PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF MASTER DEGREE IN OBSTETRICS AND GYNECOLOGY

Title of the Protocol: Effect of Pudendal Nerve Block versus perineal local infiltration of analgesia in post episiotomy pain relief: A randomized controlled clinical trial

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What is already known on this subject? AND

What does this study add?

Episiotomy or tearing of perineal tissues during childbirth is associated with significant pain in the postpartum period. Local perineal infiltration of analgesia is the standard analgesia used for episiotomy repair.

This study compares the efficacy and duration of pudendal nerve block versus local infiltration on post episiotomy pain relief.

1. INTRODUCTION/ REVIEW

Episiotomy or tearing of perineal tissues during childbirth is associated with significant pain in the postpartum period. Although the use of episiotomy is often debated, it remains the most common surgical procedure experienced by women. Pain from episiotomy is poorly treated, though it may be severe and can result in significant discomfort and interference with basic daily activities and adversely impact motherhood experiences **(Ahlberg et al., 2013)**.

Furthermore, episiotomy may increase the risk of chronic perineal pain which is estimated to occur in 13% to 23% of women after episiotomy **(Dodd et al., 2015)**. Post-episiotomy pain has been treated with systemic analgesia, including non-steroidal anti-inflammatory drugs (NSAID) and oral or IV opioids as well as epidural opioids and local anesthetics.

Prior to the widespread use of epidural anesthesia in obstetrics, pudendal nerve block was a commonly used anesthesia technique for vaginal birth **(Novikova et al., 2015)**. Reported as early as 1908 pudendal nerve block became popular in the mid-1950s and was an often used anesthesia for childbirth into the mid-1980s. As epidural use grew in popularity, pudendal nerve block declined in the United States.

Unlike epidural anesthesia; pudendal nerve block could be performed in the labor room just like the perineal local infiltration of analgesia done by obstetricians prior to episiotomy or vaginal tears repair. A 2012 study from Italy cited pudendal nerve block as the anesthetic procedure most commonly used in Europe when no analgesia was requested by parturients or in hospitals without a service for obstetric analgesia **(Goldman et al., 2012)**.

The pudendal block gets its name because a local analgesic is injected into the pudendal canal where the pudendal nerve is located. This allows quick pain relief to the perineum, vulva, and vagina. A pudendal block is usually given in the second stage of labor just before delivery of the fetus. It relieves pain around the vagina and rectum as the fetus comes down the birth canal **(Cunningham et al., 2015)**. It is also helpful just before an episiotomy is done.

It offers a safe and feasible option for obstetric analgesia with very few possible complications such as allergic reaction to the anesthetic injected avoided by proper history taking and availability of medications for proper management of any allergic reaction that could happen. While allergic reaction is not a specific complication for the pudendal nerve block as it would still happen if local perineal infiltration was performed; other complications

are specific for pudendal nerve block such as vascular injury, fetal injury especially scalp injury which can be avoided by the use of needle guide **(Kurzel et al., 2012)**.

When the neurobehavioral responses of newborns whose mothers received bupivacaine, mepivacaine, or 2-chloroprocaine for pudendal nerve block were studied, there was no significant effect of any of the agents on newborn neurobehavioral indices at 4 and 24 hours, with the exception of a better response to pinprick at 4 hours in the mepivacaine-exposed neonate **(Svancarek et al., 2015)**.

Local infiltration analgesia is the most commonly used method of analgesia during normal labor. This type of local analgesia is achieved by injecting the analgesic agent into the perineum just before delivery with crowning of the fetal head. It is also widely used just before an episiotomy. This study compares the efficacy and duration of pudendal nerve block versus local infiltration on post episiotomy pain relief. **(Chestnut et al., 2009)**.

Hypothesis:

In women in labor and undergoing episiotomy pudendal nerve block may be similar to local infiltration by analgesic as regard post episiotomy pain relief.

Question:

In pregnant women in labor and undergoing episiotomy does pudendal nerve block similar or effective as local perineal infiltration of analgesic for post episiotomy pain relief?

AIM:

This study aims to compare the effect of Pudendal Nerve Block with perineal local infiltration of analgesia in post episiotomy pain relief.

3. METHODOLOGY:

Patients and Methods

Study design: Randomized controlled trial.

Settings: Ain Shams University Maternity Hospital in the period between August 2018 and Jan 2019.

