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The Role of Local Anesthetics in The Management of Adverse Effects Associated with Intrauterine Device Application

Nura Fitnat Topbas Selcuki[1, *], Pinar Yalcin Bahat[2], Kubra Bagci Cakmak [3], Cihan Kaya[4], Hüseyin Nazlikul[5]

[1]University of Health Sciences, Istanbul Sisli Hamidiye Etfal Training and Research Hospital, Department of Obstetrics and Gynecology, Istanbul/TURKEY

[2]University of Health Sciences, Istanbul Kanuni Sultan Suleyman Training and Research Hospital, Department of Obstetrics and Gynecology, Istanbul/TURKEY

[3]Esenler Maternity and Children's Hospital, Obstetrics and Gynecology, Istanbul/TURKEY

[4]University of Health Sciences, Istanbul Sadi Konuk Training and Research Hospital, Department of Obstetrics and Gynecology, Istanbul/TURKEY

[5]President of International Federation of Medical Associations of Neural Therapy (IFMANT), Private Clinic, Istanbul/TURKEY

[*]**Corresponding Author:** Nura Fitnat Topbas Selcuki, University of Health Sciences, Istanbul Sisli Hamidiye Etfal Training and Research Hospital, Department of Obstetrics and Gynecology, Istanbul/TURKEY.

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Abstract

To evaluate the effectiveness of local anesthetics (LA) in the treatment of pelvic pain, infection, and abnormal vaginal bleeding following intrauterine device (IUD) application. IUD application can cause effects such as pelvic pain, abnormal bleeding, and pelvic infection. Neural therapy (NT) or also referred to as therapy with local anesthetics (TLA) is a treatment modality, which could be used in the treatment of these adverse effects associated with IUD application. The database of our family planning clinic was searched retrospectively. 81 patients who received IUDs for contraception purposes between January 2018 and July 2019 were included in the study. 40 patients who received IUDs and NT/TLA treatments were included in the study group and 41 patients who only received IUDs were included in the control group. Patients' pelvic pain, infection, and bleeding status were recorded at the one-month follow-up. The pain was evaluated using a visual analog scale (VAS). When the VAS scores of patients reported one month after the application of IUDs were compared, scores were significantly lower in the study group ($p < 0.001$). Furthermore, a significant difference between the two groups in terms of infection was observed ($p < 0.001$). The application of LA lead to IUD associated pain relief and decrease the rate of infection whereas their effects on IUD associated abnormal bleeding is still uncertain. LA in the form of NT/TLA treatments can safely be used in a gynecological outpatient clinic for the management of adverse effects associated with the IUD application.

Keywords: neural therapy, local anesthetics, intrauterine device, pelvic pain, infection, vaginal bleeding

Introduction

The use of the intrauterine device (IUD) for contraception is highly common among women. It has been reported in 2019 that worldwide 159 million women use IUDs for contraception purposes **[1]**. The Popularity of IUDs lie in their long-lasting acting mechanism, easy application, and reversible nature. However, the IUD application can cause several adverse side effects. Cramping/pelvic pain, abnormal bleeding, menorrhagia, and pelvic infection are among the most common ones. The severity and duration of these adverse symptoms determine the patient's compliance. Approximately 10-15 % of women using copper IUDs have it removed due to menorrhagia **[2]**. Therefore, treatments that address and alleviate these adverse symptoms have been the focus of research concerning contraception with IUD. Neural therapy (NT) is a treatment modality that could be used in the treatment of these adverse effects. NT or also referred to as therapy with local anesthetics (TLA) is the diagnostic and therapeutic application of local anesthetics (LA). In addition to the short-term effects of LA in regional anesthesia through their inhibition of the depolarization of neurons leading to the disruption of the neuronal conduction, LA also manifest prolonged therapeutic effects through long-term action mechanisms. These mechanisms either rely on the modulation of the autonomic nervous system (ANS) by enhancing the sympatholytic activity or on the anti- inflammatory characteristic of LA **[3, 4]**. Through these prolonged action mechanisms, acute or chronic pain, functional disorders, vegetative disorders, and chronic inflammation can be treated with NT/TLA **[5, 6].** Multiple sclerosis **[7, 8]**, musculoskeletal diseases, gynecological

disorders **[9, 10]**, and chronic pain **[11, 12]** are among the disorders in which the benefits of NT/TLA have already been shown.

In this study, we aim to evaluate the effectiveness of NT/TLA treatment on pelvic pain, pelvic/vaginal infection, and abnormal vaginal bleeding following IUD application to determine whether it can be offered as a treatment option to those patients suffering from the adverse side effects of IUDs.

