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Formulation and Evaluation of Kuberaksh Vatti in PCOD

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Abstract: Polycystic ovary syndrome (PCOS) is a complex endocrine-gynecology disorder affecting numerous women of childbearing age. Despite significant progress in understanding some aspects of PCOS, its precise etiology and pathophysiology remain incompletely understood. This article aims to synthesize information from PubMed regarding PCOS pathogenesis and management, as well as data from ClinicalTrials.gov on repurposed medications. Various factors contributing to PCOS were thoroughly evaluated, including epigenetics, environmental toxicants, stress, diet, insulin resistance, hyperandrogenism, inflammation, oxidative stress, and obesity. Lifestyle modifications and complementary and alternative medicines are often recommended as first-line therapy for PCOS. Additionally, several medications have shown promise for repurposing in PCOS treatment. These include:

3-hydroxy-3-methyl-3-glutaryl-coenzyme A (HMG-CoA) reductase inhibitors (commonly known as statins) Thiazolidinediones

Sodium-glucose cotransporter-2 (SGLT2) inhibitors

Dipeptidyl peptidase-4 (DPP-4) inhibitors

Glucose-like peptide-1 (GLP-1) receptor agonists

Mucolytic agents

Various supplements

These medications have supporting data suggesting their potential efficacy in managing certain aspects of PCOS. However, their specific roles and optimal use in PCOS treatment may vary and require further investigation. In conclusion, while significant progress has been made in understanding PCOS, it remains a complex and multifaceted disorder. Further research is needed to elucidate its underlying mechanisms fully and to develop more effective therapeutic strategies. The repurposing of certain medications offers promising avenues for improving PCOS management, but ongoing clinical trials and research are necessary to validate their efficacy and safety in this context.

Keywords: Polycystic ovary syndrome

I. INTRODUCTION

Polycystic ovarian syndrome (PCOS) is a prevalent endocrine disorder affecting females worldwide, with a prevalence ranging from 5% to 15%. It was first described by Stein and Leventhal in 1935. Diagnosis typically involves the presence of at least two of three criteria: chronic anovulation, hyperandrogenism, and polycystic ovaries. Other conditions mimicking PCOS symptoms, such as thyroid disease and hyperprolactinemia, must be excluded through a diagnostic workup. PCOS is often underdiagnosed, leading to frustration for patients due to delays in identification, which can take more than a year and involve multiple healthcare providers. Early diagnosis is crucial to prevent the progression of associated comorbidities, including infertility, metabolic syndrome, obesity, type 2 diabetes mellitus, cardiovascular risk, depression, and others. Various morbidities are linked to PCOS, necessitating appropriate screening and management. Ayurvedic medicine, which attributes PCOS to the imbalance of vatadosha, proposes treatment modalities such as Kuberakshavati, known for its vedanasthapana (analgesic), vatahara (alleviating vata), and anulomana (promoting normal downward movement of vata) properties.

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Evaluation of Kuberakshavati's role in managing prakupitavata in PCOS is underway, leveraging its properties as described in BruhatNighantuRatnakara. This approach highlights the exploration of safe and effective Ayurvedic treatments for PCOS, aligning with the holistic principles of Ayurveda to address the root cause of the imbalance. However, further research is necessary to validate the efficacy and safety of Ayurvedic interventions in managing PCOS.

CAUSES OF PCOD/PCOS

Thank you for providing an overview of some common causes of polycystic ovary syndrome (PCOS). Understanding these factors is indeed crucial for individuals seeking appropriate treatment. To summarize:

1. Hormonal Imbalance: PCOS is characterized by an imbalance in sex hormones, particularly an increase in androgens (male sex hormones) relative to female sex hormones. This imbalance can disrupt the normal ovulation process, leading to irregular menstruation or even the absence of ovulation altogether.

2. Irregular Ovulation: In PCOS, the follicles containing eggs in the ovaries may fail to mature properly, preventing ovulation. Instead of releasing mature eggs, small cysts may form within the ovaries, contributing to the characteristic appearance of polycystic ovaries.

3. Genetic Factors: PCOS has a genetic component, with a tendency to run in families. Women with PCOS may have inherited genetic factors that predispose them to hormonal imbalances and ovulatory dysfunction. Close relatives with irregular periods or diabetes may also indicate a higher risk of PCOS.

