles can be visualized anteriorly and superiorly and can be traced.

Internal sphincter (low echogenicity). A well-defined ring serves as an important anatomical landmark for ultrasound. It has a thickness of about 2 mm. It may appear thinned anteriorly and does not always have symmetrical thickness, but all marked defects in thickness are abnormal. The length of the internal anal sphincter (ВътрАС) measured with 3D ultrasound averages 34 mm and ends at 8 mm (15 mm in males) from the edge of the anus. It originates from the circular smooth muscle of the rectum, which has evolved into the internal sphincter through increased thickness.

Longitudinal muscle layer (low to intermediate echogenicity). This is a complex structure consisting of fibroelastin tissue from the pubocervical fascia, smooth muscle from the longitudinal layer of the rectum, and striated muscle from m. puboanalis. Muscle fibers in the upper part of the canal merge and disappear before the end of the internal sphincter, so low-reflective muscle fiber groups are visible in the upper longitudinal layer, while the mid-reflective fibroelastin tissues are visible only in the lower part.

External anal sphincter (high echogenicity). This striated muscle has low to medium reflectivity. The internal sphincter can be easily distinguished from the longitudinal layer and subepithelium. Differences in echogenicity, respectively, in the reflectivity of the structures are essential for differentiating the longitudinal layer from the external sphincter, as well as distinguishing the external anal sphincter from the ischioanal fat tissue. Structures involved in the sphincter mechanism and its anatomical integrity include the rectum, m. levator ani and its fascia, and the perineal muscles. Although anatomical details vary between sexes, only female anatomy will be described here.

M. puborectalis forms a U-shaped sling around the upper part of the anus at the anorectal junction, merging laterally and posteriorly with the deep part of the external sphincter. The most medial fibers of m. puborectalis merge with the longitudinal layer and are called m. puboanalis. More superficially than m. puborectalis, the mm. transversi perinei merge anterior-laterally with the external sphincter.The anterior body of the perineum contains a large amount of fibroelastic tissue and appears relatively homogeneous and hyporeflective. The merging of mm. transversi perinei with the external sphincter creates a anterior muscular bundle, which is shorter than the posterior external sphincter, and inserts into the central part. At the level of the upper puborectalis, there is no muscle anteriorly, only low-reflective connective tissue of the perineal body.

The striated muscle of the external sphincter is involved at the level of the lower border of the puborectalis, where the probe is withdrawn and merges along the midline with mm. transversus perinei.

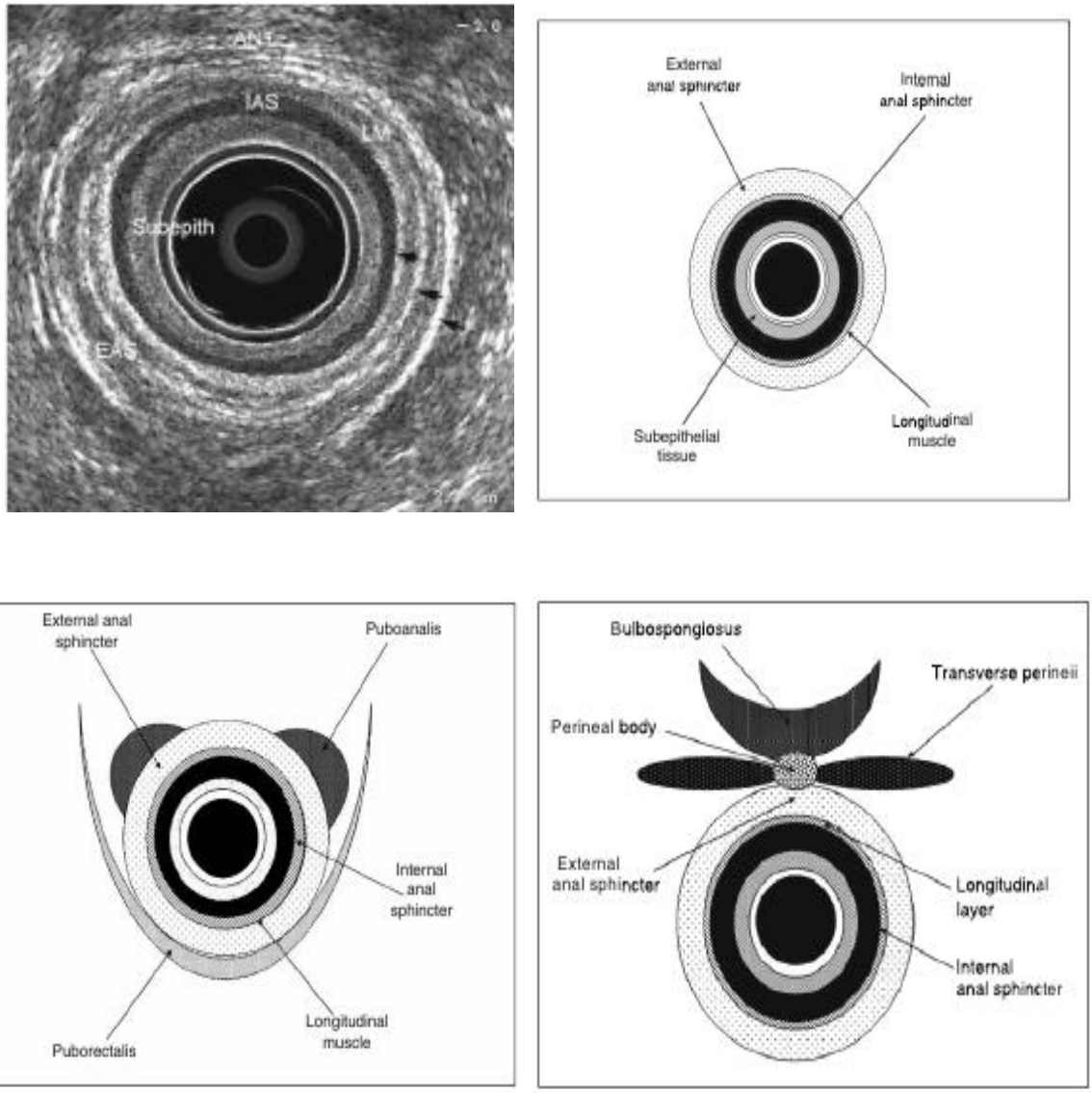


Figure 2 Schematic representation of anatomical structures in endoanal ultrasound

Sometimes, it is possible to visualize the longitudinal muscle from the external anal sphincter. High in the anal canal, only the puborectalis muscle, which is difficult to distinguish sonographically, can be seen posteriorly in women. The transverse muscles of the perineum and bulbospongiosus muscles are also visible.

At the middle level of the anal canal, the internal anal sphincter and the external anal sphincter can be visualized, with a well-defined boundary in the anterior part of the ring.

At the lowest level of the anal canal, caudal to the internal sphincter, only the subcutaneous external sphincter is visible.

