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Evaluation of Lifestyle Modification Program for Polycystic Ovary Syndrome in Infertile Women

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Abstract

Problem: Polycystic Ovary Syndrome (PCOS) affects a large proportion of the female population worldwide. PCOS can have a wide variety of health implications for the woman including difficulty achieving pregnancy.

Methods: A retrospective chart review of 368 patient records were assessed for inclusion criteria yielding 163 patients with PCOS suffering from infertility. Demographic and health data were gathered for each patient to provide a baseline comparison between the first two quarters of 2019 and the first two quarters of 2020.

Results: The results of the study were mixed. Patients who lost weight did have a higher positive pregnancy rate. However, as a byproduct of the study it was found that the Health and Wellness program is being underutilized and is using only a single modality for treatment. The clinic is losing patients due to a lack of follow-up and there are communications disconnect between the Health and Wellness program and the clinic.

Implications for Practice: The study has shown that weight loss does help improve positive pregnancy rates. The study also identified some areas of improvement that needs to be addressed in the Health and Wellness program. Implementing a more well-rounded and holistic program by adding components to address physical activity, stress reduction, and mental and physical health oversight would transform the Health and Wellness program into a true lifestyle modification program.

Evaluation of Lifestyle Modification Program for Polycystic Ovary Syndrome in Infertile Women

Polycystic ovary syndrome (PCOS) is one of the most common endocrine and metabolic disorders existent in women (Bozdag, Mumusoglu, & Zengin, 2016). PCOS effects women of all ages, income levels, ethnicities, and education levels. Studies performed in North America, Europe, Australia, and Asia revealed approximately 5-21% of the population has PCOS (Arasu, Moran, Robinson, Boyle, & Lim, 2019; Bozdag, Mumusoglu, & Zengin, 2016; Regidor & Schindler, 2016). Many women with PCOS are misdiagnosed or never referred for treatment by their primary care providers (Tomlinson et al., 2017).

The etiology of PCOS is fascinating. The evolving consensus among leading experts in the field is that PCOS is an evolutionary advantage developed through natural selection during periods of nutritional shortages (Shaw & Rosenfield, 2020). This advantage was critical to survival because it increased the body's ability to preserve anabolism and reproductive ability by way of increasing androgen and insulin production thus promoting fat storage (Shaw & Rosenfield, 2020). The increased ability to retain fat allowed women to still be capable of reproduction when others would fall below the needed fat levels to ovulate. In the modern times when food is plentiful and where starvation is unlikely this trait leads to obesity and other associated medical issues, including infertility (Shaw & Rosenfield, 2020).

Today PCOS is recognized as a disorder with complex genetic attributes in which environmental issues and multiple different genes result in the development of a syndrome that has a multitude of complications in a variety of body systems (Bozdag,

Mumusoglu, & Zengin, 2016). There are currently three diagnostic criteria in use for classifying and diagnosing PCOS (Tannus, Tan, Son, & Dahan, 2017). They are the Rotterdam criteria, Androgen excess and PCOS society criteria, and the National Institute of Health (NIH) criteria (Bozdag, Mumusoglu, & Zengin, 2016; Tannus et al., 2017). For the diagnosis of PCOS the most commonly used criteria is the Rotterdam (Genazzani, 2016). The Rotterdam criteria require at least two of three features be present for diagnosis; these are oligo or anovulation, polycystic ovary morphology, and clinical or chemical symptoms of hyperandrogenism (hirsutism, acne, male-pattern hair loss) (Bergh, Moore, & Gundell, 2016; Bozdag, Mumusoglu, & Zengin, 2016; Tannus et al., 2017). Up to 18% of patients with PCOS do not manifest hyperandrogenism (Tannus et al., 2017). In addition to the three primary manifestations of PCOS, there also exists a higher risk for other life altering ramifications including heightened risk of infertility, diabetes mellitus, metabolic syndrome, cardiovascular disease, endometrial cancer, and psychological issues (Arasu et al., 2019; Shaw & Rosenfield, 2020; Tomlinson et al., 2017). However, social determinants of health (SDOH) (examples include income, location and insurance status) strongly impact a woman's ability pay for medical care to reduce the impact of these risk factors (King et al., 2016). The patient's ability to receive treatment, despite potential SDOH, for PCOS manifestations can help reduce obesity resulting in a higher chance of becoming pregnant (Arasu et al., 2019).

The purpose of this descriptive study project is to evaluate the impact of a treatment regime consisting of lifestyle modifications and pharmaceutical aids in assisting infertile women of reproductive age with PCOS becoming pregnant. The overall aim of this project is to evaluate an existing lifestyle modification program to determine

if it assists infertile women with PCOS achieve pregnancy in at least 10% of cases during a 12-month period. The primary outcome measure of interest will be the rate of positive pregnancies achieved. Secondary outcome measures will be the resumption of menstrual cycle, weight change, attendance in lifestyle modification program, patient retention data and demographic information. These variables will be evaluated via a retrospective chart review from patients who took part in the lifestyle modification program during the first two quarters of 2020 and historical chart review from the first two quarters of 2019 prior to implementing the Lifestyle Modification Program. The question for study is in infertile women aged 18- to 39 -years with PCOS, what is the impact of lifestyle modification and medication for fertility on the ability to conceive within six-months of the treatment? This will be a Plan-Do-Study-Act Cycle (PDSA) descriptive study.