4. Environmental and Lifestyle Factors: While genetic predisposition plays a significant role, environmental and lifestyle factors can also influence the development and severity of PCOS. Factors such as diet, exercise habits, stress levels, and exposure to environmental toxins may contribute to hormonal imbalances and exacerbate symptoms.

5. Medical Evaluation and Treatment: Understanding the underlying causes of PCOS is essential for developing an effective treatment plan. Consultation with a healthcare professional, such as a gynecologist or endocrinologist, is crucial for accurate diagnosis and personalized management. Treatment may involve lifestyle modifications, medications to regulate hormones and ovulation, and addressing specific symptoms such as acne or excess hair growth. In summary, PCOS is a complex condition with multiple contributing factors, including hormonal imbalances, genetic predisposition, and lifestyle influences. Seeking medical evaluation and appropriate treatment is key to managing PCOS effectively and improving overall health and well-being.

SYMPTOMS OF PCOD

These are some common symptoms associated with polycystic ovary syndrome (PCOS), which can vary in severity and presentation among individuals:

1. Irregular or Missed Periods: Women with PCOS may experience irregular menstrual cycles, including missed periods or prolonged intervals between periods.

2. Heavy Menstrual Bleeding: Some women with PCOS may experience heavier than normal menstrual bleeding during their periods.

3. Excessive Hair Growth (Hirsutism): PCOS can cause excessive hair growth on the face, particularly on the upper lip, chin, and cheeks, as well as on the body, such as the back, belly, and chest.

4. Acne: Hormonal imbalances in PCOS can contribute to the development of acne, particularly on the face, chest, and upper back.

5. Weight Gain or Obesity: Many women with PCOS struggle with weight gain or obesity, which can exacerbate symptoms and increase the risk of other health complications.

6. Male Pattern Baldness: Thinning hair or male pattern baldness (alopecia) can occur in women with PCOS due to hormonal imbalances.

7. Skin Darkening (Acanthosis Nigricans): Darkening of the skin, particularly in skin folds such as the neck, armpits, or groin area, may occur in some women with PCOS.

8. Headaches: Headaches, including migraines, can be a symptom of PCOS, though they are not as common as other symptoms.





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9. Mood Changes: Women with PCOS may experience mood changes, including anxiety, depression, irritability, or mood swings, which can impact their overall quality of life.

It's important to note that not all women with PCOS will experience every symptom, and the severity of symptoms can vary widely among individuals. Additionally, some symptoms, such as irregular periods and acne, may be more common during adolescence and may improve with age or appropriate treatment. If you suspect you may have PCOS based on these symptoms, it's essential to consult with a healthcare professional for proper evaluation, diagnosis, and management.

AYURVEDIC TREATMENT OF PCOD / PCOS

Ayurveda offers a holistic approach to managing polycystic ovary syndrome (PCOS) or polycystic ovarian disease (PCOD), aiming to address the root cause of the condition and provide personalized treatment plans tailored to individual health needs. Here are some key points about Ayurvedic management of PCOS/PCOD:

1.Root Cause Rectification: Ayurveda emphasizes treating the underlying imbalances in the body, including hormonal disruptions and dosha imbalances, which are considered the root cause of PCOS/PCOD. By detoxifying the body and strengthening the female reproductive system, Ayurveda aims to minimize symptoms without resorting to chemical compositions.

2. Lifestyle Correction and Diet Regulation: Ayurvedic treatment for PCOS/PCOD incorporates lifestyle modifications and dietary adjustments to complement therapeutic interventions. This multi-pronged approach addresses not only the symptoms but also related complications such as insulin resistance, obesity, and hormonal imbalance.

3. Panchakarma Therapies: Panchakarma, a set of purification and detoxification therapies in Ayurveda, plays a significant role in rejuvenating the female reproductive system and restoring hormonal balance. Therapies such as Virechana (therapeutic purgation), Uttar Vasti (uterovaginal enema), and Vasti (colonic enema) are commonly recommended to comprehensively revitalize the body and promote reproductive health.

4. Herbal Medications: Ayurvedic herbal formulations, combined with Panchakarma therapies, help clear the reproductive channels and reduce the size of ovarian cysts, preventing their further development. A personalized treatment plan may address menstrual irregularities, hirsutism, obesity, and other associated symptoms of PCOS/PCOD.