When examining women, it is important to distinguish between physiological "defects" (hypoechoic areas with smooth, even edges) and true sphincter ruptures (mixed echostructure due to tear, with irregular edges), which are visible in the upper anterior part of the anal canal (see figure 3).

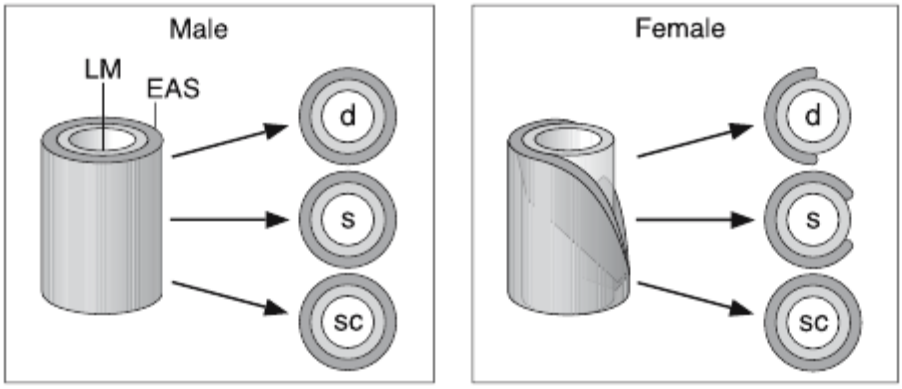


Figure 3 Anatomical features of the anal sphincter in women and men

Ultrasound images of sphincter defects:

Defects of the external sphincter high in the anal canal are difficult to detect because there are no identifiable points in the amorphous tissues of the perineum. The external anal sphincter forms a complete ring at the mid-level of the canal when the probe is moved outward.

Loss of ring integrity is abnormal and indicates a defect. Connective tissue indicates replacement of the normal structure of the anal sphincter with a zone of amorphous tissue, usually with low reflectivity and contractility. Thinning of any part of the internal anal sphincter is a sign of trauma and often seen together with damage to the same area of the internal sphincter.

Any discontinuity in the integrity of the internal anal sphincter (IAS) is abnormal and indicates trauma; this is often observed with compensatory thickening of the remaining part of the internal sphincter.

The probe is then carefully withdrawn downward along the anal canal toward the anus, and the ultrasound images of m. puborectalis, the internal anal sphincter (longitudinal muscle layer), and the external anal sphincter are assessed.

The internal anal sphincter appears as a hypoechoic ring, surrounded by a heterogenous hyperechoic ring composed of external anal sphincter muscles.

Damage to the external anal sphincter appears as a hypoechoic gap in the ring of varying width, which increases with contraction. Tears of the anal sphincter are seen as gaps in the hypoechoic ring.

Ultrasound Technique

The devices used in this study at the University Clinical Center – Ljubljana, Slovenia, and at the Obstetrics Clinic of UMHAT "Dr. Georgi Stranski" – Pleven, Bulgaria, are respectively: an Olympus colonoscope with a 7 MHz ultrasound probe, which allows 360-degree imaging, and a B&K ultrasound machine (B&K Medical, Herlev, Denmark) with endosonode 1850 and a rotational transducer 10 MHz (B-K 6004), covered with a plastic cone with a diameter of 12 mm. The latex tips are particularly suitable because they change shape and do not produce a proper circular echonegative image. The probe is filled with distilled water. The entire probe is covered with a single-use latex cap.

Patients were referred for ultrasound examination on the second or third day after delivery. All patients with a diagnosed third or higher degree of perineal tear, chronic bowel diseases, hemorrhoids, or other anal canal conditions were excluded. All patients were examined without anesthesia, using a 360° rotational endosonode of the available equipment at the clinic, following a standard protocol for investigation.

Clinical Algorithm for Endoanal Ultrasound Examination:

- Explain the procedure to the patient, including its purpose.
- Obtain informed consent.
- Position the patient on a medical bed (examination on a gynecological chair is not recommended for this method, due to perineal strain during limb abduction).
- Inspect the perineum for visible defects.
- Place the patient in a gynecological position on the gynecological chair.
- Rectal anesthesia is administered; assess the patient's discomfort level or presence of pain.
- Cover the anal probe with gel to facilitate penetration into the rectum, following the anoretal angle.
- Visualize key landmarks during orientation — m. puborectalis and the vagina.
- Perform sequential caudal movements and systematically visualize remaining structures of the anal canal and pelvis.
- Document the results with ultrasound images.
- Remove the probe.
- Reassess the patient's discomfort or pain symptoms.
- The obtained results were recorded in the research protocol (see appendix).

3.4 Therapeutic Methods

4.4.1 Transvaginal Application of Obstetric Gel

The obstetric gel Dianatal® from the company HCB Happy Child Birth AG, Switzerland, was used. The product was developed based on the idea of Dr. Andreas F. Schaub, an obstetrician-gynecologist from Zurich, Switzerland, and the concept has been adopted and further developed in several clinics across Western Europe. The product is registered as a Class IIa medical device and

holds certifications for use within the European Union and the USA. It is intended for use only by qualified medical personnel. Each kit contains three sterile syringes for single use, each with 11 ml of gel:

Two syringes of Dianatal® for Stage 1: white plunger, highly bio-adhesive,

One syringe of Dianatal® for Stage 2: blue plunger, moderately bio-adhesive,

Two applicators for vaginal application of Dianatal® obstetric gel.

Dianatal® obstetric gel was specially developed to assist vaginal delivery. It is highly bio-adhesive and has a strong ability to bind with water. The gel is used during vaginal delivery to facilitate the process for both mother and baby, and to protect the perineum by forming a lubricating bio-adhesive film inside the birth canal, which reduces friction that might hinder delivery.

Dianatal® obstetric gel shortens both the first and second stages of labor, which is why it should be used throughout the entire labor. Specifically, Dianatal® Stage 1 is used during the first phase, and Dianatal® Stage 2 during the second.

Contraindications

Dianatal® obstetric gel was not used in cases where:

- There are suspicions of amniotic infection syndrome,
- Signs of fetal asphyxia,
- Vaginal delivery is impossible or contraindicated.
- Indications for Use

Facilitation of vaginal delivery by reducing friction, thereby protecting both mother and baby, especially in first-time and previously pregnant women, as well as after cesarean section, water birth, or preterm labor after rupture of membranes.

Treatment of prolonged labor.

Facilitation of vaginal surgical procedures.

Protection of the perineum during vaginal delivery.

Manual removal of the placenta.

The main indication for use in this study was to shorten the second stage of labor and to reduce the frequency of intrapartum injuries (IPI) of the perineum and pelvic floor, including episiotomies.

The gel was applied to all patients in active labor (cervical dilation > 4 cm as per Friedman), guided by the lead obstetrician, following the instructions for initial and subsequent doses.

During the first phase of labor, syringes of Dianatal® Stage 1: blue plunger, highly bio-adhesive, were used.