Literature Review

Preparation for the literature review started with research using a general UMSL library database search, CINAHL, Cochrane, Ovid Medline, and Wiley. Key search terms used were pcos OR polycystic ovary syndrome OR polycystic ovarian syndrome OR ovarian follicle, AND pregnancy, AND fertility, AND treatment OR intervention OR therapy OR management. The initial search in CINAHL for pcos OR polycystic ovary syndrome OR polycystic ovarian syndrome OR ovarian follicle, generated 6155 results. For inclusion criteria the search was limited to articles from 2005 to 2020, included only peer reviewed articles, and added the term ‘human’. Terms including cancer patients, Turners and Fowlers were excluded. These resulted in 212 articles for consideration. After individually evaluating the remaining articles for relevance to the project topic, 24 were chosen to be included in this literature review.

Insulin resistance and the associated hyperinsulinemia appears to be a key feature in the pathology of PCOS and reinforces reproductive and endocrine features such as hyperandrogenism and ovarian dysfunction (Arasu et al., 2019; Cassar et al., 2016; Song, Hong, Sung, & Lee, 2017). This insulin resistance leads to the disruption of gonadotrophin secretion and paradoxically insulin stimulates androgen production by the insulin sensitive ovaries leading to infertility and other symptoms of PCOS (Cassar et al., 2016; Rosenfield & Ehrmann, 2016). The overabundance of androgens hinders follicle growth and ovulation that causes ovarian follicles to freeze at the preovulation stage (Bergh et al., 2016).

Insulin resistance affects women with PCOS irrespective of their Body Mass Index (BMI) (Arasu et al., 2019; Regidor & Schindler, 2016; Song et al., 2017; Stepto et al., 2013), though a very high percentage of women with PCOS are also obese or overweight (Legro et al., 2015; Tomlinson et al., 2017). According to the cross-sectional research study by Stepto et al., (2013) the incidence of insulin resistance in lean women with PCOS is 75% while in overweight/obese PCOS women levels of insulin resistance reach 95%. In the overweight control group insulin resistance was only 62% showing the profound endocrine effects of PCOS (Naderpoor et al., 2015). Insulin resistance is often underdiagnosed in primary care settings in lean women with PCOS (Song et al., 2017). Clinically, it is critical to identify insulin resistant infertile women to improve reproductive outcomes and to reduce the risk of life-effecting metabolic and cardiac issues (Alebić, Bulum, Stojanović, & Duvnjak, 2014; Tomlinson et al., 2017). The focus of any treatment regimen for PCOS needs to address insulin resistance.

A review of available literature illustrates many women with PCOS have a higher BMI on average, elevated rates of insulin resistance, and higher levels of weight gain during shorter periods of time. This results in an increased level of clinical severity for a variety of health issues (Cassar et al., 2016; Tomlinson et al., 2017). Given this information, a vital clinical focus for a first line treatment should encourage lifestyle modifications including diet, and exercise to help patients reach a healthier weight (Alebić et al., 2014; Bergh et al., 2016; Cassar et al., 2016). The addition of insulin sensitizers along with the lifestyle modifications have resulted in a greater body fat loss, subsequent to reduced insulin resistance and PCOS symptoms when compared to lifestyle modifications alone (Alebić et al., 2014; Cassar et al., 2016; Rosenfield & Ehrmann, 2016).

Ideally, the best and most comprehensive lifestyle modification program would be tailored to the individual patient (Bergh et al., 2016; Marzouk & Sayed, 2015). A comprehensive plan should address nutrition, physical activity, mental and emotional health, stress reduction and weight loss strategies in addition to necessary medications; this combination therapy is intended to help decrease androgen levels and restore ovulation (Bergh et al., 2016; Kim, Chon, & Lee, 2020). Obesity is highly associated with PCOS infertility and unfavorably effects reproduction. Weight loss is a vital component in treating infertile women with PCOS. As little as a 5% to 10% reduction in total body weight has been shown to restore ovulation and increase fertility (Balen et al., 2016; Bergh et al., 2016; Einarsson et al., 2017; Marzouk & Sayed, 2015). Weight reduction has shown to increase the rate of spontaneous pregnancies in PCOS women (Einarsson et al., 2017). Pharmacotherapy, in the form of insulin sensitizers, in addition

to lifestyle modifications is recommended to optimize weight loss (Naderpoor et al., 2015).

