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Ocena czynników wpływających na skuteczność terapii integracji sensorycznej u dzieci w wieku przedszkolnym i wczesnoszkolnym

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Influence of visceral manipulation on hormonal profile in women with polycystic ovarian syndrome: A randomized trial

Wpływ manipulacji trzewnej na profil hormonalny u kobiet z zespołem policystycznych jajników: Badanie randomizowane

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Abstract

Background. Polycystic ovary syndrome (PCOS) is the most common endocrine condition in women of reproductive age and has been suggested as a risk factor for cardiometabolic disease. Depending on which diagnostic criteria are applied, approximately 10–15% of the women of reproductive age are affected by PCOS.Objective. To examine how viscera manipulation Influences hormonal profile in women with PCO. Design. A prospective randomized single-blind controlled trial. Setting. Outpatient clinics of Sadat General Hospital.

Methods. Thirty patients of PCO females were recruited and randomized into two equal groups: the control group received a diet guidelines therapy in the form of the hypocaloric Mediterranean diet for 12 weeks, and the study group received the same control group interventions in addition to visceral manipulation (VM). biochemical analysis (FSH & LH) and BMI was the primary outcome. All variables were measured at the baseline and after 12 weeks of the intervention.

Results. Statistical analysis was done by using paired' test which showed significant improvement in both groups. Therefore, using mixed design MANOVA and multiple pairwise comparison tests (Post hoc tests) for the BMI and LH/FSH ratio post-treatment revealed that there were significant decreases in LH/FSH ratio ($p = 0.007$) in favor to group B when compared with group A, with no significant differences in BMI between both groups ($p = 0.443$), showing that VM group (B) is more effective than group (A) on biochemical analysis ($p < 0.05$).

Conclusion. Using visceral manipulation with a standard program of hypocaloric Mediterranean diet has more beneficial effects on hormonal profile in women with PCO.

Keywords

polycystic ovarian syndrome, visceral manipulation, hypocaloric diet, luteinizing hormone, follicle stimulating hormone

Streszczenie

Wstęp. Zespół policystycznych jajników (PCOS) jest najczęstszym zaburzeniem endokrynologicznym u kobiet w wieku rozrodczym i uważany jest za czynnik ryzyka chorób kardiometabolicznych. W zależności od stosowanych kryteriów diagnostycznych, około 10–15% kobiet w wieku rozrodczym dotkniętych jest PCOS.

Cel. Zbadanie wpływu manipulacji trzewnej na profil hormonalny u kobiet z PCO.

Założenia. Prospektywne, randomizowane, pojedynczo ślepe badanie kontrolowane.

Miejsce. Ambulatoryjne kliniki Szpitala Generalnego Sadat.

Metody. Do badania rekrutowano trzydzieści pacjentek z PCO, które losowo przydzielono do dwóch równych grup: grupa kontrolna otrzymała wytyczne dotyczące diety w postaci hipokalorycznej diety śródziemnomorskiej przez 12 tygodni, a grupa badawcza otrzymała te same interwencje co grupa kontrolna, dodatkowo zastosowano u nich manipulację trzewną (VM). Głównymi wynikami były analizy biochemiczne (FSH i LH) oraz BMI. Wszystkie zmienne mierzono na początku i po 12 tygodniach interwencji.

Wyniki. Analiza statystyczna przeprowadzona za pomocą testu parowego wykazała znaczącą poprawę w obu grupach. Stosując mieszany projekt MANOVA i wielokrotne testy porównawcze par (testy post hoc) dla BMI i stosunku LH/FSH po leczeniu, wykazano, że wystąpiły znaczące spadki stosunku LH/FSH ($p = 0,007$) na korzyść grupy B w porównaniu z grupą A, bez znaczących różnic w BMI między obiema grupami ($p = 0,443$), co pokazuje, że grupa VM (B) jest skuteczniejsza niż grupa (A) w analizie biochemicznej ($p < 0,05$).

Wnioski. Stosowanie manipulacji trzewnej w połączeniu ze standardowym programem diety hipokalorycznej śródziemnomorskiej ma korzystniejsze efekty na profil hormonalny u kobiet z PCO.