After full cervical dilation, syringes of Dianatal® Stage 2: blue plunger, with moderate bio-adhesiveness, were used.

Throughout the entire labor, 3 to 5 ml of gel was applied at each session using a sterile vaginal applicator, included in the original packaging of the product. Application was performed before each vaginal examination, spreading the gel evenly along the vaginal walls with a sterile glove. An additional amount of gel (15–30 ml) was applied 15-30 minutes after rupture of membranes.

In women with spontaneous rupture of membranes before hospitalization, a maximum dose of 5 ml of Dianatal® gel was applied during the first vaginal exam as a single application.

The obtained results were recorded in the research protocol. (see Appendix)

3.3 Statistical Analysis of the Results

5.3.1 Computer Processing

The tables and diagrams were created using Windows Office Pack 8.

4.3.2 Statistical Methods

The statistical analysis was performed using MedCalc (v12.2.1.0, Ostend, Belgium: MedCalc Software) and SPSS (Version 19.0, Armonk, NY: IBM Corp). The following methods were applied:

Descriptive analysis – the frequency distribution of examined features was presented in tabular form, broken down by research groups.

Variation analysis – calculation of measures of central tendency and dispersion.

Graphical analysis – for visualization of the obtained results.

Alternative analysis – to compare relative shares.

Fisher's exact test and Chi-squared (χ^2) test – to examine hypotheses regarding the presence of relationships between categorical variables.

Kolmogorov–Smirnov and Shapiro–Wilk non-parametric tests – to verify the distribution type.

One-way ANOVA – to test hypotheses about differences between several independent samples.

Stuart-t-test – to assess hypotheses about differences between two independent samples.

Kruskal–Wallis non-parametric test – to examine hypotheses regarding differences between several independent samples.

Mann–Whitney non-parametric test – to evaluate hypotheses about differences between two independent samples.

4.3 Epidemiological Methods

Additional information regarding the course of labor, anthropometric data of the fetus, interventions, and other factors were collected from hospital documentation, such as the case history (sample from the Ministry of Health) and the "Porodni zapisnik" (sample from the Ministry of Health – Slovenia).

IV. OWN RESULTS AND DISCUSSION

Regarding Tasks 1 and 2:

To determine the true frequency of intrapartum injuries to the anal sphincter using imaging methods for early diagnosis (endoanal ultrasound examination), and to formulate the problem of intrapartum pelvic floor injuries as a cause of commonly encountered fecal incontinence (FI) in the older female population.

Clinical Material

For the purpose of Tasks 1 and 2, 29 women after vaginal delivery were studied. These women satisfied the specified criteria and delivered at the Ljubljana Maternity Hospital between January and June 2009, as well as 34 women from July 2009 to March 2012 who delivered at the Obstetrics Clinic of UMHAT – Pleven.

Ultrasound examinations were performed on the second or third postpartum day after obtaining informed consent, approved by the Ethics Committees of both clinics.

All women were examined without anesthesia using a 360° rotational endosonode on equipment available in each clinic, following a standard examination protocol.

Women from UMHAT Pleven also signed informed consent for participation in a scientific research project at MU Pleven.

Additional information regarding the course of labor, fetal anthropometric data, interventions, and other details were collected from hospital documentation, such as the case history and the "Porodni zapisnik" (delivery record).

All deliveries were attended by midwives according to standard protocols for active labor management in the respective delivery units.

All performed episiotomies were mediolateral.

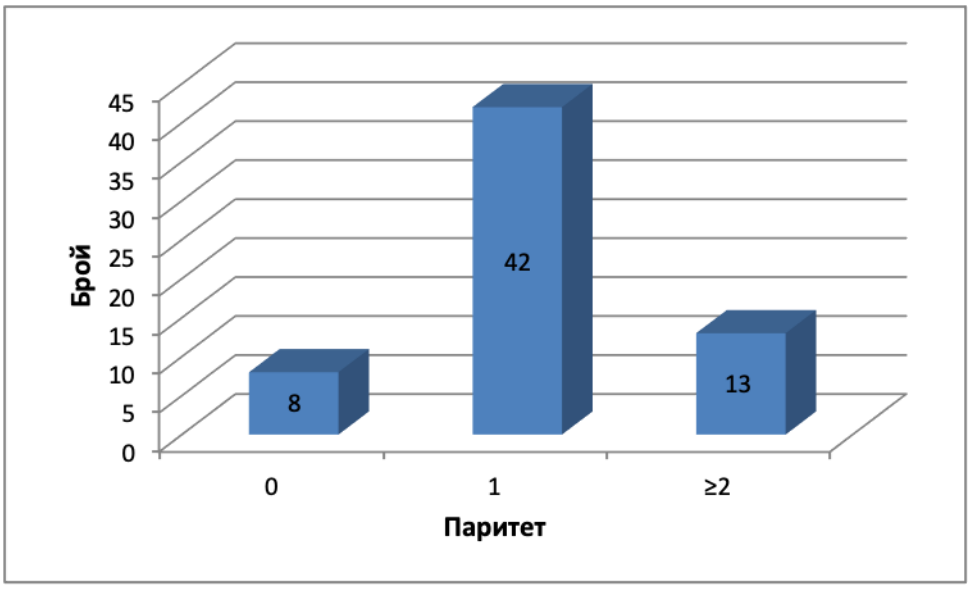


Figure 4 Demographic characteristics of the study participants by parity.

Inclusion criteria: Vaginal delivery; gestational age from 38 to 41 weeks inclusive; fetal presentation in vertex position; singleton pregnancy.

Exclusion criteria: Fetal weight over 4000 grams; atypical or pathological presentations; women who delivered by cesarean section; women with identified anal sphincter rupture at delivery or perineal surgeries; history of irritable colon or other inflammatory gastrointestinal diseases.

Results

The minimum required number of participants (60 women) in the study was determined based on literature data regarding the frequency of intrapartum anal sphincter injuries (OIAS), as well as previous studies by our team, assuming a 95% confidence interval (Type I error) and 80% statistical power (Type II error). In all cases, a clinical examination of the perineum and the soft birth canal was performed after delivery, and the observed tears were properly documented in the medical records. No anal sphincter injuries were identified in any of the women; only incomplete ruptures and episiotomies were noted.

