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Research Article

EFFICACY OF MANUAL THERAPY ON SIZE OF CYST AMONG UNMARRIED FEMALES SUFFERING FROM POLYCYSTIC OVARY SYNDROME

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Abstract:

Background: Polycystic Ovary Syndrome (PCOs) is a heterogeneous endocrine abnormality with a reported rate of incidence estimated to be 3-10%. It decreases the quality of life among unmarried females by increasing the chances of diabetics, hirsutism, obesity and much more. There is a need of a therapy to treat the symptoms of PCOs with minimum side effects. The present study is aimed to determine the impact of manual therapy-based technique in improving the symptoms and complication related to polycystic ovary syndrome patients as in long run the technique will be found to be less side effective and more cost effective.

Method: A total 6 sessions of hands on manual therapy was performed in a manner that 3 sessions were consecutive and 3 were on alternate days whereas follow-up was taken after two months. All participants were assessed on the basis of pre and post prolactin test, HbA1c, modified questionnaire while the size of cysts was measured by pelvic ultrasound imaging.

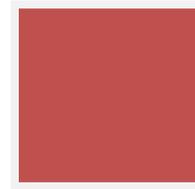
Results: Fifty patients with mean age of 26.37 ± 3.78 were recruited in which fifteen were dropout therefore in total thirty-five patients participated in this study. The results showed that there was significant improvement in all parameters after the rehabilitation protocol was performed such as the difference in prolactin test after rehabilitation was $25-40 \text{ ng/ml}$ to 27.8 ± 3.51 with a mean difference of 4.24 ml , HbA1c from 6.00 ± 0.31 to 5.36 ± 0.24 with a mean difference of 0.63 mmol/mol and ultrasound imaging from 3.60 ± 3.58 to 2.60 ± 2.69 with a mean difference of 1.00 cm in right ovaries whereas 4.50 ± 0.16 to 3.18 ± 0.49 with a mean difference of 1.32 cm in left ovaries.

Conclusion: The prolactin test, HbA1c and diagnostic ultrasound showed significant improvement therefore, manual therapy is a safe and cheap technique that can give timely and unprecedented results without any adverse effects.

KEYWORDS: Hba1c, Manual Therapy, Polycystic Ovary Syndrome, Prolactin, Ultrasound Imaging, Visceral Manipulation

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INTRODUCTION:

Polycystic Ovarian Syndrome (PCOs) is a heterogeneous endocrine abnormality; characterized by clinical or biochemical hyperandrogenism that is accompanied by frequent ovulatory dysfunction and exclusion of underlying disorders like hyperprolactinemia, thyroid disorder and non-classical adrenal hyperplasia [1]. The multiple symptoms have been correlated with this disease such as acne, alopecia (male pattern balding), hirsutism (excessive hair growth), infertility, skin tags and high androgen hormone levels [2]. The presence of hirsutism is one of the first clinical signs of hyperandrogenism in 70% of the women with PCOs. The tool that is used to evaluate hirsutism is known as Ferriman-Gallwey scoring system. It evaluates the hair growth on seven sites that include upper lip, chin, chest, back, abdomen, arms and thighs. The score of 0 is given for the absence of terminal hair, score of 4 to extensive hair growth and score of 8 for the presence of hirsutism [3]. Acne is also associated with high androgen levels but is less specific and occurs only in 15% to 20% of females with PCOs [4]. Additionally, infertility affects 40% of the women with PCOs. It is estimated that 90% to 95% of anovulatory females are diagnosed with polycystic ovary syndrome [5].

In earlier days of 1960s and 70s this disease was known as "Stein-Leventhal syndrome". When ultrasound imaging was introduced doctors found polycystic ovaries and from then it was referred to as PCOs or polycystic ovary syndrome and polycystic ovaries was recognized as the cardinal feature for this disease [6]. The syndrome is mainly identified by transvaginal ultrasound but for unmarried females transabdominal route is preferred. This syndrome is diagnosed with the presence of oligomenorrhea (less than 9 menstruation cycle per year), amenorrhea (cycles lasting more than 90 days) and the presence of at least one ovary greater than 10 cm or the presence of more than 12 or more follicles between 2-9 mm in diameter [7]. In spite of known features this is a very complex disease and cannot be diagnosed easily the example of which is that it is not compulsory that every woman with PCOs have polycystic ovary syndrome and not every woman with polycystic ovaries has PCOs [8]. Along with this there is also difference in the severity of the symptoms for example some females may have mild to severe symptoms, some have few symptoms while others have more [9].