Material and Methods

NT/TLA is offered as a treatment option at the outpatient gynecology and family planning clinic at Istanbul Health Sciences University Kanuni Sultan Suleyman Training and Research Hospital. For this study, we retrospectively searched the hospital's database and recorded data of women who visited our family planning clinic between January 2018 and July 2019 to receive IUDs for contraception purposes. Women of reproductive age without any history of chronic pelvic pain, dysmenorrhea, dyspareunia, dysuria, vaginal infection, vaginal discharge, or pelvic inflammatory disease were included in the study. Women with underlying chronic diseases that could cause chronic pelvic pain such as endometriosis and which made them prone to infections such as diabetes mellitus were excluded from the study. Furthermore, women by whom a complication occurred during the IUD insertion, such as uterine perforation, were also excluded from the study. Data of patients who gave informed consent at the time of treatment were included in the study.

Patients who visited our family planning clinic and opted for IUD application for contraception purposes were also offered NT/TLA treatments. 40 patients who matched the inclusion criteria and received IUDs and NT/TLA treatments were included in the study group and 41 patients who only received IUDs were included in the control group. All patients received copper IUDs and none of them were on additional hormonal treatment. Before the insertion of IUD, women in the therapy group received NT/TLA treatment with 6 ml of 1 % procaine injected transvaginal into the cervix at 5 and 7'o clock localizations. Following IUD insertion, another 6 ml of 1 % procaine was injected into the Frankenhauser ganglia bilaterally. A final dose of 8 ml of 1 % procaine was injected into the abdominal trigger points and intracutaneously into the L4-S4 dermatomes as quaddies. See literature for detailed information on the injection techniques **[5]**. Patients rested for approximately 30 minutes before discharge to avoid any side effects that might occur due to LA injections such as dizziness and orthostatic dysregulation. All NT/TLA treatments were applied by a gynecologist who is also a certified neural therapist.

Patients were asked to come for a control follow-up one month after receiving their IUDs. At the control visit patients' post IUD pain was routinely evaluated using a visual analog scale (VAS) from 0 to 10; 0 indicating no pain and 10 being severe pain. Patients were also asked to report if they had experienced any prolonged or heavy menstrual bleeding, non-menstrual bleeding, or spotting, and if they observed any vaginal discharge, vaginal discomfort, or fever indicating a vaginal/pelvic infection. At the follow-up visits, patients also received a routine vaginal inspection and transvaginal ultrasound examination to control the location of IUDs as well as for further assessment of vaginal/pelvic infection or abnormal bleeding.

Data analysis was performed by SPSS (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). The frequency and percentage of the categorical variables and the median and range values of the nominal and continuous variables were presented. The study groups were compared using the Student t-test for parametric variables and the Mann Whitney U test for the non-parametric variables. The categorical variables were compared using the Pearson chi-square test. A p-value of <0.05 was considered statistically significant for all calculations.

Results

When the study group and the control group were compared based on their biometric data, there were no differences between groups in terms of their age and body mass index (BMI) **(Table 1)**. However, a difference between the two groups could be observed, when the comparison was made based on gravidity and parity ($p = 0.002$ and $p = 0.007$, respectively). Abortus status of women in both groups was also statistically similar **(Table 1)**. The VAS scores of patients in both groups reported one month after the application of IUDs were compared using the Mann Whitney U test. A median of 4 in the control group and 2 in the study group were observed **(Table 1)**. VAS scores were significantly lower in the study group with a p-value of < 0.001.

Table 1. Comparison of biometric data and VAS scores using the Mann-Whitney U test.

	Control Group Median (min-max)	**Study Group Median (min-max)**	**P-Value**
Age (years)	27 (21-41)	29 (22-39)	0.259
Gravidity	2 (0-3)	2 (1-5)	**0.002**
Parity	1 (0-2)	2 (1-3)	**0.007**

Abortus	0 (0-2)	0 (0-3)	0.102
BMI (kg/m^2)	22.6 (18.8-26.6)	22.4 (18.8-26.6)	0.755
VAS score	4 (1-7)	2 (1-4)	**<0.001**

Abnormal bleeding and infection were the other two comparison parameters following the IUD application. 20 patients in the control group reported vaginal/pelvic infection or infection was observed at the control examination whereas this number was 2 in the study group. A comparison with Pearson's chi-squared test revealed a significantdifference between the two groups in terms of infection (p = < 0.001) **(Table 2)**. However, the number of patients reporting abnormal bleeding in terms of prolonged or heavy menstrual bleeding, non- menstrual bleeding, or spotting was similar in both groups (p = 0.11).

Table 2. Comparison of bleeding and infection using Pearson's chi-squared test.

		Control Group n (%)	**Study Group n (%)**	**P-value**
Bleeding	+	13 (31.7%)	7 (17.5%)	0.110
Bleeding	-	28 (68.3%)	33 (82.5%)	0.110
Infection	+	20 (48.8%)	2 (5%)	**<0.001**
Infection	-	21 (51.2 %)	38 (95%)	**<0.001**

Discussion

In this study the efficacy of NT/TLA in the treatment of adverse effects of IUD the application was evaluated. Comparison between patients receiving NT/TLA along with IUD application with patients only receiving IUDs revealed that NT/TLA treatment decreased post-IUD pain and infection significantly whereas it did not have a significant effect on IUD associated abnormal bleeding.