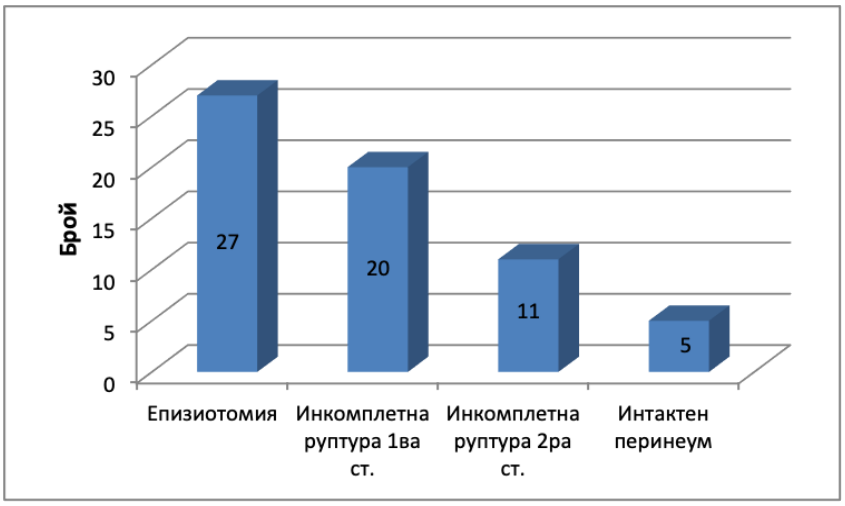


Figure 5 Described perineal injuries during clinical examination

According to the research protocol, within 48 hours of delivery, all patients underwent endoanal ultrasound, and the results were documented in the clinic's records (Appendix 3). In the study, after performing the endoanal ultrasound, we found an incidence of intrapartum anal sphincter injuries (OIAS) of 25.4%, i.e., in 16 out of 63 women. All these tears were classified as IIIA or less than 50% of the total thickness of the external anal sphincter.

Figure 6 Distribution of patients according to OIAS status

Of the five women with diagnosed OIAS (5/16), labor was assisted with a vacuum extractor, which is an independent risk factor for pelvic floor tears.

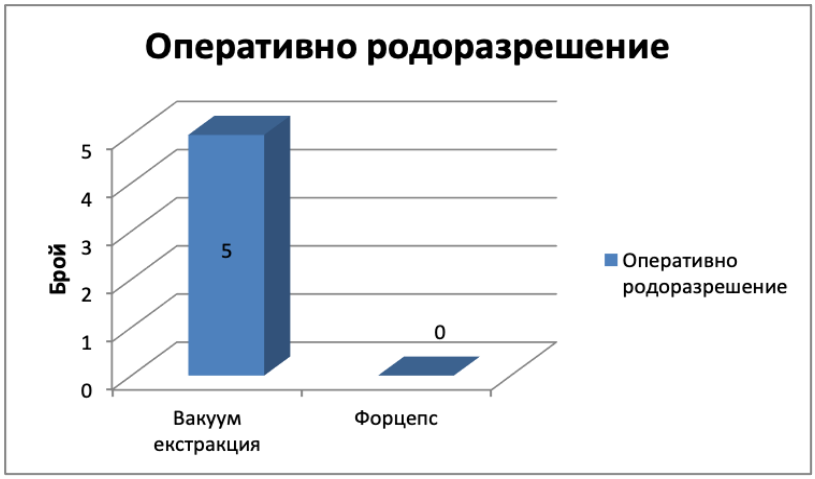


Figure 7 Distribution of women with operative vaginal delivery

None of the women included in the study showed damage to the internal anal sphincter (IAS).

In 79.4% (50/63) of the women, there were no clinical symptoms, while 13 women (20.6%) reported transient problems with gas retention.

Figure 8 Incidence of OIAS depending on presence or absence of symptoms

Among 10 women with pronounced clinical symptoms of anal incontinence, concomitant OIAS was also diagnosed. Conversely, in 3 women with significant symptoms, no OIAS was found. This may be explained by overstretching of the pelvic floor muscles and transient loss of tone and sensation after delivery. This ratio confirms that most women with symptoms of anal incontinence should be examined with endoanal ultrasound, as there is a high likelihood that early diagnosis and treatment of OIAS will be missed otherwise.

Additionally, there are cases (3 women) with diagnosed OIAS who do not present clinical symptoms. For these women, damage manifestations may only appear later in life, and early clinical follow-up is essential to detect subtle initial changes in tone and function of the anal sphincter complex. This can guide early rehabilitation or surgical correction, depending on the severity of symptoms.

Figure 9 Incidence of women with clinically evident symptoms

Discussion

The incidence of intrapartum anal sphincter injuries (OIAS) in this study indicates a frequency of partial damage to the anal sphincter, consistent with the

literature — 25.4%, i.e., in 16 out of 63 women. The differences observed in reported OIAS rates within hospital documentation across studied populations highlight problem underestimation, diagnostic gaps, and inadequate clinical management and follow-up of patients. From these results, we can conclude that the most common clinical symptom in the first days after delivery—difficulty retaining gases—is often accompanied by anatomical damage to the anal sphincter complex — in 76.9% (10/13). This percentage explains the high prevalence of anal incontinence in women later in life, following hormonal changes with age and reduced compensatory mechanisms of the pelvic floor — consequences of the intrapartum OIAS. This is one reason why obstetricians tend to overlook the problem—they do not encounter obvious clinical symptoms that develop years after delivery.

In 23.1% of cases, complaints may occur even when structures are anatomically intact. From this, we can deduce that clinical symptoms can point to an anatomical defect but are not a definitive method for diagnosing OIAS.

The clinical approach should not automatically include endoanal ultrasound after every vaginal delivery to identify potential sphincter defects, as this technique is relatively costly due to the technical requirements of ultrasound equipment. Obstetricians and gynecologists should be trained and experienced in intrapartum diagnosis of sphincter injuries, early repair, and subsequent follow-up in specialized clinics for women at increased risk.

Endoanal ultrasound visualizes the morphology of the anal sphincter, and there are no other diagnostic methods that are better suited for detecting its defects. This makes it one of the most important methods for investigating anal incontinence. The ultrasound technique we used is a step towards creating tertiary clinical centers — similar to those in other European countries — to which women with suspected OIAS or prominent clinical symptoms should be

referred. Such centers should emphasize early detection, rehabilitation, and treatment of women with OIAS after delivery, involving highly specialized teams including urogynecologists, colorectal surgeons, physiotherapists, and even psychotherapists.

Regarding Task 3:

To determine the influence of the most common risk factors and their relative severity on the development of occult intrapartal injuries of the anal sphincter.

Clinical Material

To achieve the study objectives, 42 women after vaginal delivery were examined, who gave birth at the Ljubljana Maternity Hospital between January and September 2009, and 38 women at the Obstetric Clinic of UMBAL "Dr. Georgi Stranski" – Pleven, from July 2009 to November 2011. In all cases, anal sphincter injury was confirmed using endoanal ultrasonography. The ultrasound examinations were performed on the second or third postpartum day, after obtaining informed consent approved by the Ethics Committees of both clinics. All women were examined without anesthesia using a 360° rotational endosonwithout on the available equipment, following standard examination protocols. Women at UMBAL Pleven also signed informed consent to participate in the research project at Medical University – Pleven.

Additional data regarding labor progression, fetal anthropometric data, interventions, etc., were collected from hospital records, disease history, and birth records. All deliveries were managed by midwives according to standard protocols, and all episiotomies performed were mediolateral.