For women with PCOS, weight loss is more difficult than for most women because of the elevated androgen levels. These elevated androgen levels cause increased appetite and insulin secretion resulting in increased weight gain and retention (Bergh et al., 2016). Regular low impact physical activity and dietary changes help increase insulin sensitivity and lower androgen levels resulting in weight loss (Bergh et al., 2016). Exercise causes a high level of sex binding globulin to be released into the blood resulting in reduced insulin and testosterone level as well as lower levels of free androgens in the system (Bergh et al., 2016). Since extreme physical activity (over exercising) has been shown to be suggestive of negatively impacting fertility, it is recommended exercising is limited to three to five times a week for 30 minutes a day (Bergh et al., 2016; Legro et al., 2015).

Along with physical activity, an important part of treating infertile women with PCOS is to include dietary changes to reduce total body weight (Marzouk & Sayed, 2015). Weight loss from diet changes in women with PCOS has been found to lead to significant increases in menstrual cycles, including ovulation, and decreases in BMI, waist circumference, and other androgen related symptoms (Balen et al., 2016; Kim, Chon, & Lee, 2020; Marzouk & Sayed, 2015). Women with PCOS lose weight when placed on a dietary protocol of complete proteins and low carbohydrates combined with an insulin sensitizer such as metformin (Marzouk & Sayed, 2015). The low carbohydrate and complete protein diet have shown impressive results in lowering body weight, waist circumference, insulin resistance, and dyslipidemia (Marzouk & Sayed, 2015). Changing

a patient to a low carbohydrate diet is effective in lowering body mass, in improving glucose control in diabetic patients and those patients with insulin resistance (Bolla, Caretto, Laurenzi, Scavini, & Piemonti, 2019). In women with PCOS a low carbohydrate diet, such as the Keto Diet, can be used as an effective non-pharmacological treatment (Paoli, Mancin, Giacona, Bianco, & Caprio, 2020). This results in an increase in estradiol, progesterone, and sex hormone binding globulin and a corresponding decrease in luteinizing hormone, follicle stimulating hormone, and total and free testosterone (Paoli et al., 2020). These hormone reductions along with a decrease in blood glucose and blood insulin levels results in a reduction of PCOS side effects on a woman who is seeking to achieve better fertility (Paoli et al., 2020).

Waist circumference is a valuable insulin resistance predictor in both women affected and unaffected by PCOS. As a predictive tool waist circumference can be used to monitor insulin resistance levels (Marzouk & Sayed, 2015). A reduction in waist circumference indicated a corresponding reduction in insulin resistance (Marzouk & Sayed, 2015). A systematic review conducted by Kim, Chon and Lee (2020) found that lifestyle modifications along with metformin for PCOS resulted in reduced body weight, reduced insulin resistance, and hyperandrogenism while promoting increased ovulation. A weight loss study, random controlled trial, also found that obese women with PCOS who lost weight had a higher number of spontaneous pregnancies (Einarsson et al., 2017). The two most prescribed medications for inducing ovulation are metformin and clomiphene citrate (Bergh et al., 2016).

Metformin is shown to be highly effective in treating obese women with PCOS and is associated with increased ovulation rates and successful clinical pregnancies

(Bergh et al., 2016). Metformin acts on the body by reducing hepatic gluconeogenesis and insulin sensitivity that helps to reduce androgen levels and can restore ovulation in up to 50% of women affected by PCOS (Bergh et al., 2016; Haas & Bentov, 2017; Rosenfield & Ehrmann, 2016). A course of pre-fertility treatment metformin for three months, followed by the addition of an ovulation inducing agent, such as clomiphene citrate has been shown to result in improved pregnancy rates (Diamanti-Kandarakis, 2012).

Clomiphene citrate blocks the estrogen receptors in the hypothalamus leading to an increase in follicle stimulating hormone and ultimately ovulation (Bergh et al., 2016). Up to 30% of patients do not resume ovulating with clomiphene citrate as a monotherapy and require metformin as an adjuvant agent (Bergh et al., 2016; Haas & Bentov, 2017). Medical management for these patients has traditionally been on an individualized basis and personalized to their history (Bergh et al., 2016).

This descriptive study project will utilize the PDSA evidence-based framework to evaluate the program. A historical chart review will be conducted to evaluate the effectiveness of the current program and promote the best evidence-based practices for patient centered care. There exists a high level of motivation in infertile women who are trying to become pregnant. This motivation to conceive a child makes the women more likely to practice new behavioral skills and lifestyle modifications taught as part of the treatment regimen (Bergh et al., 2016). Patients with infertility desiring to achieve pregnancy are highly goal driven and open to following recommendations by their healthcare providers.

Methods

Design

This project will evaluate the existing Health and Wellness program, referencing PDSA Cycle of evidence-based practice, utilizing a descriptive design approach. The study will be conducted using a retrospective chart review for the first two quarters of 2020 for the Health and Wellness Program. A comparison will also be made between patient groups with PCOS who participate in the clinic's life-style modification program in 2020 compared to PCOS patients who were seen at the clinic in the first two quarters of 2019 prior to the life-style modification program being implemented.