Sample size justification: Sample size was calculated using PASS® version 15, setting the power (β) at 0.02 and the significance level at 0.05. Data from previous reports **(Arslan et al., 2004)** indicated that mean VAS scores for pain intensity with local perineal infiltration and unilateral pudendal nerve block were 30.1 +/- 16.5 and 17.1 +/- 13.5 respectively. Calculation according to these values to yield statistically significant results produced a minimal sample size of 88 women to be randomized into two groups. Assuming a drop-out rate of 10%, a total sample size of approximately 100women will be needed, i.e. 50 women in each of the groups.

RESEARCH METHODOLOGY

After approval of the ethical committee, women will be enrolled in the study according to the following criteria:

Exclusion criteria:

Presence of infection, Coagulation abnormalities, History of sensitivity to local anesthetics, Malpresentation, Previous vaginal operations and or presence of any Obstetric complications.

Inclusion criteria:

Primigravida, Singleton term pregnancy, Age (20-35 years) and Free of medical disorders.

Informed consent will be taken from the patients after explanation of the details of the study to them.

All subjects will be subjected to the following:

a- History

Complete history will be taken from the patients with special emphasis on:

- Personal history.
- Menstrual history including: the last menstrual period, duration of menses, amount and regularity.
- Obstetric history: parity, time of last delivery, route of delivery, any complications after delivery.
- Present history of current pregnancy.
- Past and present medical history.
- Past surgical history.

b- Examination:

1. Measurement of the patient's blood pressure.
2. Dipstick testing of patient's urine sample.
3. General inspection at the end of the bed. Comment on:
    a) General appearance
    b) Pallor and anemia
    c) Breathlessness
    d) Pain
    e) Difficulty walking and getting up from waiting room.
4. Inspection
    a) Size of the uterus and shape
    b) Pfannenstiel scars and other surgical scars
    c) Skin changes
    d) Fetal Movements
    e) Umbilicus
5. Palpation
    a) Measure the fundal height.
    b) First Manoeuver – fundal palpation.
    c) Second Manoeuver – lateral palpation: to determine lie, number of pregnancies and liquor volume.
    d) Third Manoeuver and Pawlik's grip.

Randomization:

Patients fulfilling the inclusion criteria will be randomized into two equal groups.

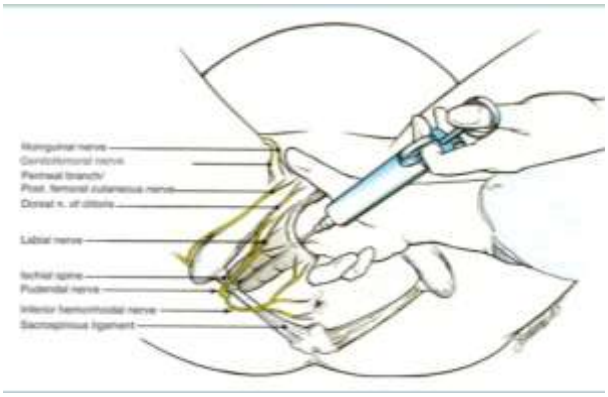
Study group:

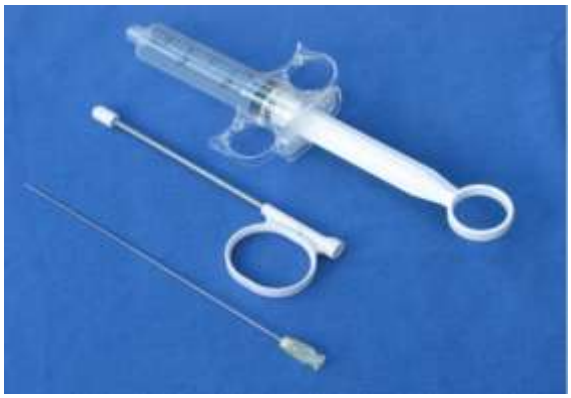
Pudendal Nerve Block

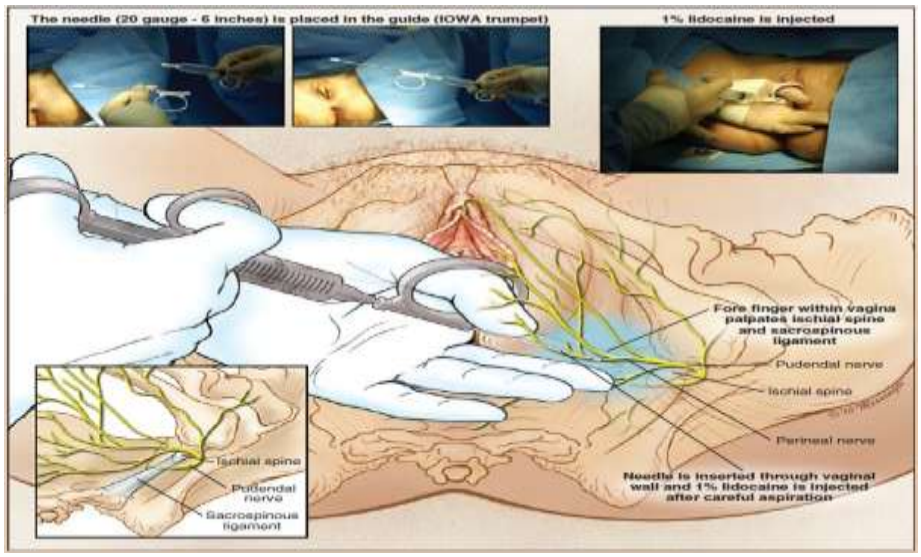
Vaginal sterilization with betadine 10% is performed. A needle with a guide **(Iowa Trumpet)** is used to limit the depth of submucosal penetration and to prevent injury to the fetus. Palpation of the ischial spine is done transvaginally.

To perform a **left-sided block**, palpation of the ischial spine with the index finger of the left hand is done, syringe is held in the right hand, and the needle is guided between the index and middle finger of the left hand toward the ischial spine through the sacrospinous ligament 0.5 cm medial and posterior to the ischial spine. After the needle is introduced nearly 1 cm in depth careful aspiration is performed before injection to exclude vascular puncture. Injection of 5ml Bupivacaine hydrochloride 0.25% (**Marcaine®**; 0.25%, 5 ml) plus 0.5ml dexamethasone dihydrogen phosphate 8 mg (**Fortecortin®** 8mg, 0.5 ml). The same maneuver will be repeated for the right side.

To perform a **Right-sided block**, palpation of the ischial spine with the index finger of the right hand is done, syringe is held in the left hand, and the needle is guided between the index and middle finger of the right hand toward the ischial spine through the sacrospinous ligament 0.5 cm medial and posterior to the ischial spine. After the needle is introduced nearly 1 cm in depth careful aspiration is performed before injection to exclude vascular puncture. Injection of 5ml Bupivacaine hydrochloride 0.25% (**Marcaine®**; 0.25%, 5 ml) plus 0.5ml dexamethasone dihydrogen phosphate 8 mg (**Fortecortin®** 8mg, 0.5 ml). The same maneuver will be repeated for the right side.







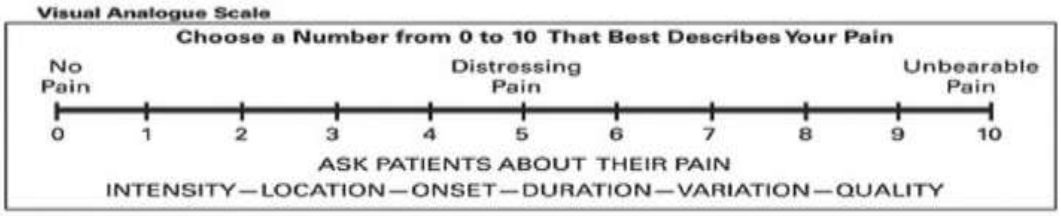
Control group:

Local Perineal Infiltration of analgesia

Injection of 5ml Bupivacaine hydrochloride 0.25% (**Marcaine®**; 0.25%, 5 ml) plus 0.5ml dexamethasone dihydrogen phosphate 8 mg (**Fortecortin®** 8mg, 0.5 ml) into the perineum at the episiotomy site just before delivery.

Duration of analgesia will be measured and recorded since starting the procedure in both the pudendal nerve block and local infiltration technique using cold pack sensation test.

For pain scoring we are using the Visual Analogue Scale for pain assessment.



Scale	Pain Level
0	**No Pain**
1–3	**Mild Pain**
4–6	**Moderate Pain**
7 – 10	**Severe Pain**

Primary outcomes:

- Pain score using the Visual Analogue Scale assessed every hour for the first 6 hours post-partum starting by the time of injecting the analgesia.