Parameter	Average / %
Age of women (years)	27
Maternal weight (kg)	80.5
Height of women (cm)	169.4
Gestational age (days)	278.2
Parity:	
- Primipara (%)	19.8
- Multipara (%)	80.2
Fetal weight (g)	3458.3
Fetal head circumference (cm)	35.42

Table 1

Inclusion Criteria:

Vaginal delivery, Gestational age between 38 and 42 weeks, Fetal weight between 3000 and 4500 grams,Anterior-tilted fetal presentation,Singleton pregnancy

Exclusion Criteria:

Atypical or pathological fetal presentations, Caesarean section deliveries

Recognized anal sphincter tears at delivery or perineal surgeries, History of irritable colon or other inflammatory gastrointestinal diseases

Ultrasound Technique:

The equipment used at Ljubljana University Clinical Center and Pleven Obstetric Clinic included Olympus colonoscope with a 7 MHz ultrasound probe (360° imaging) and B&K ultrasound with a 1850 endoson and a 10 MHz rotary transducer covered by a plastic cone. The probes were filled with distilled water and covered with a disposable latex cover.

Results

Logistic regression analysis indicated that the following independent variables are risk factors for the development of occult intrapartal anal sphincter injuries (OASIS)

Variable	Coefficient	Std. Error	p-value	Odds Ratio (OR)	95% Confidence Interval (CI)
Primipara	0.74441	0.33444	0.0031	6.00	4.23 – 15.35
Gestational age > 41 weeks	1.71532	0.34549	< 0.0001	8.51	5.32 – 19.73
Birth weight > 4000 g	2.62578	0.23831	< 0.0001	11.34	6.54 – 22.37

Table 2

Discussion

The results of this study indicate that each examined factor has a positive predictive value regarding the occurrence of intrapartum anal sphincter injuries, specifically primiparity, gestational age, and fetal weight.

These findings confirm data from other publications regarding risk factors influencing pelvic floor tears. Due to the limited number of patients in the studied population, we were unable to include other risk factors (such as race, BMI, instrumental delivery) and to assess their impact on the development of OIAS, which could be investigated in future studies.

From these results, we can conclude that knowing the main risk factors for pelvic floor injuries allows for a significant prediction of their occurrence. In the preparation and follow-up of such pregnancies, the impact of these factors can sometimes be reduced (e.g., selective induction at a specific gestational age and expected high fetal weight), while in other cases, it should only serve to alert the obstetrician to actively monitor for the development of OIAS. These data should form the basis of a clinical algorithm for prevention and early detection

of OIAS in modern obstetric practice, which can significantly reduce late consequences such as anal and urinary incontinence, changes in pelvic organ statics, and ultimately, a decrease in the quality of life for patients.

Regarding Task 4:

To determine the changes in the duration of the second stage of labor as an independent risk factor for pelvic floor tearing in clinical practice after application of the obstetric gel.

Clinical Material and Methods

To answer this goal, we studied 33 primiparous women who delivered between January and June 2012 at the Gynecology Department of the General Hospital – Trbovlje, Slovenia, 19 women from May to July 2011 who delivered at the Obstetrics Clinic of UMHAT – Pleven, Bulgaria, and 8 women from February to October 2013 who delivered at the "Nadezhda" Women's Health Hospital – Sofia.

The women were divided into Group A (20 women), where the obstetric gel Dianatal® was used during the pushing phase, and Group B (40 women), serving as controls. The control group was assembled from consecutive deliveries in the hospitals, including only women meeting the criteria and selected via software. Additional data on labor type, fetal anthropometry, interventions, etc., were collected from hospital records, including the case history and the "Porodni zapisnik". All deliveries were attended by midwives, following standard protocols for active management of labor. All performed episiotomies were mediolateral.

Characteristic	Average / Values
Age of the mother (years)	26.8
Maternal weight (kg)	74.9
Maternal height (cm)	165.8
Gestational age (days)	277.9 ± 11.6
Fetal weight (g)	3214 ± 314
Fetal head circumference (cm)	34.0

Table 3

Inclusion criteria: Vaginal delivery; gestational age from 38 to 41 weeks inclusive; vertex presentation; singleton pregnancy.

Exclusion criteria: Fetal weight over 4000 g; atypical or pathological presentations; women who had cesarean section; contraindications for applying Dianatal® gel—such as suspicion of amniotic infection syndrome, signs of fetal asphyxia.

In this study, only primiparous women were included to reduce the influence of the increased elasticity typical of multigravidas during delivery. Parameters followed included mother's age, BMI, fetal sex, gestational age, fetal weight, head circumference, induction or stimulation, analgesia, type of perineal injury, surgical technique, and suturing material used for repair. Elective or emergency cesarean sections were exclusionary.

The gel was applied to all women during active labor (cervical dilation > 4 cm), following usage instructions for initial and subsequent doses. Women were instructed to push only when feeling an uncontrollable urge, i.e., when the presenting part reached the pelvic floor. All women remained in lithotomy position during pushing.

Data were recorded in the research protocol, which included key information about labor course. At the end of each protocol, the patient's informed consent was documented.

Results

Characteristic	With Dianatal®	Without Dianatal®	Confidence Interval (P)
Average duration of the second stage (minutes)	19.3	32.5	P < 0.005

Table 4

Data analysis was performed using "SPSS Statistics Professional®" (IBM®, version 19.0.0

To assess the significance of the obtained results, we used Fisher's exact test. Values of $p < 0.05$ were considered statistically significant. In our study, no side effects from the application of Dianatal® were observed in either the newborns or the mothers. The results demonstrate a clear trend towards a substantial reduction in the duration of the second stage of labor following the use of the obstetric gel Dianatal®.

Discussion

An extended second stage of labor is one of the main risk factors for the development of intrapartum anal sphincter injuries (OIAS). Shortening this period through the use of a medical obstetric gel with such indications can significantly reduce the incidence of these obstetric traumas, decrease maternal fear and discomfort during labor, and minimize late complications such as anal and urinary incontinence, pelvic organ prolapse, sexual dysfunction, and ultimately, deterioration in quality of life. Our findings support existing data from numerous other studies indicating that Dianatal® is an effective option for shortening the pushing phase in primiparous women.

The obstetric gel is indicated for preventive use in primiparous and multiparous women with a history of difficult labor, as well as women seeking to facilitate vaginal delivery—protecting the soft birth canal from overstretching and tearing, and preventing subsequent changes in sexual life after childbirth. A combination of manual techniques alone does not guarantee success. An individualized approach to each patient—considering her anatomical structure, physiology, and psychological attitude—can significantly reduce the prevalence of severe intrapartum pelvic floor injuries.

In conclusion, we can say that Dianatal® does not guarantee an easy delivery but certainly facilitates it considerably. Prevention of pelvic floor tears requires detailed knowledge of the biomechanics and physiology of the birth process.

Regarding Task 5:

Based on the conducted research, develop an obstetric management algorithm for the prevention, diagnosis, and appropriate treatment of intrapartum pelvic floor injuries.