Setting

This project takes place in an urban Midwestern fertility clinic. Most patients seeking assistance with fertility issues at this clinic either have insurance or can pay for services. The clinic offers multiple services to patients including artificial insemination, invitro fertilization (IVF), and a health and wellness program. The clinic is located in a city of approximately 126,000 (World Population Review, 2020). The majority of the fertility patients using the clinic come from within the city limits and surrounding counties. The average household income for the city where the clinic is located is $71,311 (World Population Review, 2020). Patients are managed by a supervising physician with a reproductive endocrinology specialty, a medical laboratory specialist oversees IVF procedures and semen thawing, and nurses assist patient by conducting ultrasounds and performing inseminations.

Sample

A convenience sample of women with fertility issues, who also have the diagnosis of polycystic ovary syndrome, was examined during this project. The sample was gathered from patients at a midwestern fertility clinic who were taking part in a health

and wellness program during a 6-month period. A second convenience sample group of infertile women, seen at the clinic prior to the start of the health and wellness program was evaluated to compare outcome results with patients who participate in the program. Patients included in the study will be women between the ages of 18-39 with a diagnosis of PCOS who were trying to achieve a pregnancy. Patients with partners who have male factor infertility and patients with uncorrected reproductive abnormalities or are outside the project age group were excluded.

Data Collection and Analysis

Data will be collected via retrospective medical chart review. Demographic variables including (age, race/ethnicity, payer status, marital status), and study variables such as health history, official diagnoses, BMI, insulin resistance status, pregnancy status, medications, laboratory testing, and records from participation in lifestyle modification program including attendance were examined (see Table 1).

Patient privacy was protected by de-identifying the records of individual patients with unique identifiers (A1, A2, A3, etc) and stored on a secured laptop. Descriptive data and confounder results from the study were displayed in tables, histogram, scatter plots, pie charts and bar graphs.

Approval Processes

Consent to conduct the project was obtained in May 2020 from the supervising physician of the fertility clinic where the research is to be conducted. The project topic and access to the patient charts for review and analysis was approved. The project was approved by the student's doctoral committee, and the University of Missouri St. Louis (UMSL) Graduate School. Quality improvement (QI) determination form was submitted

for approval by UMSL Institutional Review Board for human subject research prior to the start of the project. The risk to human subjects is limited because no interventions or changes in treatment will be taken during the project. The information gathered during the project was historical in nature. The primary risk to subjects was a potential data breech of medical information. This risk was addressed by de-identifying patient data with unique identifiers and all research being retained on a secure, password protected laptop. The patient data will be retained for a period of three years.

Procedures

Planning consisted of a series of short meetings in May and June of 2020 with the head physician of the fertility clinic. During these meetings the topic of a program evaluation for the clinics new lifestyle modification program was broached and items to study were refined. A separate meeting phone conference in July 2020 with the head of the Doctor of Nursing Practice program was needed to receive approval for the project topic and location. A zoom conference with project chair to outline the parameters of the project was conducted in August 2020. A literature review was conducted to study

current treatments and therapies being utilized for helping PCOS infertile women conceive. It was decided by the researcher and the committee to conduct a program evaluation via retrospective chart review to evaluate the effectiveness of the current lifestyle modification program used at the fertility clinic. In January 2021, a completed project paper proposal was submitted to committee members for editing and feedback. The project proposal meeting was conducted and approved with all committee members present in March 2021. The approved project proposal was submitted to the Institutional Review Board (IRB) for Quality Improvement project determination. Quality

Improvement project status not requiring IRB review was granted on May 11, 2021. In mid-May data collecting and review from the clinic was started with data collating and analysis completed by the end of the month. In June 2021, the remaining sections of the paper were written including the program evaluation results.

Results

Of the 368 total patient charts reviewed for inclusion in this study, 163 (44%) were found to have met study admission criteria. Patients were broken down into calendar year quarters in order for each quarter to be compared to the same quarter the following year and to attempt to account for COVID 19 variances. The first two quarters of each year were assessed for patterns.

The first quarter of 2019 contained 40 patients who met criteria with an age range between 21 and 39 years old. The average patient age was 30.1 years. 35 (88%) patients were of Caucasian decent, 3 were African America, 1 was Asia, and 1 identified as mixed race. The majority 93% (n=37) had some form of insurance coverage. Marital status varied but the majority were married or in a committed relationship 80% (n=32), while the remainder were pursuing fertility treatment without a partner. 68% (n=27) of patients had official diagnoses of PCOS, the other 32% (n=13) were clinically suspected to have PCOS.

Patient starting BMI ranged from 20.6 to 47 with an average BMI of 31.1. Due to data gaps ending BMI's and weights did not accurately reflect the included patients. Starting weights ranged from 147 to 297 pounds during this quarter with an average patient weight of 197.6 pounds. Of the comorbidities listed in the medical charts' obesity was by far the most common with 68% (n=27) patients being labelled obese to morbidly

obese. The plans for treatment included 20 patients being referred for weight loss, 21 having an end goal of IUI, 7 utilizing IVF. Twenty-seven of these patients were prescribed or had fertility medications in their treatment plan. During treatment patients lost an average of 8.5 pounds with the range of weight change being -44 to +20 pounds. Ending weights were only able to be located for 20 of the 40 patients included in the study for first quarter 2019.