Secondary outcomes:

- Need for analgesics assessed every hour for the first 6 hours post-partum starting by the time of injecting the analgesia.
- Delivery time (minutes) after injection of analgesia.
- Apgar score (at 1 min & 5 min) will be used for evaluation of pregnancy outcome on the neonate.

Statistical analysis:

Statistical analysis will be performed using Microsoft Excel 2007 and statistical package for social sciences (SPSS version 15.0). Data will be prescribed as range, mean and standard deviation (for parametric variables), range, median and interquartile range (for non-parametric variables), numbers and percentage (for categorical variables). Difference between variables of two groups will be analyzed using student's t-test (for non-parametric variables) and chi-squared test (for categorical variables). Differences between more than two groups will be analyzed using one way ANOVO test (for parametric variables), Kuskal Wallis test (for non-para metric variables) and Chi-squared test (for categorical variables). Correlation between two variables will be estimated using Pearson's correlation coefficient (for parametric variables) and Spearman's rank correlation coefficient (for non-parametric variables). Significance level will be set at 0.05.

Ethical and Legal Aspects:

Delegation of investigator responsibilities:

The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, any amendments to the protocol, their trial-related duties and functions. The investigator will maintain a list of sub-investigators and other appropriately qualified persons to whom he or she has delegated significant trial-related duties.

Patient information and informed consent:

Before being admitted to the clinical study, the patient must consent to participate after the nature, scope, and possible consequences of the clinical study have been explained in a form understandable to her. An informed consent document, in Arabic language, contains all locally required elements and specifies who informed the patient. After reading the informed consent document, the patient must give consent in writing. The patient's consent must be confirmed at the time of consent by the personally dated signature of the patient and by the personally dated signature of the person conducting the informed consent discussions. If the patient is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to patients must take place in the presence of an impartial witness. Consent must be confirmed at the time of consent orally and by the personally dated signature of the patient or by a local legally recognized alternative (e.g., the patient's thumbprint or mark).

The witness and the person conducting the informed consent discussions must also sign and personally date the consent document. The original signed consent document will be retained by the investigator. The investigator will not undertake any measures specifically required only for the clinical study until valid consent has been obtained.

Confidentiality:

Only the patient number and patient initials will be recorded in the CRF, and if the patients name appears on any other document *(e.g.*, pathologist report*)*, it must be kept in privacy by the investigators. The investigator will maintain a personal patient identification list (patient numbers with the corresponding patient names) to enable records to be identified.

Protocol approval:

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents will be declared for ethical and research approval by the council of obstetrics & gynaecology department, Ain Shams University.

4. REFERENCES

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بروتوكول مقدم توطئة للحصول على درجة الماجستير
في أمراض النساء والتوليد

عنوان البروتوكول: تأثير إحصار العصب الفرجي بالمقارنة بحقن المخدر الموضعي بالعجان في تخفيف الام ما بعد قص العجان: تجربة سريرية عشوائية مضبوطة

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ما المعروف مسبقاً عن موضوع الدراسة؟ ماذا تضيف هذه الدراسة؟
يرتبط قص العجان أو تمزق الأنسجة العجانية أثناء الولادة بألم كبير في فترة ما بعد الولادة. يعد حقن المخدر الموضعي بالعجان الطريقة المثلى لتسكين الألم. في هذه الدراسة نقارن فعالية ومدة إحصار العصب الفرجي مقابل حقن المخدر الموضعي بالعجان في تخفيف آلام ما بعد الولادة.

١ ـ المقدمة ومراجعة الدراسات السابقة

يرتبط بضع الفرج أو تمزق الأنسجة العجانية أثناء الولادة بألم كبير في فترة ما بعد الولادة. على الرغم من أن استخدام بضع الفرج غالباً ما يكون موضع نقاش ، إلا أنه يبقى الإجراء الجراحي الأكثر شيوعًا بين النساء. الألم من بضع الفرج يتم التعامل معه بشكل سيئ ، على الرغم من أنه قد يكون شديدًا ويمكن أن يؤدي إلى إزعاج كبير والتدخل في الأنشطة اليومية الأساسية والتأثير سلبًا على تجارب الأمومة.