Słowa kluczowe

zespół policystycznych jajników, manipulacja trzewna, dieta hipokaloryczna, hormon luteinizujący, hormon folikulotropowy

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Introduction

Polycystic ovarian syndrome is a common endocrine dysfunction in women during their fertile years. Globally, the prevalence is thought to be between 10% and 15% [1]. This syndrome is characterized by its wide range of signs and symptoms. It is recognized that this syndrome frequently coexists with obesity, insulin resistance, compensatory hyperinsulinemia, and a persistent low-grade inflammatory state, however the exact mechanism linking them is unknown. Patients with PCOS are more likely to experience negative maternal and neonatal outcomes, adrenal incidentalomas [2], metabolic syndrome, type 2 diabetes mellitus (T2D), infertility, cardiovascular diseases (CVD), and endocrine and metabolic disorders [3]. According to the most recent, inclusive definitions, the prevalence of Polycystic Ovary Syndrome in females varies from approximately 6% (based on previous, more restrictive criteria) to approximately 20%. The syndrome is considered complex since up to 70% of patients remain misdiagnosed. It's crucial to remember that PCOS can affect lean women as well as fat ones. Lean and obese PCOS women have higher levels of visceral adiposity and worse metabolic outcomes when compared to the control group [4]. This suggests that non-obese PCOS patients have a similar metabolic risk as obese patients because they have similar amounts of visceral adipose tissue [5].

Certain PCOS symptoms can be effectively treated with traditional medical treatments, however these therapies are frequently narrowly focused, may not be appropriate for certain patients, may have unfavorable side effects, and in other situations, may not work for up to 30% of women. Women with PCOS have indicated a need for more all-encompassing, safe treatment methods with fewer side effects, and they are interested in supplementary techniques to control their symptoms. It becomes obvious that dietary practices and other environmental factors are crucial in both preventing and treating PCOS in women. According to international standards, one of the primary treatment options for PCOS is weight reduction because obesity exacerbates the syndrome's clinical presentation [6]. Physical therapists employ manual manipulation therapy as a routine treatment for a wide range of medical diseases, including disorders related to the joints. On the other hand, there weren't enough studies done on women's health. The optimal course of treatment for PCOS is still up for debate [7]. Owing to the high incidence of PCOS globally and the negative health effects it causes, PCOS also poses a significant financial and health burden. The goal of the current study is to assess how manual treatment affects the hormonal profile of women who have polycystic ovarian syndrome. The goal of the study was to determine the best procedure for PCO management.

Materials and methods

Participants

A convenience sample of thirty volunteer PCOS women was recruited for this study. They referred by physician to outpatient clinics of Sadat General Hospital, Egypt. They were between the ages of 25 and 35 years. They had a body mass index (BMI) of 25 to 29.9 kg/m^2.

Any participant was excluded if she with BMI > 30 Kg/m^2, Females who receive hormone replacement therapy within the last 3 months pre-study, hyperprolactinemia, androgen screening neoplasia, thyroid dysfunction, Cushing's syndrome, ovarian tumor, malignancy, using medication (that affects hypothalamic pituitary ovarian drugs and anti-inflammatory drugs) and females with implanted devices also excluded.

Study design and randomization

A randomized, single-blind, pre-posttest trial was used in this research. Participants were randomly assigned to two equal groups, control group and visceral manipulation group. The randomization process was conducted by a blinded independent researcher who sequentially opened envelopes containing computer-generated randomization index cards. The Statistical Package for Social Science (SPSS) program (version 25 for Windows; IBM SPSS, Chicago, IL, USA) was utilized. One identification number was to allocate participants to one of the two groups. Notably, no dropouts occurred among the participants following randomization.

Ethical considerations

Before the study began, Ethical approval was obtained from Re¬search Ethics Committee of the faculty of physical therapy, Cairo university, Egypt. The ethical committee clearance and informed consent of the subjects were taken. patients had all rights to withdraw from the study at any time with¬out any responsibility.

Procedures

Assessment procedures: complete medical history will be checked including age, weight, and height and body mass index (BMI). All patients were assessed before and after the treatment program.

Treatment procedures

The control group (A) involved 15 PCO females who followed diet guidelines therapy during the study period for 12 weeks in the form of the hypocaloric Mediterranean diet; followed the literature dietary advice which considered in women with PCOS include high-carbohydrate (55% calories) and low fat (30% of calories) with average protein (15%) [8]. First, the Harris-Benedict formula was used to calculate each woman's total daily energy requirement, which is as follows: for women, BMR = 655 + (9.6 * weight in kg) + (1.8 * height in cm) - (4.7 * age in years)]. Then, the result was multiplied by the activity multiplier, which is BMR * 1.2, 1.375, 1.55, 1.725, and 1.9 for sedentary, lightly active, moderately active, very active, and extremely active, respectively. Next, lower the estimated total daily energy requirement by 500–1000 kcal/day. Every two weeks, this process was repeated to establish each woman's allowable calorie intake based on her weight. The study group (B) included 15 PCO females who followed same diet program, as the control group, in addition to visceral manipulation applied (once per week in the first month then once every other week in the next two months for a total of 8 sessions).