Even though diagnosis of PCOs is mainly categorized into three groups as offered by National Institutes of Health (NIH), European Society for Human

Reproduction and Embryology (ESHRE) and Androgen Excess Society (AES) one thing that is commonly provided by all three groups is the clinical and or biochemical hyperandrogenism followed by menstrual dysfunction, oligoovulation or anovulation (infertility) and ovarian dysfunction. Now a days increased androgen levels (hyperandrogenemia) have become the focus of clinical setups [10]. The high blood level concentrations of androgenic hormones such as aldosterone, testosterone, DHEA, DHEAS along with luteinizing hormone are focused upon due to its endocrine nature that forms the basis of this disease. Collectively these hormones increase the secretion of ovarian androgen that in turn along with the combination of hyperinsulin and obese phenotype enhance the possibilities of obesity in patients suffering from PCOs [11]. The increase of these hormones also affects the secretion of SHBG (sex hormone binding globulin) levels that contributes to the development of non-feminine conditions such as menstrual irregularities, alopecia, hirsutism and anovulation. Women are often diagnosed with PCOs when they seek treatment for menstrual irregularities or when they have difficulty becoming pregnant. Some of the women with PCOs may have normal menstrual cycle but they may not ovulate thus causing difficulty in getting pregnant.

The exact prevalence of PCOs is limited and unclear due to its reproductive, endocrine and metabolic implications yet the reported rate of incidence is estimated to be 3-10% in developed countries [12]. However, the recent findings from developing countries like China and India indicate similar prevalence rates of PCOs [13]. It has been determined that the prevalence of this syndrome varies according to the ethnicity and geographical location due to the difference between usage of diagnostic criteria and dietary habits. Majority of the studies consistently suggests that the prevalence estimated by the Rotterdam criteria is two to three times bigger than NIH/NICHD criteria [14].

The sudden increase in the incidence rate of this syndrome has been found from past few years. The reason could be more women are developing PCOs or the disease is now well-known and health care practitioners are becoming better in diagnosing it. The prevalence rate of PCOs in obese women is higher as compared to non-obese women. Obese females with PCOs have reduced response to fertility treatments, greater menstrual irregularities and increased hirsutism at 73% compared to 56% in non-obese women [15]. Following a healthy lifestyle has shown to reduce abdominal fat, reduced body weight,

decreased testosterone level, improve insulin resistance and decrease hirsutism in PCOs patients.

METHODOLOGY:

The Study Design was Quasi-Experimental. This study was conducted in the Department of Rehabilitation Sciences, Ziauddin Hospital. This study was completed in the duration of six months. Sample size of 50 participants was calculated by using an open Epi-software. By taking CI of 95% and Power of test 90% a sample size was calculated by using a following formula. $n = \frac{Z_{(1-\alpha/2)} \cdot Z_{(1-\beta)} \cdot (\sigma)^2 \Delta^2}{\dots}$

A total 6 sessions of hands on manual therapy was performed in a manner that 3 sessions were consecutive and 3 were on alternate days whereas follow-up was taken after two months. All participants were assessed on the basis of pre and post findings of prolactin test, HbA1c, diagnostic ultrasound imaging and Modified PCOs Questionnaire. The procedure of diagnostic ultrasound imaging was performed under the supervision of certified practioner. The 7 MHz transducer of diagnostic ultrasound was used to evaluate the number of cysts and follicles in both left and right ovaries. The imaging was performed at the early follicular phase that is within five to ten days of mensuration cycle or amenorrhea for more than three cycles. The right and left ovary was scanned in the longitudinal cross-section from inner to outer margins in order to count the number of follicles which measured between 2 to 9 mm in diameter and cyst size measured between 2 to 4 inches. The hand on manual technique (visceral mobilization) was performed under the supervision of certified therapist. The technique was performed for twenty-five to thirty minutes with small breaks in between them. Care was taken to keep the procedure pain free. The patient was positioned in supine position, legs bent and feet on a cushion to increase hip flexion and reduce muscular tension. The therapist then placed fingers just above the pubic symphysis on the inferior origin of the rectus abdominis muscle in order to direct them posteriorly on the bladder. The therapist then griped the area and performed side to side movements that were slow and deep in order to release the tension in that area.

Inclusion criteria:

- Females with diagnosed polycystic ovary syndrome.
- Age: 18-45 years.
- Cysts size between 2 - 4 inches (10cm).
- Prolactin falling within the range of 30 – 118 ng/ml.
- HbA1c within the range of 5.7% – 6.4%.