علاوة على ذلك ، قد يزيد بضع الفرج من خطر حدوث آلام العجان المزمنة التي تشير التقديرات إلى حدوثها في ١٣٪ إلى ٢٣٪ من النساء بعد بضع الفرج. تم علاج آلام ما بعد بضع الفرج بالتسكين النظامي ، بما في ذلك العقاقير غير الستيرويدية المضادة للالتهابات والأفيونيات الفموية أو الوريدية وكذلك المواد الأفيونية فوق الجافية والمخدرات الموضعية.

قبل الاستخدام الواسع للتخدير فوق الجافية في التوليد ، كان إحصار الأعصاب الفرجي تقنية تخدير شائعة الاستخدام للولادة المهبلية. وقد تم الإبلاغ عنه في وقت مبكر من عام ١٩٠٨ وأصبح إحصار العصب الفرجي شعبية في منتصف ١٩٥٠ وكان التخدير المستخدم في كثير من الأحيان للولادة في منتصف ١٩٨٠. كلما نمت استخدام فوق الجافية في شعبية ، انخفض إحصار العصب الفرجي في الولايات المتحدة.

على عكس التخدير فوق الجافية. يمكن إجراء إحصار العصب الفرجي في غرفة الولادة تماما مثل القن الموضعي للعجان من التسكين الذي قام به أطباء التوليد قبل قص العجان أو إصلاح الجروح المهبلية. أشارت دراسة أجريت عام ٢٠١٢ من إيطاليا إلى إجراء إحصار العصب الفرجي كإجراء التخدير الأكثر شيوعًا في أوروبا عندما لم يتم طلب أي تسكين من قِبل المرضى أو المستشفيات بدون خدمة لتسكين التوليد.

يحصل إحصار العصب الفرجي على اسمه لأنه يتم حقن مسكن محلي في قناة الفوهة حيث يقع العصب الفرجي. وهذا يسمح بتخفيف الألم بسرعة إلى العجان والفرج والمهبل. عادة ما يتم إعطاء إحصار العصب الفرجي في المرحلة الثانية من المخاض قبل الولادة. إنه يخفف الألم حول المهبل والمستقيم عندما ينزل الجنين إلى قناة الولادة. ومن المفيد أيضا فقط قبل القيام بقص العجان.

وهو يوفر خيارًا آمنًا وعاجلاً للتسكين التوليدي مع عدد قليل جدًا من المضاعفات المحتملة ، مثل تفاعل الحساسية مع التخدير المحقن من خلال أخذ التاريخ السليم وتوافر الأدوية للإدارة السليمة لأي تفاعل تحسسي قد يحدث. في حين أن رد الفعل التحسسي ليس تعقيدًا محددًا لإحصار العصب الفرجي حيث أنه سيحدث إذا تم إجراءحقن موضعي بالعجان ؛ المضاعفات الأخرى محددة لإحصار العصب الفرجي مثل إصابة الأوعية الدموية ، إصابة الجنين وخاصة إصابة فروة الرأس التي يمكن تجنبها عن طريق استخدام دليل الإبرة.

عندما تمت دراسة الاستجابات السلوكية العصبية للأطفال حديثي الولادة الذين تلقوا أمهاتهم بوبيفكائين ، أو ميبيفاكائين ، أو ٢ - كلوروبوبروكايين لإحصار العصب الفرجي ، لم يكن هناك تأثير معنوي لأي من العوامل على مؤشرات السلوك العصبي لدى الأطفال حديثي الولادة في ٤ و ٢٤ ساعة ، باستثناء وجود أفضل استجابة في ٤ ساعات في حديثي الولادة.

الحقن الموضعي بالعجان هي الطريقة الأكثر شيوعا من التسكين أثناء المخاض العادي. ويتحقق هذا النوع من التسكين المحلي عن طريق حقن عامل المسكن في العجان قبل الولادة مباشرة بتتويج رأس الجنين. كما يستخدم على نطاق واسع قبل بضع الابيزي. في هذه الدراسة نقارن فعالية ومدة إحصار العصب الفرجي مقابل الحقن الموضعي على آلام ما بعد الولادة.

٢ - الهدف من الدراسة

الهدف من هذه الدراسة هو مقارنة تأثير إحصار العصب الفرجي مع حقن المخدر الموضعي بالعجان في تخفيف الالم في مرحلة ما بعد قص العجان.