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It was chosen based on recommendations from the pertinent literature [9]. sessions took place in a peaceful space. Following the intervention sessions, which took place from 9:30 AM to 1:00 PM, the following osteopathic management was provided: A muscle decongestion technique was used at the start of each session to improve circulation, lessen pelvic congestion, and promote relaxation of the organs and tissues that were going to be treated. Application technique: the patient was lying in a crock. The patient raised her pelvis and held it there while taking a deep diaphragmatic breath. The patient was told to fully exhale and then open her knees, doing hip abduction against the therapist's resistance, maintaining a raised pelvis. The patient kept pushing their knees apart against the resistance during the following breath. With their final exhalation, they lowered their pelvis back to the plinth. Application method: in-person with the therapist. Application time: The process was carried out five times, and no changes were made to any of the application methods during the investigation.

Evaluation and management of uterine mobility by direct and indirect methods

I. Direct method: Method of use – direct skin contact. The patient was placed in a supine position with their legs bent and their feet on a cushion to increase hip flexion in order to measure their uterine mobility. The hands of the therapist were placed on the inferior origin of the contralateral rectus abdominis muscle, just above the symphysis pubis on the abdominal wall. Carefully applied pressure from the back approached the region lateral to the uterine fundus. Pulling transversely in the other direction while observing the sensitivity and unusual strains was how the mobility was tested. Application method: in-person with the therapist. Application time: two minutes; test was repeated on the opposite side after six seconds of relaxation; application protocols were left unchanged throughout the investigation.

II. Leg-lever indirect technique from supine position: Method: Using the leg lever in the supine position, direct touch, the indirect approach, and a combined technique were used to mobilize the uterus. The patient's leg was held by the caudal hand of the therapist, whose cranial hand was positioned to reach the side of the uterus. The uterus was moved laterally, or away from the therapist, with the medial (cranial) hand and held for six seconds. The patient's legs were then moved with the caudal hand in the opposite direction, or towards the therapist, until the uterus felt stretched. Anomalies in the form of irregular rhythm and diminished amplitude were evident. The method used to treat motility was positioning the hand's palm slightly above the symphysis and pushing it posteriorly and progressively upward for three seconds while expiring. Application method: in-person with the therapist. Application time: two minutes.

Evaluation and management of ovarian mobility

Method

The patient was in direct contact and had their legs bent in a supine position. The therapist's hands were placed on the abdomen on a line between the anterior superior iliac spine-symphysis pubis (between the median axis and the left or right anterior superior iliac spine), slightly medial to the edge of the psoas. This allowed them to visualize the projection of the ovary on the abdominal wall. By comparing the two sides, noting the sensitivity and unusual tensions, and testing the elasticity, When there were limitations, the therapist's hand rotated clockwise for three seconds while inspiration occurred for the left ovary, moving the palm slightly in the superolateral direction. Repeat to both sides. Application method: in-person with the therapist. Application time: two minutes; no changes were made to any application process during the course of the research.

Outcome measures

Each subject in both groups was evaluated before treatment and after the intervention. pre and after 12 weeks of treatment in a row. The times of the two sessions were set for the same day and within the allotted window of 9:30 am to 1 pm.

Hormonal analysis

Assess the level of LH and FSH by using Human Elisa Kits and Architect Chemistry Instrument which is immunoassay analyzer used for measuring hormones.

Weight and BMI

Weight was measured by valid and reliable scale is a model no. FM-S7031 and BMI was calculated.

Statistical analysis

Independent t tests were used to compare subject age, height, and body weight in order to assess group similarities at baseline. There were two independent variables in the current test. The first was the "tested group," which consisted of two groups of subjects: Group A received diet control therapy for a duration of 12 weeks, while Group B received visceral manipulation for the same amount of time. The second component, which had two levels (before and after), was the treatment durations; this was a subject factor. Furthermore, two dependent variables were evaluated in this test (BMI and LH/FSH). Thus a 2x2 Mixed design MANOVA was employed. The Statistical Package for the Social Sciences (SPSS) application, version 25 for Windows (IBM SPSS, Chicago, IL, USA), was used to do statistical analysis. A statistical significance was known as p-value < 0.05. Shapiro-Wilk test was used to look for signs of covariance homogeneity and test for normality in the data, respectively.