Exclusion criteria:

- Individuals with medical red flags.
- Individuals with recent abdominal surgeries (less than 6 months)
- Individuals currently in an acute inflammatory phase of known gastrointestinal or urinary diseases
- Taking blood thinning medications/anticoagulants.

A Quasi-Experimental study was conducted at the Department of Rehabilitation Sciences, Ziauddin Hospital Karachi. The purposive sampling technique was applied to enroll fifty diagnosed PCOs patients in the research. Fifteen participants were dropout due to certain reasons so remaining thirty-five patients who met the criteria and agreed to be the part of the study were given the consent form to read and sign. Prior to the treatment, baseline values were obtained for HbA1c, prolactin, ultrasound imaging and modified PCOS Questionnaire from all the participants. Then the participant received a treatment protocol lasting for 6 weeks. The tests were repeated after two months since the intervention was started, to evaluate post intervention findings in outcomes measures along with the regularity of the mensuration cycle. Diagnostic Ultrasound imaging was performed to determine the impact of hands on manual technique strategy on the size and number of cysts. The test was performed once at the beginning and then on the follow-up (after two months). The intraclass correlation coefficient, was 0.71 and 0.82 (95% confidence interval) [16]. The data was stored and analyzed by a software SPSS version 23.0. The demographic details were presented in the form of frequency and percentage. For the purpose of determining normality Kolmogorov–Smirnov test was applied. The data was normally distributed so paired t test will be applied. Level of significance was taken at 95% of CI. P-value of less than 0.05 was considered significant. The privacy, anonymity, and dignity of all participants was maintained throughout the research. The confidentiality of the data was maintained and only accessed by authorizing personals whereas informed consent was obtained prior to conduction of the research procedure.

RESULT:

This study was conducted to evaluate the effects of manual therapy among unmarried females suffering from polycystic ovary syndrome. Fifty patients with mean age of 26.37 ± 3.78 were recruited in which fifteen were dropout therefore in total thirty-five patients participated in this study. The data was recorded in SPSS version 23.0 and then analyzed to investigate the effects of manual therapy on prolactin

test, HbA1c, diagnostic ultrasound imaging and modified questionnaire of a PCOs patient.

Table 1: Comparison of Ovary Size (Right) Before and After Treatment

Table 1 showing within group analysis of right ovary						
Variable	N	Mean± SD (Pre)	Mean± SD (Post)	MD ± SD	95% of CI	p Value (<0.05)
Right ovary	35	3.60±3.58	2.60±2.69	1.0±0.01	1.0 to 1.0	<0.0001

n= sample size

SD= Standard Deviation

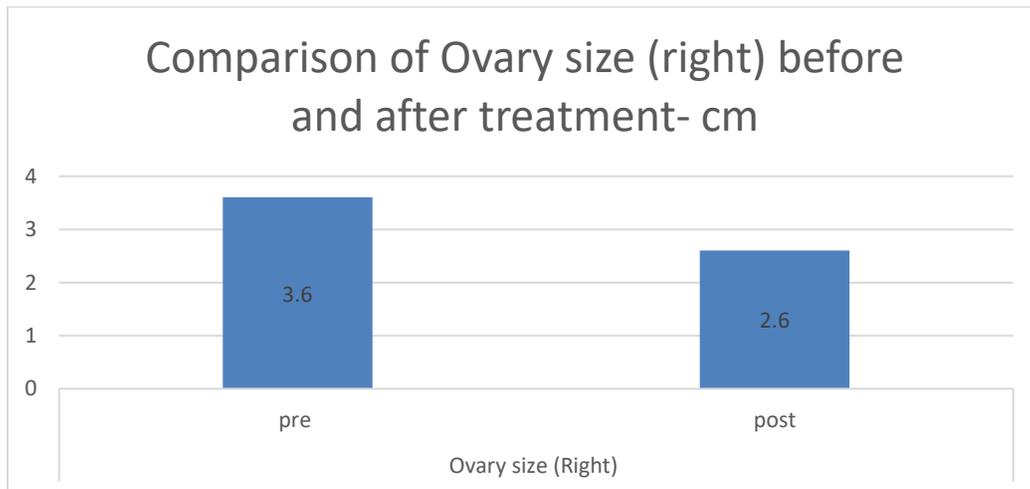
MD= Mean Difference

CI= Confidence Interval

P value showing level of significance

According to table 1 there was substantial difference between pre and post values diagnostic ultrasound imaging. The readings improved from 3.60±3.58 to 2.60±2.69 with a mean difference of 1.00cm.

Figure 1: Comparison of Right Ovary Size Before and After Treatment



According to figure 1 there was substantial difference between pre and post sizes of right ovary. The readings improved from 3.6 to 2.6 after four weeks of rehabilitation program.