Based on our research and obtained results, we developed a practical clinical algorithm for Bulgaria aimed at prevention, diagnosis, treatment, and follow-up of obstetric injuries to the soft birth canal, which can be integrated into obstetric practice. It has been adapted as much as possible to Bulgarian obstetric standards.

We hope the proposed scheme will be useful for obstetric gynecologists and resident doctors, especially those without experience in managing intrapartum perineal and pelvic floor injuries, during training courses on the subject.

The described steps are recommendations and do not limit the individual approach of each doctor towards every patient.

Prevention of Perineal Injuries

Exercises for pelvic floor strengthening during pregnancy

Perineal massage before and during delivery

Choosing appropriate body positions during the first stage of labor

Use of active substances that reduce friction of the presenting part

Proper pushing technique — only when there is an uncontrollable urge

Protecting the perineum — using Rithgen (or Rithgen-like) technique or delayed head delivery

Risk Factors

Fetal weight over 4000 grams

Nulliparity

Induction of labor

Epidural anesthesia

Second stage longer than 1 hour

Shoulder dystocia

Medial episiotomy

Atypical cephalic presentation

Perineal width less than 3 cm

Use of Kristeller maneuver during the second stage

Instrumental delivery

Mediolateral episiotomy (which reduces the relative risk of third-degree sphincter tear by 50% for every 6-degree increase in distance from the medial line of the perineum)

Episiotomy – Only on strict indications

Complicated vaginal delivery (breech presentation, shoulder dystocia, forceps, vacuum extraction, malposition or malpresentation of the fetus, most often occipito-posterior position)

Fetal distress syndrome

Scar from previous vaginal incision or poorly healed third or fourth-degree perineal tear

Post-Delivery – Mandatory Rectal Examination

Diagnosis of structural defects:

Circular movements between the index finger (in the rectum) and the thumb (in the vagina)

Visual differentiation of the integrity of the anal sphincter complex (similar to beef or pork meat) and internal anal sphincter (similar to chicken or fish meat)

Inspection of circular wrinkling around the anus — normal tone indicates anatomical integrity (reduced tone may occur with regional or general anesthesia)

Clinical Algorithm for First-Degree Perineal Tear Repair

Earliest possible surgical repair

Informed consent following detailed explanation of procedures and risks

Operator

Position: lithotomy

Disinfection of the operative field: chlorhexidine, Braunol, etc.

Anesthesia: local infiltration or superficial application (lidocaine, Chirocain, combination)

Surgical instruments: hemostatic clamp, anatomic and surgical forceps, needle holder, scissors, tampon with suture, gauze

Optimal lighting

Suture material and technique: absorbable multifilament, 2-0 or 0, single or intradermal sutures

Operative protocol with schematic

Clinical Algorithm for Second-Stage / Episiotomy (Grade 2) Perineal Tear Repair

Earliest possible surgical repair

Informed consent with detailed explanation

Operator

Position: lithotomy

Disinfection: chlorhexidine, Braunol, etc.

Anesthesia: local infiltration (lidocaine, Chirocain, combination)

Instruments: vaginal retractor, hemostatic clamp, both anatomic and surgical forceps, needle holder, scissors, tampon with suture, gauze

Optimal lighting

Suture and technique:

Absorbable multifilament, 0 or 1

Continuous, non-locking, or interrupted in two or three layers

Intradermal skin suturing

Operative protocol with schematic

Clinical Algorithm for Third-Degree Perineal Tear Repair

Earliest possible surgical repair, possibly delayed up to 12 hours

Informed consent with detailed explanation

Operator: experienced — at least 5 repairs of anal sphincter or training course completion

Position: lithotomy

Disinfection: chlorhexidine, Braunol, etc.

Anesthesia: regional, short-term intravenous

Instruments: vaginal vulva set, vaginal retractor, Weitlaner retractor, 2 forceps of Alice, 2 hemostatic clamps, forceps, needle holder, scissors, tampon with suture, gauze

Lighting: optimal

Suture and technique:

Rectal mucosa: monofilament PDS 3-0 or multifilament slow-absorbable, single interrupted sutures

External anal sphincter (BAC): interrupted, multifilament slow-absorbable, 2-0 or 0, end-to-end with P-shaped or layered technique

Perineum: multifilament quick-absorbable, 0 or 1, continuous or interrupted in two or three layers, intradermal skin suture

Operative protocol with schematic

Antibiotic prophylaxis: broad-spectrum antibiotics, metronidazole

Analgesia: NSAIDs (per os)

Laxative for 15 days: lactulose

Clinical Algorithm for Fourth-Degree Perineal Tear Repair

Earliest possible surgery, possibly delayed up to 12 hours

Informed consent following detailed explanation

Operator: with experience of over 5 repairs of anal sphincter or completion of a training course

Position: lithotomy

Disinfection: chlorhexidine, Braunol, etc.

Anesthesia: regional, short-term intravenous

Instruments: vaginal vulva set, vaginal retractor, Weitlaner retractor, 2 forceps of Alice, 2 hemostatic clamps, forceps, needle holder, scissors, tampon with suture, gauze

Lighting: optimal

Suture and technique:

Rectal mucosa: slow-absorbable multifilament (poliglecaprone or similar), 3-0, single interrupted, using a sliding (mattress) technique with knots in the lumen

Internal anal sphincter (ВътрАС): monofilament PDS 3-0 or slow-absorbable multifilament 2-0

External anal sphincter (ВАС): interrupted, multifilament, 2-0 or 0, end-to-end with P-shaped or layered technique

Perineum sutured with absorbable multifilament, 0 or 1, longer or interrupted sutures in two or three layers, with intradermal skin sutures.

Surgical protocol with schematic.

Antibiotic prophylaxis: broad-spectrum antibiotics and metronidazole.

Analgesia: NSAIDs (per os).

Mild laxative for 15 days (lactulose).Follow-up and Monitoring

Postpartum follow-up of women should be carried out outpatient, following these steps:

Active monitoring through targeted questioning for third-degree or higher tears — looking for symptoms of anal incontinence (AI) or fecal incontinence (FI) immediately after delivery.

Active follow-up with targeted questioning at 6 months postpartum — screening for symptoms of AI or FI.

Routine active monitoring for all women — requesting symptoms of AI or FI at 6 months after delivery.

If positive signs of AI or FI are found → referral for endoanal ultrasound and neurological examination.

Diagnosis of anal sphincter defect (АСК) → referred to a colorectal specialist.