Of the 13 patients who did end up losing weight, 11 of them became pregnant. Then 45% (n=18) of patients were clinically identified as being diabetic or insulin resistant. Fifty-three percent (n=21) of patients had a history of previous positive pregnancies, some went to term and delivery while others resulted in miscarriage. Prior to seeking fertility services, 30% (n=12) of patients had a history of one or more miscarriages. While 50% (n=20) patients had a positive pregnancy test during treatment at the fertility clinic, this does not mean they went to term, but does indicate the patients were able to resume ovulation with treatment. Of the 40 patients, 55% (n=22) continued to seek services at the clinic with 45% (n=18) patients being lost to fertility clinic services.

The second quarter of 2019 also contained 40 patients who met criteria with an age range between 22 and 37 years old. The average patient age was 28.2 years. 88% (n=35) patients were of Caucasian decent, 1 was African America, and 4 were Hispanic. The majority 93% (n=37) had some form of insurance coverage. Marital status varied but the majority were married or in a committed relationship 83% (n=33), while the remainder were pursuing fertility treatment without a partner. 80% (n=32) patients had official diagnoses of PCOS, the other 20% (n=8) were clinically suspected to have PCOS.

Twenty percent (n=8) of the patients were identified as having lean type PCOS. Patient starting BMI ranged from 17.9 to 55.3 with an average BMI of 31.9.

Due to data gaps ending BMI's and weights did not accurately reflect the included patients. Starting weights ranged from 111 to 322 during the second quarter with an average patient weight of 191.6 pounds. Of the comorbidities listed in the medical charts' obesity was by far the most common with 50% (n=20) patients being labelled obese to morbidly obese.

The plans for treatment included 65% (n=26) being referred for weight loss, 33% (n=13) having an end goal of IUI, 1% (n=4) utilizing IVF. With 85% (n=34) of these patients were prescribed or had fertility medications in their treatment plan. During treatment patients lost an average of 8.3 pounds with the range of weight change being -22.5 to +23 pounds. Ending weights were only able to be located for 19 of the 40 patients included in the study for second quarter 2019. Of the 15 patients who did end up losing weight, 14 of them became pregnant. Forty-five percent (n=18) of patients were clinically identified as being diabetic or insulin resistant. There was 48% (n=19) of patients who had a history of previous positive pregnancies, some went to term and delivery others resulted in miscarriage. There was 33% (n=13) of patients who had a history of one or more miscarriages prior to seeking fertility services. Then 48% (n=19) patients had a positive pregnancy test during treatment at the fertility clinic, this does not mean they went to term, but does indicate the patients were able to resume ovulation with treatment. Of the 40 patients, 55% (n=22) continued to seek services at the clinic with 45% (n=18) patients being lost to fertility clinic services.

The first quarter of 2020 contained 45 patients who met criteria with an age range between 22 and 39 years old. The average patient age was 29.3 years. Ninety-eight percent (n=44) patients were of Caucasian decent, and 1 identified as being of mixed race. The majority, 91% (n=41) had some form of insurance coverage. Marital status varied but the majority were married or in a committed relationship 78% (n=35), while the remainder were pursuing fertility treatment without a partner. 73% (n=33) patients had official diagnoses of PCOS, the other 27% (n=12) were clinically suspected to have PCOS. Eighteen percent (n=8) of the patients were identified as having lean type PCOS. Patient starting BMI ranged from 20.7 to 55.4 with an average BMI of 41.4. Due to data gaps ending BMI's and weights did not accurately reflect the included patients. Starting weights ranged from 128 to 370 during this quarter with an average patient weight of 231.8 pounds. Of the comorbidities listed in the medical charts' obesity was by far the most common with 73% (n=33) patients being labelled obese to morbidly obese.

The plans for treatment included 73% (n=33) being referred for weight loss, 44% (n=20) having an end goal of IUI, 20% (n=9) utilizing IVF. Fifty-six percent (n=25) of these patients were prescribed or had fertility medications in their treatment plan. During treatment patients lost an average of 16.1 pounds with the range of weight change being -69 to +10 pounds. Ending weights were only able to be located for 23 of the 45 patients included in the study for first quarter 2020. Of the 19 patients who did end up losing weight, 14 of them became pregnant. There were 36% (n=16) patients clinically identified as being diabetic or insulin resistant. While 47% (n=21) of patients who had a history of previous positive pregnancies, some went to term and delivery others resulted in miscarriage. There were 31% (n=14) patients who had a history of one or more

miscarriages prior to seeking fertility services. There were 42% (n=19) patients who had a positive pregnancy test during treatment at the fertility clinic, this does not mean they went to term, but does indicate the patients were able to resume ovulation with treatment. Of the 45 patients, 55% (n=25) continued to seek services at the clinic with 45% (n=20) patients being lost to fertility clinic services.