Table 2: Comparison of Ovary Size (Left) Before and After Treatment

Table 2 showing within group analysis of left ovary						
Variable	N	Mean± SD (Pre)	Mean± SD (Post)	MD ± SD	95% of CI	p Value (<0.05)
Left ovary	35	4.50±0.16	3.18±0.49	1.32±0.52	1.473 to 1.171	<0.0001

n= sample size

SD= Standard Deviation

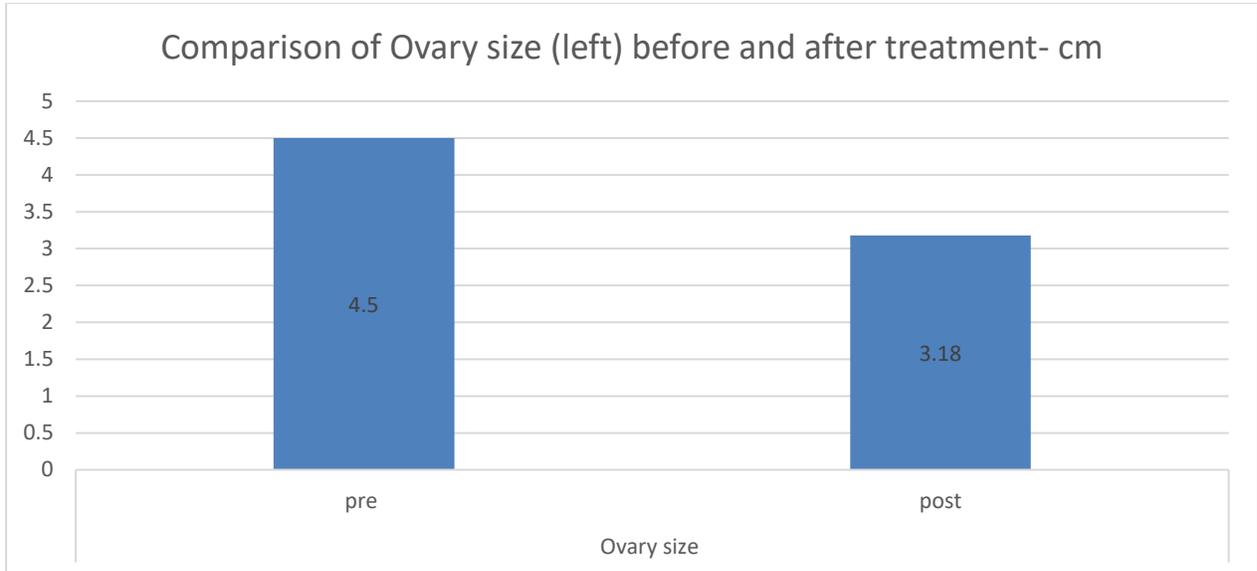
MD= Mean Difference

CI= Confidence Interval

P value showing level of significance

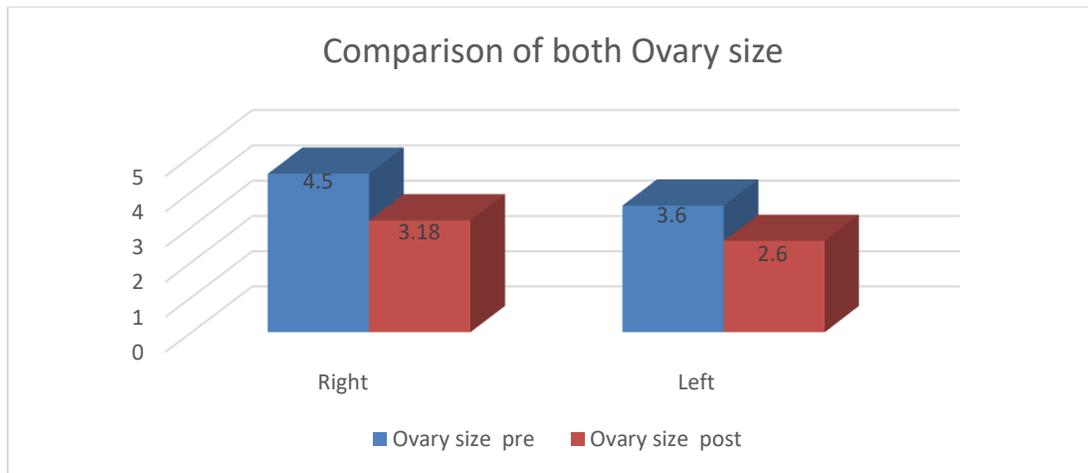
According to table 2 there was substantial difference between pre and post values of diagnostic ultrasound. The readings improved from 4.50 ± 0.16 to 3.18 ± 0.49 with a mean difference of 1.32cm.