Results

Demographic characteristics

Table 1 showed the demographic characteristics of both groups. There was no significant difference between both groups in the mean age, weight and height ($p > 0.05$).

Data were displayed as mean ± standard deviation (SD), p-value = probability value, the significant level was set at $p < 0.05$.

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Table 1. Baseline demographics of the included participants

	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Age [years]	27.13 ± 2.47	27.53 ± 1.80	0.617
Body mass [kg]	66.7 ± 5.37	65.72 ± 6.89	0.668
Height [cm]	158.8 ± 6.06	159.86 ± 6.47	0.645

Statistical analysis using mixed design MANOVA analyzed thirty patients assigned into two equal groups. It revealed that there were significant within subject (F = 164.9, p = 0.0001*) and treatment*time (F = 4.79, p = 0.017) but there were no significant effects between subject (F = 1.764, p = 0.191). Table (2) present descriptive statistic and multiple pairwise comparison tests (Post hoc tests) for the BMI and LH/FSH ratio. The multiple pair wise comparison tests post-treatment revealed that there were significant decreases in LH/FSH ratio (p = 0.007) in favor to group B when compared with group A, with no significant differences in BMI between both groups (p = 0.443).
Table (2): Descriptive statistic and multiple pairwise comparison tests (Post hoc tests) for the BMI and LH/FSH ratio for both groups at different measuring periods.

Table 2. Descriptive statistic and multiple pairwise comparison tests (Post hoc tests) for the BMI and LH/FSH ratio for both groups at different measuring periods

Variables	Group A		Group B	
	Pre	Post	Pre	Post
BMI	26.47 ± 1.91	24.16 ± 1.43	25.69 ± 1.83	23.77 ± 35
LH/FSH	2.36 ± 0.42	1.79 ± 0.39	2.35 ± 0.38	1.38 ± 0.37

P-value	Within groups (Pre Vs. post) BMI	LH/FSH
Group A	0.0001*	0.0001*
Group B	0.0001*	0.0001*

P-value	Between groups (group A Vs. group B) BMI	LH/FSH
Pre treatment	0.266	0.947
Post treatment	0.443	0.007*

**The mean difference is significant at the alpha level (p < 0.05)*

Discussion

PCOs being regarded as a vicious circle, is a complex and heterogeneous disorder that commonly affects women in the reproductive age group. It accounts for about 38.5% of female-related infertility and has characteristics that suggest a combination of metabolic illnesses like women's obesity, hypertension, and hyperglycemia, and functional reproductive disorders such anovulation and hyperandrogenism [10]. The purpose of this study was to ascertain how visceral manipulation affected the LH/FSH ratio and BMI of women with polycystic ovarian syndrome. The study's findings show that, when comparing pre- and post-treatment data for groups A and B, there was a highly significant decrease in BMI and the LH/FSH ratio. Additionally, there was a highly significant difference in all measured parameters between the groups (pre vs. post measure), with the study group's LH/FSH ratio being higher after three months of the program. The study indicates that VM approaches may be less successful in obese individuals due to increased adipose tissue depth, which makes it more difficult to precisely target and palpate the important structures. This is the reasoning behind excluding fat people and concentrating on those who are overweight. Positioning challenges: Because of bodily limits and size, it may be harder to reach and apply the right amount of pressure. Because the targeted syndrome can appear as early as the second decade of life, the study concentrated on people who were 25 to 35 years old [11].
In order to rule out any other causes of anovulation and hyperandrogenism besides polycystic ovarian syndrome and LH & FSH imbalance, this research excluded people with hyperpro-

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lactinemia, androgen screening neoplasia, thyroid dysfunction, Cushing's syndrome, and ovarian tumours. This is because hyperprolactinemia affects fertility by interfering with ovulation and impairing gonadotropin-releasing hormone (GnRH) secretion. Anovulation, oligomenorrhea, and amenorrhoea are common signs of Hyper-PRL [12]. Additionally, low thyroid hormone levels might affect ovulation—the process by which an ovum is released from the ovary—which reduces fertility. Furthermore, certain autoimmune or pituitary illnesses are among the underlying causes of hypo- or hyperthyroidism that may compromise fertility [13].