The second quarter of 2020 contained 38 patients who met criteria with an age range between 20 and 39 years old. The average patient age was 30.1 years. 97% (n=37) patients were of Caucasian decent, and one was mixed race. The majority 89% (n=34) had some form of insurance coverage. Marital status varied but the majority were married or in a committed relationship 84% (n=32), while the remainder were pursuing fertility treatment without a partner. 45% (n=17) patients had official diagnoses of PCOS, the other 55% (n=21) were clinically suspected to have PCOS. Eleven percent (n=4) of the patients were identified as having lean type PCOS.

Patient starting BMI ranged from 19.8 to 50.3 with an average BMI of 33.3. Due to data gaps ending BMI's and weights did not accurately reflect the included patients. Starting weights ranged from 133 to 310 during this quarter with an average patient weight of 217.8 pounds. Of the comorbidities listed in the medical charts' obesity was by far the most common with 71% (n=27) patients being labelled obese to morbidly obese.

The plans for treatment included 66% (n=25) being referred for weight loss, 47% (n=18) having an end goal of IUI, 18% (n=7) utilizing IVF. 68% (n=26) of these patients were prescribed or had fertility medications in their treatment plan. During treatment patients lost an average of 23.8 pounds with the range of weight change being -43.8 to +13 pounds. Ending weights were only able to be located for 14 of the 38 patients

included in the study for second quarter 2020. Of the 11 patients who did end up losing weight, 5 of them became pregnant. There were 47% (n=18) patients who were clinically identified as being diabetic or insulin resistant. While 47% (n=18) patients had a history of previous positive pregnancies, some went to term and delivery, others resulted in miscarriage. Thirty-seven percent (n=14) of patients who had a history of one or more miscarriages prior to seeking fertility services. While 24% (n=9) of patients had a positive pregnancy test during treatment at the fertility clinic, this does not mean they went to term, but does indicate the patients were able to resume ovulation with treatment. Of the 38 patients, 45% (n=17) continued to seek services at the clinic with 55% (n=21) of patients being lost to fertility clinic services.

Several overall themes can be concluded from assessing the data gathered during the first two quarters of 2019 and 2020. The first is that when patients lose weight, they are more likely to start ovulating and become pregnant. The second is there are an overwhelming number of patients seeking fertility treatment at the Midwestern clinic who are obese or morbidly obese in addition to having polycystic ovarian syndrome. Other common comorbid conditions that frequently showed up in the patient population meeting criteria for the study included being underweight, endometriosis, hypothyroidism, a history of chlamydia, advanced maternal age, tubal issues, peritoneal adhesion's, repeated pregnancy loss, anxiety, depression, and hypertension.

Potentially due to COVID-19 there were fewer patients seen during the second quarter of 2020. However, the patients who were seen where unhealthier and had a higher starting weight. This is borne out by the elevated average starting BMI and weight for this quarter. The second quarter of 2020 resulted in far more unofficial diagnosis’ of

PCOS because of virtual consults and a lack of initial physical exam. This resulted in patients not having an official diagnosis of PCOS.

When addressing the information gathered from the Health and Wellness program results were mixed. During the first quarter of 2020, 10 patients participated in the health and Wellness program. Since then, nine of those patients have been archived and no longer participate in the program. Five of the patients achieved a pregnancy, two were spontaneous and two were the result of intrauterine insemination (IUI), the fifth patient had a biochemical pregnancy after a IUI cycle. All ten of the patients did lose some weight. Patients participated in the Health and Wellness program for between two and 24 sessions. Disregarding outliers who had a far higher number of sessions the average number of sessions varied between two and six.

There were eight patients from the second quarter of 2020, who have been confirmed in the program. Of those eight patients, six are now archived and no longer participating in the program and only two of the eight have achieved a pregnancy. One of the pregnancies was biochemical and the other pregnancy was achieved using in vitro fertilization. Four of the eight patients lost weight participating in the program, three of the patients ended up gaining weight, and for the last patient no recorded weight was able to be located after the initial weigh-in at the fertility clinic. The number of sessions patients participated in with the Health and Wellness program varied between one session and 18. The more typical number of sessions participated in seems to be between three and six.

Of the 58 patients who were referred to the Health and Wellness program for weight loss, only 18 patients participated. The current Health and Wellness program

focuses solely on nutrition utilizing the ketogenic diet. Areas of a lifestyle modification program that are not addressed include physical activity, stress reduction, mental health wellness, and monitoring/treatment of comorbid medical conditions.

Discussion

This program evaluation project of the Health and Wellness program implemented at a Midwestern fertility clinic evaluated patient data for the first two quarters of 2019 and 2020. The goal of this evaluation was to gather baseline data both pre and post implementation of the Health and Wellness program. Analyzing the data quarter by quarter allowed for unexpected changes due to the COVID-19 pandemic.

As expected, numbers were reduced slightly but overall, the number of patients seen at the clinic remained steady. The interesting thing that did occur in the data was that patient body mass indexes and weights shifted up from the other three quarters evaluated. This potentially indicates that patients with more severe medical problems are more likely to seek treatment, even elective treatment during a pandemic, when compared to patients who are not as severely ill.