V. Conclusions

Following the analysis of the obtained results, we conclude the following:

- ✓ In our study, after performing endoanal ultrasound, we found a frequency of intrapartum anal sphincter injuries (OIAS) of 25.4%, i.e., in 16 out of 63 women. All identified tears were classified as IIIA or less than 50% of the total thickness of the external anal sphincter.
- ✓ In five women with diagnosed OIAS (5/16), labor involved assisted vaginal delivery using vacuum extraction, which is an independent risk factor for pelvic floor tears.
- ✓ No damage to the internal anal sphincter (ВътрАС) was detected in any of the women in the study.
- ✓ In 79.4% (50/63), there were no clinical symptoms, while 13 women (20.6%) reported subjective problems with gas retention, of transitory character.
- ✓ Among 10 women with pronounced clinical symptoms of anal incontinence, co-existing OIAS was also diagnosed.
- ✓ We conclude that the most common clinical presentation of difficulty retaining gases in the first days postpartum is accompanied by anatomical damage to the anal sphincter complex — in 76.9% (10/13).
- ✓ The logistic regression analysis indicated that the examined independent variables are risk factors for the occurrence of OIAS: primiparity (OR 6.00; CI 4.23–15.35), gestational age > 41 weeks (OR 8.50; CI 5.32–19.73), and fetal weight > 4000 g (OR 11.34; CI 6.54–22.37).
- ✓ No side effects from the application of Dianatal® were observed in either the newborns or the mothers.

- ✓ An extended second stage of labor is one of the main risk factors for developing OIAS.
- ✓ Shortening the pushing phase using a medical obstetric gel with such indication can significantly reduce the incidence of these birth traumas, decrease maternal fear and discomfort during labor, and minimize late complications such as anal and urinary incontinence, pelvic organ prolapse, sexual dysfunction, and ultimately, deterioration in quality of life.
- ✓ Our study shows a pronounced trend towards a significant reduction in the duration of the second stage of labor following the use of the obstetric gel Dianatal®.

VII. Contributions of the Dissertation

Scientific-Theoretical Contributions:

The actual frequency of intrapartum pelvic floor and perineal injuries in primiparous women (25.4% in the studied population) has been established, confirming the results of international studies.

Main risk factors for intrapartum injuries and their impact on the relative risk of severe perineal tear have been identified, including primiparity (OR 6.00; CI 4.23–15.35), gestational age over 41 weeks (OR 8.50; CI 5.32–19.73), and fetal weight over 4000 g (OR 11.34; CI 6.54–22.37).

For the first time in Bulgaria, a clinical study employs the internationally accepted ICS and IUGA classification of intrapartum perineal injuries, based on the foundational principles of the integral theory of Ulmsten and Papapetros regarding the functional unity of the pelvic floor.

Scientific-Practical Contributions:

The application of endoanal ultrasound, as a fast, non-invasive, highly specific, and reliable method for early diagnosis of intrapartum pelvic floor injuries in obstetric practice, is introduced for the first time in Bulgaria. The method used is objective, comparable, and standardized for diagnosing OIAS.

The demonstrated positive effect of using medical devices (obstetric gel), which significantly shortens the second stage of labor, offers a new opportunity to reduce their frequency and severity, thus minimizing late complications resulting from missed diagnosis or incomplete recovery.

The developed practical algorithm for prevention, diagnosis, treatment, and follow-up of patients with intrapartum pelvic floor injuries serves as a useful tool for all trainees and practicing obstetricians, based on current research and clinical practices aligned with evidence-based medicine.

VIII. PUBLICATIONS AND CONGRESS PARTICIPATION ASSOCIATED WITH THE DISSERTATION

Application of KIWI vacuum extractor in obstetric practice – Bojinova, S., D. Tsvetkov; 27th National Obstetrics Conference, Kiten, June 19-21, 2008

Intrapartum anal sphincter injuries, or how the "ostrich principle" harms – D. Tsvetkov, Stoykov Sv., Lukanovich A.; 29th Anniversary National Obstetrics Conference, Pomorie, June 24-26, 2010

Intrapartum pelvic floor injuries – clinical diagnosis and modern obstetric management algorithm – D.L. Tsvetkov, Sv. Stoykov, A. Lukanovich; Obstetrics and Gynecology, April 2010

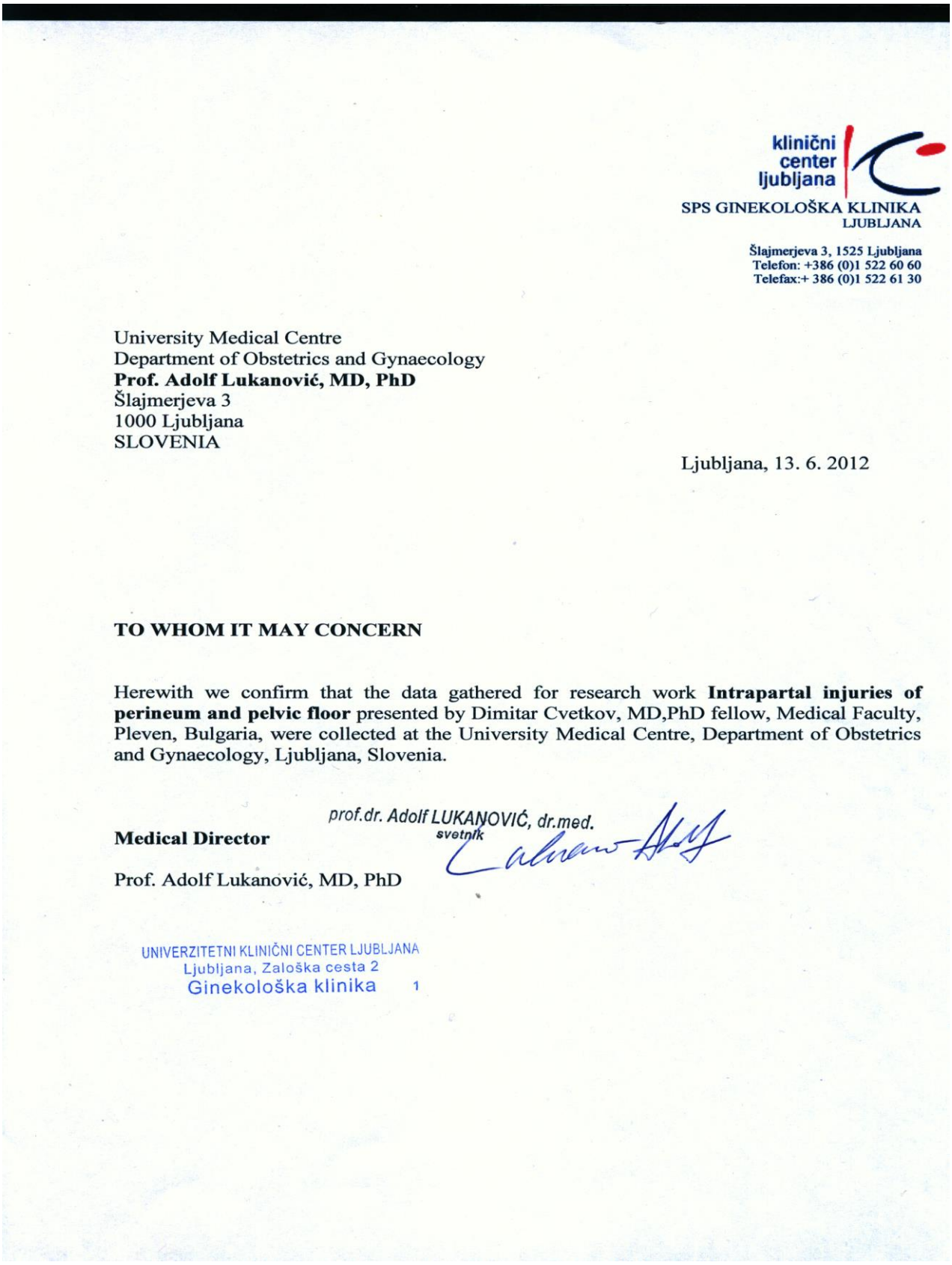
Study on the prevalence of occult postpartum tears of the anal sphincter using endoanal ultrasound – D.L. Tsvetkov, Sv. Stoykov, A. Lukanovich, Ignatov P.; Obstetrics and Gynecology, 2016; 55(5):15–21