When comparing the two groups' BMI and LH/FSH ratios pre- and post-study, the results showed a considerable reduction, indicating that this kind of diet control is helpful for PCOS women. Before beginning fertility therapy, weight loss by lifestyle modification is recommended as the initial step for overweight/obese PCOS women who are trying to conceive. The findings of this study are corroborated by several studies that show improving a PCOS woman's androgen levels and hormonal profile by reducing her weight by 5 to 10% from her starting weight. This decline was observed in the Mediterranean diet, as multinutrient supplements containing folic acid, glycyrrhizin, vitamin E, omega-3 fatty acids, and selenium were found to be beneficial in reducing the levels of testosterone, LH:FSH ratio, and anti-müllerian hormone (AMH). Additionally linked to scavenging free radicals and preventing the oxidation of proteins and lipids are vitamin E, omega-3 fatty acids, and selenium. Additionally, they function as antioxidants and impact the pro-inflammatory state in PCOS. They also lessen central and abdominal fat mass, which influences insulin sensitivity. Insulin sensitivity therefore lowers androgen levels and restores ovulation [14].

It's important to keep in mind that while group (B) showed the most improvement, there were no appreciable differences between the groups in terms of weight reduction or the percentage of the LH/FSH ratio decreasing. This can be explained by the fact that infertile patients with adhesion issues or malfunctioning reproductive organs would become more fertile if certain areas in the soft tissues of the abdomen and pelvis were adjusted.

The manual therapy intervention, as demonstrated by Wójcik et al., (2023), is also simple to use, noninvasive, almost entirely devoid of unfavourable side effects, and it may be used with other therapies like diet, exercise, and medicine to improve the hormonal axis. Reducing the adhesions that bind the organs appears to help the body function and respond in a more appropriate physiological manner. Manual manipulation focuses on deforming the adhesive collagen cross-links that comprise adhesions and appear to contribute to the underlying causes of infertility, including hormonal imbalances [15]. The findings of this investigation, along with those of the study conducted by Akre et al., (2022), suggested that the diet might have a separate and/or combined effect on systemic inflammation, which in turn affects ovarian function and follicular development. meals high in inflammation include animal protein sources other than fish, high glycemic index meals, and saturated fats. It has been demonstrated that dietary therapies such the anti-inflammatory and Mediterranean diets reduce metabolic syndrome symptoms [16]. These results were also supported by Abdolahian et al., (2020), who reported that lifestyle intervention is thought to be the first-line treatment for metabolic complications in overweight and obese females with PCOS and may potentially enhance ovulatory function and fertility. The intervention primarily focuses on diet and physical therapy treatment [17]. Xenou and Gourounti (2021), who carried out a systematic review, approved the study's findings. Of the 123 papers they obtained, seven appeared to be pertinent to the study's goals. The results showed that nutrition plays a significant influence in PCOS laboratory results and clinical manifestation. A better clinical outcome for the patient was linked to a Mediterranean diet [18].

These findings were in line with those of Yosri et al., (2022), who described visceral manipulation (VM) as a manual therapy aimed at promoting normal tone and mobility within and between internal organs. In addition, tensions in the fascia (connective tissue), blood vessels, nerves, and other bodily components, along with mental problems, may be addressed. Allowing the body to self-correct will ultimately lead to better health and optimal bodily function, which is the ultimate purpose of VM [19]. The findings coincided with those of Hewett (2021) which conducted on infertile patients between the ages of 25 and 40. Seventy percent of the patients became pregnant within nine months after the study started, indicating that patients undergoing manual treatment had a higher likelihood of getting pregnant during or after the study [20]. It also suggested that a key support strategy for that condition is manual intervention. The results of the current study were validated by Kocyigit (2022) and Sharma et al., (2023), who also clarified the significance of the ovaries for hormone functions. The ovaries must have a sufficient blood supply and be able to move. Ineffective ovulation could lead to changed hormone production, which could make conception more challenging. The uterus is a very flexible organ that can tilt and bend forward in response to changes in the contents of the intestines and bladder. The uterus's mobility may be hindered if it gets overly compressed, which could result in pelvic congestion and impaired function [21,22].

The patients treated with visceral manipulation in addition to hypocaloric diet showed a great and statistically significant reduction in BMI and hormonal profile. Therefore, visceral manipulation demonstrates to have a very effective treatment in patients with PCO with a major advantage and without any harmful effects.

Conclusion

Based on the results of our study we may conclude that visceral manipulation could be recommended as a treatment of choice for reduction of LH/FSH ratio, improving of symptoms in patients with PCO. Further studies are needed to clarify the best treatment protocol and the long-term results.

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