Overall, as expected the patients who lost weight had a higher likelihood of becoming pregnant. Participation in the Health and Wellness program did result in several patients losing weight and achieving a pregnancy. Of the 18 patients who participated in the Health and Wellness program 7 patients achieved a positive pregnancy result, two of those were biochemical. If you remove the biochemical pregnancies the success rate is 28%. However, when compared to the number of patients from the first two quarters of 2019 who lost weight (n=32) and became pregnant (n=25) the clinic had a 78% pregnancy success rate. It is possible that more patients in the first two quarters of

2019 lost weight than were indicated in the data. In some quarters half the patients did not have a follow-up weight listed in their charts. However, hypothetically doubling the number of patients who lost weight (n=64) the pregnancy success rate would still be 40%.

Barriers identified for getting patients enrolled and participating in the health and Wellness program include the lack of follow up, issues with scheduling initial interviews, the program only being offered via distance consultations, cost, and a lack of well-rounded services usually present during a lifestyle modification program. Often patients with fertility issues, who also have PCOS, suffer from comorbid depression or anxiety.

Other factors related to the Health and Wellness program that showed up in the chart review indicate that the program is being underutilized. There were instances when patients with lean PCOS, who were underweight or had a lower BMI, would have benefited from a referral to the Health and Wellness program. In addition many of the patients preferred to have better access to their Health and Wellness coach and did not wish to pursue a program that was distant based.

The impact of the COVID-19 pandemic on the sample from 2020 did affect the results of the study, especially for the second quarter of 2020, when many of the appointments had to be done via Telehealth. Appointments conducted via Telehealth did not elicit the same amount of data as in a traditional clinic visit. Namely vital statistics such as height, weight, and body type were often an estimate. There were many instances where data was missing from the charts, most notably weights. Often the first weight when the patient was seen initially at the clinic was the only weight able to be located

within the chart unless the patient became pregnant. Keeping track of a patient's weight changes are vital when addressing fertility issues.

Conclusion

The Health and Wellness program associated with this Midwestern fertility clinic shows great promise but is currently underdelivering. Most of the patients participating in the Health and Wellness program are losing weight, but the focus exclusively on the ketogenic diet is failing some of the other patients. The Health and Wellness program needs to expand into a true lifestyle modification program that goes beyond nutrition and includes physical activity, stress reduction, mental health, patient education, and monitoring comorbid medical conditions such as hypertension and blood glucose levels. One strength of this study was the ability to evaluate data from both before and after the Health and Wellness program was implemented to see the changes that occurred in health outcomes. The implementation of a well-rounded Health and Wellness program is recommended for the coordination of care and the improvement of patient health outcomes.

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Appendix A

Table 1 Data Collection Instrument

	Patient	A1	A2	A3	A4	A5	A6	A7	A8
Data Categories									
Age									
Race (White-1, African American-2, Asian-3, Hispanic-4, Mixed-5)									
Payer Status (Private Pay-1, Private Insurance-2, Medicare/Medicaid-3)									
Martital Status (Single-1, Married-2, Divorced-3)									
PCOS Diagnosis (Official-1, Suspected-2, None-3)									
BMI Before LMP									
BMI After LMP									
Weight Before LMP									
Weight After LMP									
Difference in Weight- Before and After									
Diabetes Status (DM1-1, DM2-2, None-3, IR-4)									
A1C									
Pregnancy Status Post LMP									
Positive Pregnancy Hx (Yes-1, No-2)									
Medications									
Attendance at H/W (Number of Sessions)									
Resumption of Mensural Cycle (Yes-1, No-2)									
Participated in Lifestyle Modification Program (Yes-1, No-2)									
Comorbid Diagnosis									
Any Lab Tests Performed									
Continued To Seek Services at MF clinic									
General Plan									
Preg Hx									
miscarriages									
Live births									