Risk factors for occult postpartum tears of the anal sphincter – D.L. Tsvetkov, Sv. Stoykov, Ignatov P., Lukanovich A.; Obstetrics and Gynecology, 2016; 55(4):9–13

Impact of obstetric gel Dianatal® on the duration of the second stage of labor – D. Tsvetkov, Sv. Stoykov, Ignatov P., A. Lukanovich; Obstetrics and Gynecology, 2016; 55(5):9–14

D. Tsvetkov. (2024). Unintentional injury of the pelvic floor or surgery with strict indications — When does episiotomy make sense? Fetal medicine, obstetrics, and gynecology, 1(11). doi: 10.70926/FMOG/1/2025.0003.Epi.1.11

IX. Appendix



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1000 Ljubljana
SLOVENIA

Ljubljana, 13. 6. 2012

TO WHOM IT MAY CONCERN

Herewith we confirm that the data gathered for research work **Intrapartal injuries of perineum and pelvic floor** presented by Dimitar Cvetkov, MD,PhD fellow, Medical Faculty, Pleven, Bulgaria, were collected at the University Medical Centre, Department of Obstetrics and Gynaecology, Ljubljana, Slovenia.

Medical Director

prof.dr. Adolf LUKANOVIĆ, dr.med.
svetnik

Prof. Adolf Lukanović, MD, PhD

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Ljubljana, Zaloška cesta 2
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Appendix 1

Hospital TRBOVLJE
Department of Gynaecology
Rudarska cesta 9
1420 Trbovlje

Trbovlje, dne 15.6.2012

TO WHOM IT MAY CONCERN

Herewith we confirm that the data gathered for research work **Intrapartal injuries of paerineum and pelvic floor** presented by Dimitar Cvetkov, MD, PhD fellow, Medical Faculty, Pleven, Bulgaria, were collected at the Hospital Trbovlje, Department of Gynaecology, Trbovlje, Slovenia.

Medical director:
mag. Miro Jurca, dr.med.

Mag. Miroslav JURCA, dr.med.
specialist ginekolog in porodničar

SPLOŠNA BOLNIŠNICA TRBOVLJE
GINEKOLOŠKO PORODNI ODDELEK
PREDSTOJNIK:
mag. Mirko Franci Jurca, dr. med.

Appendix 2

DIANATAL GEL porodni zapisnik №.....

pacientka № ...../ datum …../…../201….

PUERPERA

ime:…….. starost:……...let TT:……...kg. TV:……...cm.
anamneza: P (…...) G (…...) A (…...)
dolžina presredka : > 25 mm □
OTROK
spol: M Ž GS: ..……T ..... /7 TT: ..... gr. TV:…… cm. OG:…....cm. VPD: G M

POROD

1. **urgentni carski rez**
2. **operativno dokončan porod VE**
3. **porod brez poškodbe presredka ali vagine**
4. **porod s poškodbo presredka ali vagine**

Analgesia: .....…..supp. ……....…amp i.m. …..... amp.i.v.
Nepredovanje poroda: indukcija □ (z ……..)
stimulacija □ (z ……...)
Poškodbe presredka:
Stopnja I □
Stopnja II □
Stopnja III □ 3a / 3b /3c
Stopnja IV □ Episiotomija □
Indikacija za epiziotomijo…….....….....
Unilateralna poškodba vagine □ Bilateralna poškodba vagine □
Poškodba labij □
II porodna doba ..... u ..... min

Metoda šivanja			
Vagina	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Mišice presredka	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Koža presredka	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Analna sluznica	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Notranji analni sfinkter	**Interrupted / Mattress**	**Suture used**	**PDS / Vicryl**
Zunanji analni sfinkter	**Overlap / End to end**	**Suture used**	**PDS / Vicryl**

Dodatne informacije ……..

Urethra → → →

Vagina → →

Anal sphincter → → →

Strinjam se, da se podatki o mojem porodu uporabijo za raziskavo o učinkovitosti Dianatal Gela.

Pacientka:.....

Appendix 3

DIANATAL GEL №.....

пациентка № ...../ дата ……/……/201….

PUERPERA

име:…….. год:……....г. ТТ:……....kg. ТВ:……....cm.
анамнеза: Р (……) G (……) А (……)
дължина на перинеума: > 25 mm □
ПЛОД
пол: М Ж GA: ..……Т ..... /7 ТТ: ..... gr. ТВ:……. cm. ГЦ:…….....cm.
Предлежи: Г С

РАЖДАНЕ

5. **Спешно цезарово сечение**
6. **Оперативно раждане VE**
7. **Раждане без разкъсване на перинеума или влагалището**
8. **Раждане с разкъсване на перинеума или влагалището**

Аналгезия: .....…...supp. ……..…amp i.m. …..... amp.i.v.
Напредване на раждането: индукция □ (с ……..)
стимулация □ (с ……...)
Увреди на перинеума:
Степен I □
Степен II □
Степен III □ 3a / 3b /3c
Степен IV □ Episiotomia □
Индикация за епизиотомия…….....….....
Едностранно разкъсване на влагалището □ Двустранно разкъсване на влагалището □
Разкъсване на лабиите □
II период на раждането .....ч .....мин

Шев

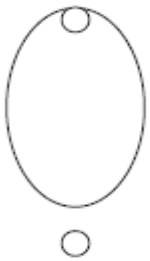
Vagina	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Мускули на перинеума	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Кожа на перинеума	**Interrupted / Continuous**	**Suture used**	**Vicryl Rapide**
Анална лигавица	**Interrupted/ Continuous**	**Suture used**	**Vicryl Rapide**
Вътрешен анален сфинктер	**Interrupted / Mattress**	**Suture used**	**PDS / Vicryl**
Външен анален сфинктер	**Overlap / End to end**	**Suture used**	**PDS / Vicryl**

Допълнителна информация……..

Urethra → → →

Vagina → →

Anal sphincter → → →



Давам своето съгласие, информацията за моето раждане да се използва за проучване ефекта от приложението на Dianatal Gela при профилактиката на разкъсванията на тазовото дъно.

Пациентка:.....