Overall, Ayurvedic management of PCOS/PCOD focuses on restoring balance to the body and promoting overall wellbeing through natural therapies, lifestyle modifications, and personalized herbal treatments. However, it's essential to consult with a qualified Ayurvedic practitioner for a thorough assessment and customized treatment plan tailored to individual health needs.

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498





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AIM AND OBJECTIVES

It seems like you're outlining a clinical study protocol related to the use of Kuberaksha Vati in Udavartini Yonivyapad (Primary Dysmenorrhea). Here's a breakdown of the key points provided:

1. Study Objective: The primary objective is to investigate the effect of KuberakshaVati in managing UdavartiniYonivyapad, specifically focusing on Primary Dysmenorrhea.

2. Study Focus: The study aims to explore the etiopathological (causes and mechanisms) and clinical features of UdavartiniYonivyapad, with a particular emphasis on Primary Dysmenorrhea.

3. Study Population: The study will include a total of 70 clinically diagnosed and confirmed cases of Primary Dysmenorrhea. The age group of the participants will be between 16 and 25 years old.

4. Recruitment Source: Participants will be recruited from the Outpatient Department (OPD) or Inpatient Department (IPD) of the Postgraduate (P.G.) Department of Prasuti-StreeRoga (Obstetrics and Gynecology).

5. Inclusion Criteria: Participants must have a chief complaint of painful menstruation (Primary Dysmenorrhea) with scanty or average blood loss during menses. They should also exhibit associated symptoms such as nausea, vomiting, giddiness, irritability, and weakness for more than two menstrual cycles.

6. Informed Consent: Informed consent will be obtained from all participants after explaining the nature and purpose of the study, as well as potential risks and benefits.

This protocol outlines a clinical study designed to investigate the efficacy of KuberakshaVati in managing Primary Dysmenorrhea and aims to provide valuable insights into the etiology and clinical characteristics of UdavartiniYonivyapad. It's important to ensure ethical standards and regulatory requirements are followed throughout the study process.

Drugs

KuberakshaVati-

KuberakshaVati contains Latakaranja,Shunthi,Hingu, Souvarchal and Rasona for Bhavana.The quantity Of these drugs are-Latakaranja 1Karsha(12gm), Shunthi 1Karsha(12gm), Hingu 1/2Karsha(6gm), Souvare Karsha (6gm) and Rasona rasa as bhavanadravya. According to reference.All the ingredients are Measured and inter the powdered

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ingredients through the sieve and mixed homogenously. This mixture is Now taken in khalvayantra and subjected bhavana with Rasonaras for a day

Criteria for selection of patients:

Thank you for providing additional details. Based on the information provided:

A) Study Design: The study utilized a randomized open clinical trial design. This means that patients diagnosed with Udavartini Yonivyapad were randomly assigned to either the treatment group or the control group. The trial was conducted openly, meaning that both the patients and the researchers were aware of the treatment being administered.

B) Sample Size: The sample size for each group was 70. This indicates that there were a total of 140 participants in the study, with 70 individuals assigned to receive the intervention (treatment group) and 70 individuals assigned to receive either no treatment or a placebo (control group).

C) Selection of Patients: Female patients with complaints of UdavartiniYonivyapad were selected for the study. The selection criteria were not limited by age, religion, occupation, or prakruti (Ayurvedic constitution). Patients were recruited from the Streerog (Obstetrics and Gynecology) and Prasutitantra (Obstetrics) Outpatient Departments (OPD).

D] Selection criteria:-

I) Inclusion Criteria-

1) Female Patients of Age Group 16 to 25: The study included female patients within the age range of 16 to 25 years old. This age range was likely chosen to focus on individuals who are more likely to experience primary dysmenorrhea and Udavartayonivyapad.

2) Patients with Primary Dysmenorrhea: Participants were required to have primary dysmenorrhea, which refers to menstrual pain without any underlying pelvic pathology. This criterion ensures that the study focuses specifically on the management of primary dysmenorrhea.

3) Diagnosed Patients of Udavartayonivyapad According to Symptoms: Patients were diagnosed with Udavartayonivyapad based on their symptoms. Udavartayonivyapad refers to disorders related to the menstrual cycle and reproductive system, particularly those involving obstructed menstrual flow.