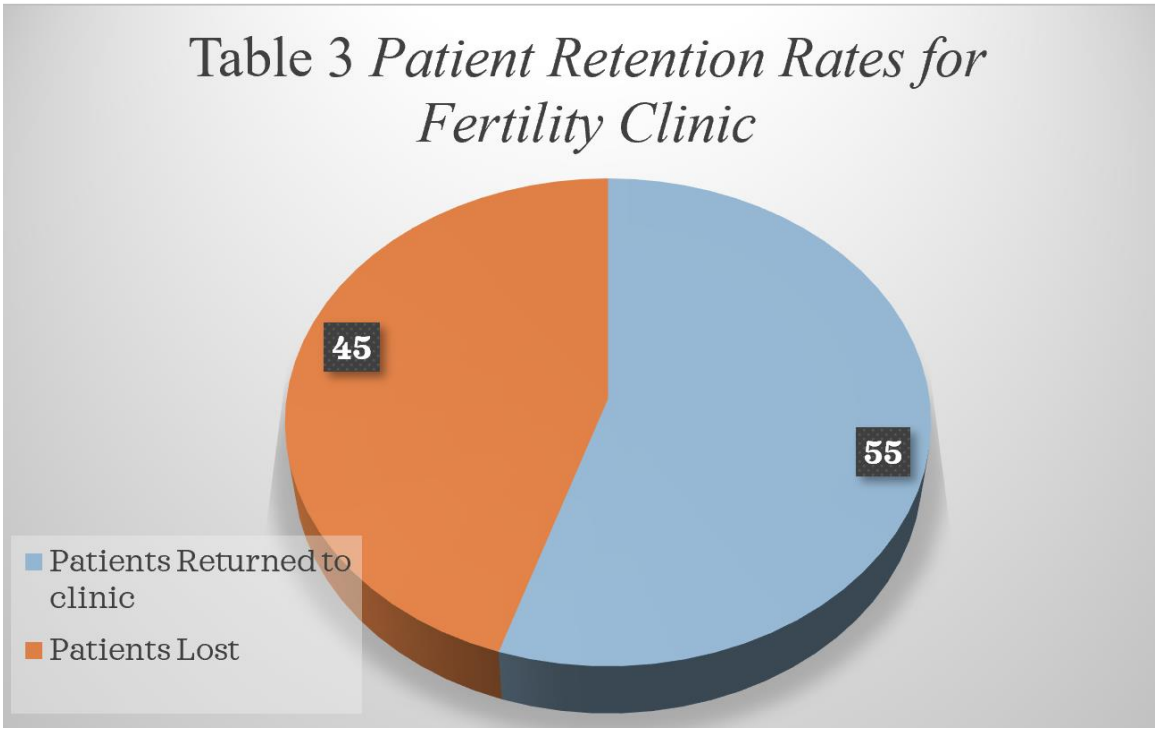
Appendix B

Table 2 Demographic Data

Quarter	Number of Patients	Average Age	Married	Insured	Average BMI	Average Weight
1st Quarter '19	40	30.1 (21-39)	32	37	31.1	197.6
2nd Quarter '19	40	28.2 (22-37)	33	37	31.9	191.6
1st Quarter '20	45	29.3 (22-39)	35	41	41.4	231.8
2nd Quarter '20	38	30.1 (20-39)	32	34	33.3	217.8

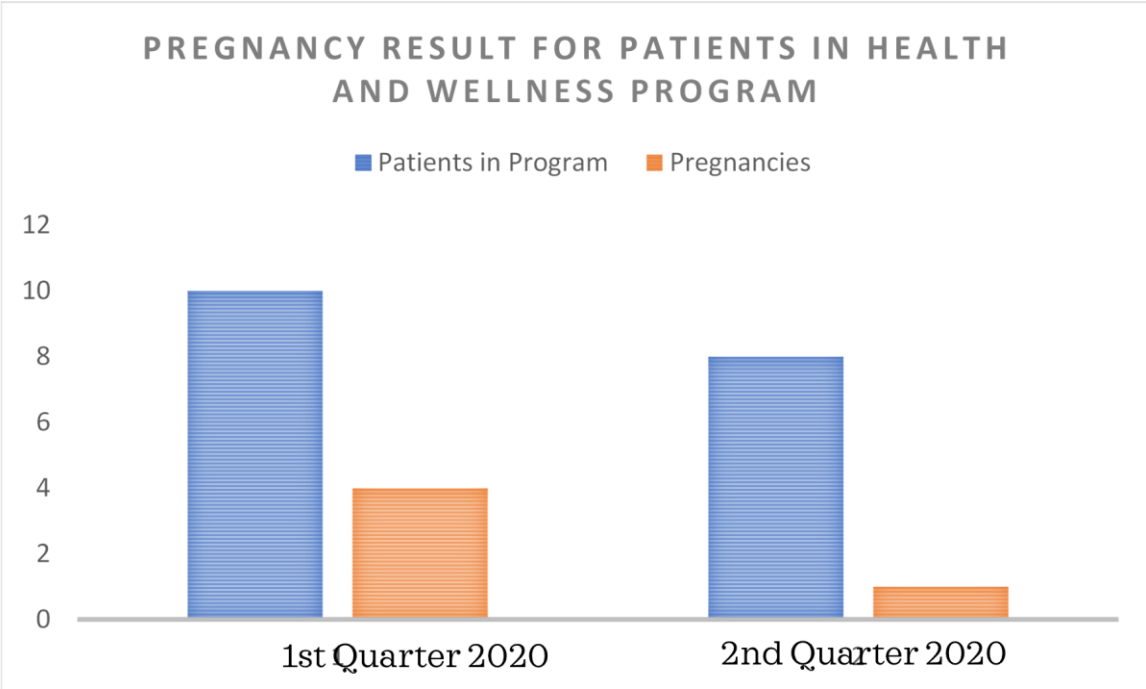
Appendix C

Table 3 Patient Retention Rates for Fertility Clinic



Appendix D

Table 4 Pregnancy Results for Patients in Health and Wellness Program



Appendix E

Table 5 Pregnancy Results After Weight Loss