There are several application techniques of NT/TLA **[5, 13]**. The most commonly used technique is the local subcutaneous application of LA directly on the symptomatic area (local therapy). Another frequently used technique in the treatment of myofascial trigger points. Injections applied to these trigger points ease the associated symptoms. Ganglia injections are categorized under the regional therapy modality of NT/TLA. Another treatment modality of NT is segmental therapy. The term 'segment' refers to the projections of autonomic innervation of an organ through neuronal reflex arcs on a dermatome, myotome, sclerotome, neurotome, and angiotome. These viscera-cutaneous projections are also called Head Zones **[14]**. The connection in a segment is not only neuronal but also functional. Thus, LA applied to a dermatome treat the associated organ. In this study, a combination of these techniques was used to address the adverse effects of the IUD application.

A literature research revealed several studies regarding the use of LA for pain relief during IUD insertion. **[15, 16 and 17].** According to a

systematic review and network meta-analysis conducted by Samy et al. local application of lidocaine-prilocaine cream is the most effective treatment of IUD insertion-related pain **[18]**. Although the administration of nonsteroidal anti-inflammatory agents has been recommended in the management of long-term pain/uterine cramping following IUD application, there is neither enough data in the literature to support their efficacy nor data on the application of other analgesic/anti-inflammatory agents. Therefore, this study was unique in its design to evaluate the long-term effects of LA on pain/uterine cramping related to the IUD application. According to the current study patients who received NT/TLA treatments experienced less pain during the one-month follow-up period when compared to patients who did not receive any pain management. This might be due to the modulatory effects of LA on uterine contractility, which was demonstrated by Weinschenk et al. on swine models **[19].** Furthermore, the sympatholytic activity of LA disrupts the synergy between the parasympathetic and sympathetic nervous system's effect on uterine contraction leading to uterine relaxation and pain relief [**3, 20 and 21].**

In addition to pain/uterine cramping, pelvic, and/or vaginal infection can also develop following IUD insertion, especially during the first 20 days **[22]**. It is known that the insertion of an IUD can contaminate the cavity by pushing vaginal and cervical bacteria into the uterus **[23].** Therefore, aseptic IUD insertion techniques reduce the risk of infection **[24]**. Thus, the significantly lower levels of infection observed in the NT/TLA treatment group can be explained by the transvaginal application of LA prior to IUD insertion, since LA also have antimicrobial characteristics. **[9, 25]**.

The local inflammation caused by copper-containing devices, which is their main action mechanism, can lead to abnormal bleeding and/or menorrhagia. Through the anti-inflammatory characteristics of LA, a reduction in the bleeding was expected in this study **[4]**. However, a significant difference between the control and the study group was not observed. This might be due to the short follow-up period of the study. Since modulating inflammation is a long-term process, longer follow- up periods for 2 or 3 months might have yielded different

results. Furthermore, sympatholytic activation of the ANS by LA leads to enhanced vasodilatation in the uterus **[3, 20]**. The vasodilatation might have counteracted the anti-inflammatory process initiated by the LA application resulting in abnormal bleeding during the first month following the IUD application.

The retrospective design of the study is one of its limitations. However, since all patients who opted for IUD application were routinely offered NT/TLA treatments, and all of them who gave informed consent were included in the study a selection bias was eliminated. Furthermore, the control group was randomly chosen from the women who received an IUD application without NT/TLA treatments during the same period of time. Due to this randomization, a difference in gravidity and parity between the control and the study groups could be observed. One could argue that this difference might have interfered with the comparability of the groups. However, according to literature, the only difference between nulliparous or women who delivered only by cesarean section and multiparous women regarding IUD insertion is observed at insertion where the former experience more pain **[26]**. Since the comparison of pain, infection, and bleeding was performed at the one-month follow-up, not right after IUD insertion, the difference between gravidity and parity did not affect the results of this study. The gravidity and parity were significantly higher in the study group. Whether gravidity and/or parity affect women's decisions in opting for supportive peri-IUD insertion analgesic/anti-inflammatory treatments can be addressed in a future study.

In this study it has been demonstrated that the application of LA leads to IUD-associated pain relief and decrease the rate of infection whereas their effects on IUD-associated abnormal bleeding are still uncertain. LA in the form of NT/TLA treatments can be used in the management of adverse effects associated with IUD application. Their positive effect on pain and infection can increase patient's compliance in the use of IUDs for contraception.

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Data availability: Raw data is available upon request.

Ethical approval: The study was conducted in accordance with the ethical standards of the Declaration of Helsinki. Ethical approval was not obtained on the basis of the retrospective design of the study. However, it was registered to ClinicalTrials.gov (NCT 04379102).

Author Contributions

NT treatments were performed by P.Y.B.

N.F.T.S. did data collection. N.F.T.S.

P.Y.B. wrote the manuscript with support from K.B.C.

C.K. H.N. supervised the project and contributed to the final version of the manuscript.

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