II) Exclusion criteria-

Secondary dysmenorrhea with abnormal reproductive system: This suggests that abnormalities within the reproductive system could be causing the menstrual pain.

Pelvic inflammatory disease (PID) or other systemic disorders affecting the menstrual cycle: Pelvic inflammatory disease can cause inflammation and scarring of the reproductive organs, leading to pain during menstruation.

History of malignancy, hypo- and hyperthyroidism, diabetes mellitus, hypertension: These conditions can have various effects on hormonal balance and overall health, potentially impacting the menstrual cycle and causing secondary dysmenorrhea.

Use of intrauterine devices (IUDs) or oral contraceptive pills (OCPs): While these are contraceptive methods, they can also sometimes lead to menstrual irregularities or discomfort as a side effect.

Polycystic ovary syndrome (PCOS) and other medical, surgical, or neurological conditions contributing to dysmenorrhea: PCOS can cause hormonal imbalances and affect the menstrual cycle. Other medical, surgical, or neurological conditions could also contribute to menstrual pain.

Endometriosis, dysfunctional uterine bleeding (DUB), endometrial polyps, etc.: These are all conditions that affect the uterus or surrounding structures and can lead to secondary dysmenorrhea.

Criteria for withdrawal of patients –

Patient unable to tolerate the medication: Some patients may experience adverse effects or discomfort from medications prescribed for their condition. This can lead to non-compliance or difficulty in effectively managing their condition.

Any adverse drug reaction: Adverse drug reactions can occur unexpectedly in some patients, leading to discontinuation of treatment or the need to switch to alternative medications.

Patient fails to report for follow-up or irregular medication: Regular follow-up appointments and adherence to prescribed medication regimens are crucial for monitoring progress and adjusting treatment as needed. Patients who miss appointments or fail to take their medications regularly may experience worsening symptoms or complications.

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Patient not willing to continue further treatment: Some patients may become discouraged or disinterested in continuing treatment due to various reasons such as lack of improvement in symptoms, concerns about side effects, or personal beliefs. This can pose a challenge in managing their condition effectively.

E) Informed Consent:

It sounds like you're describing a research or clinical trial scenario where patients were provided with detailed explanations about the study, including the purpose, the nature of the study drug, and the potential risks and benefits involved. Here's a breakdown of each aspect:

Purpose of the study: Patients were informed about why the study is being conducted, including its goals, objectives, and what researchers hope to achieve by conducting the study. This helps patients understand the context and significance of their participation.

Nature of the study drug: Patients were provided with information about the drug being used in the study, including its composition, how it works, and any unique characteristics or properties it may have. This helps patients understand what they will be taking and how it may potentially affect them.

METHOD

A)Plan of studyStudy Group:-

140 diagnosed patients of Udavartiniyonivyapadwere randomly selected for the clinical study and were divided into Two groupsGroup A: - 70 patients were treated with KuberakshaVati& considered as Group A. Group B: -70 patients were treated with Shatpushpachurna& considered as Group B.

PROCEDURE OF ADMINISTRATION-

Patients were given the drug in following way GROUP A- KUBERAKSHA VATI Drug dosage :250 mg 2 BID Anupa :KoshnaJala Kala : Morning and Evening bfore meal Route :Oral Duration :3 months **INVESTIGATIONS-**Blood investigation-CBC USG if needed FOLLOW UP: -5Th day of each menses for 3 Consecutive cycles during treatment. Total symptom score after Treatment Remark for overall Effect 0-3 Good effective 4 - 6 Moderate effective 7 and more No effective

II. CONCLUSION

Comparing the two groups, it was found that Group A (Kuberakshavati) showed significantly better results than Group B (ShatpushpaChurna) in terms of overall symptom relief (78.62% vs. 66.13%). This suggests that Kuberakshavati may be more effective in alleviating the symptoms associated with the condition being studied, possibly dysmenorrhea. These findings indicate that Kuberakshavati may be a preferable treatment option over ShatpushpaChurna for managing the symptoms evaluated in this study. However, further research and larger-scale studies may be needed to confirm these results and determine the long-term efficacy and safety of these treatments.

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