Figure 2: Comparison of Left Ovary Size Before and After Treatment



According to figure 2 there was substantial difference between pre and post sizes of left ovary. The readings improved from 4.5 to 3.18 after four weeks of rehabilitation program.

Figure 3: Comparison of Right and Left Ovary Size Before and After Treatment



According to figure 5 there was substantial difference between pre and post sizes of both left and right ovary. The readings improved from 4.5(right) and 3.18(left) to 3.6(right) and 2.6(left) after four weeks of rehabilitation program.

DISCUSSION:

The aim of this study was to evaluate the effects of manual therapy among unmarried females suffering from polycystic ovary syndrome through few parameters that were, diagnostic ultrasound imaging. 50 participants with diagnosed polycystic ovary syndrome were recruited in which fifteen were dropouts due to work commitments, time restraints, loss of contact and inability to comply with the study requirements [17]. The rehabilitation protocol of six sessions were performed on the remaining thirty-five participants in a manner that three sessions were consecutive and three on alternate days for a thirty min duration and then follow-up was taken after two months. There is not enough evidence present to consider manual therapy as a treatment option for polycystic ovary syndrome therefore this study was aimed to determine the impact of manual therapy in managing the complications of PCOs [18]. There are multiple treatment options available for the treatment of PCOs such as pharmaceutical and surgical but they are expensive, takes a lot of time, has side effects and sometimes lead to other problems. The technique introduced by this study is safe, inexpensive and provide timely results so can be used as an adequate method to treat this disease [19].

This present study is in agreement with the study conducted by Badaway (2011) which suggested that in addition to medicine there is a need of alternate therapy that uses hands on techniques such as acupressure, acupuncture, massage therapy and manual therapy as a mode of choice for the management of PCOs as these methods are cost effective and produce long-lasting effects as compared to the conventional treatment approaches [20].

Michelle Chet (2018) concluded in her study that myofascial release or manual therapy is an effective, mild and harmless hands on technique of soft tissue manipulation to release fascial restrictions and return normal tissue function. Additionally, Ajimsha et al., (2013) concluded myofascial release (MFR) or manual therapy as an emerging strategy with incredible potential [21]. The results of this present study are consistent with these researches and conclude that manual therapy or myofascial release is a cost-effective technique that relax tense muscles, break scar tissue adhesions, increase circulation in order to decrease pain and provide timely results without any risk factors [22].

Ultrasound imaging was performed to evaluate the size and number of cysts before and after performing the procedure. The criterion of PCOs was determined

by the presence of >12 follicles within the ovary with a diameter of 2-9 mm and ovarian volume >10 cm³ [23]. The same person who examined the diameter and size of the cyst before performing the rehabilitation protocol was assigned to examine the cyst on first and second follow-up because the assessment of number of follicles in a same ovary conducted by different examiners can give controversial results [24]. According to the results of ultrasound imaging there were multiple small immature follicles with a diameter of 3-9 mm accumulated in both right and left ovaries of all thirty-five participants. Along with peripheral distribution of follicles central stromal brightness or prominence was also detected. After completing the rehabilitation protocol ultrasound imaging was performed on the follow-up. On the follow-up imaging showed decrease in the size of the cyst from 3.60±3.58 to 2.60±2.69 with a mean difference of 1.00cm in right ovaries whereas 4.50±0.16 to 3.18±0.49 with a mean difference of 1.32cm in left ovaries [25].

According to the results of this study manual therapy showed substantial improvement in the condition of the patients suffering from polycystic ovary syndrome. There was improvement in size. In comparison to pharmaceutical therapy this hand on technique is an excellent approach that is cost effective and gives timely results without any side effects.

CONCLUSION:

This present study suggests that manual therapy is a positive intervention for females suffering from polycystic ovary syndrome with no results indicating an adverse impact. This hand on technique decreases the size of the cyst that improves hormonal levels and regulates the menstruation cycle. According to the results there was substantial difference in pre and post rehabilitation values of all three parameters. The prolactin test, hbA1c diagnostic ultrasound and questionnaire showed significant improvement in addition to other benefits from multiple issues. Therefore, manual therapy is a safe and cheap technique that can give timely and unprecedented results without any adverse effects.

LIMITATION:

The limitation of this study is the short observation period of the effects. Further studies should be conducted to determine the long term and permanent impact of manual therapy among females suffering from PCOs.

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