**Health education for women with unexplained resistant hyperprolactinemia: role of nursing**

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Pathologic H is an undesirable overproduction of prolactin hormone (PRL) that may occur in both sexes, but females are more sensitive to its deleterious effects (Melmed et al.,2011). It may be asymptomatic or leads to infertility, decreased libido, and decreased bone mass, menstrual irregularities, inappropriate breast milk secretion (galactorrhea), vaginal dryness or dyspareunia (Rubio-Abadal et al., 2016, Lee et al., 2012). Regardless its etiology, cases with H respond properly to prolactin-normalizing drugs (dopamine agonists, DA) which help the brain produce dopamine to control high PRL levels. DA can also shrink prolactinoma tumors. (Oh et al., 2012). However, a subset of individuals does not respond satisfactorily to DA with persistence of H (resistant) manifested by failure of decline of PRL levels to normal level (normoprolactinemia) (Dai et al., 2021) despite appropriate dose, type and course in an unexplained way. The overall prevalence of DA resistance is 20–30% for bromocriptine (BRC) and around 10% for cabergoline (CAB). Resistance to DA is defined as failure to achieve normoprolactinemia under maximally tolerated doses for at least 3–6 months, together with the lack of a 30% or more reduction in tumor diameter in case of macroprolactinoma, its frequency still varies according to the type of drug and size of the tumor (Maiter, 2019). Many women despite being well-treated in proper dose, with proper drug and for proper duration, may not respond to treatment and became upset. This will lead to extension of the treatment duration up to months or even years. Doctors usually increase the dose of the drug with high possibility of side effects and even complications. Some doctors change drug group to another without any significant improvement of H. Frequently, women ask for the cause of failure of response to treatment without convincing answers. Health care providers should exclude possible underlying causes like drugs (Davies, 1997) or pituitary adenoma which is diagnosed in about 10% of the population with H (Majumdar and Mangal, 2013). Role of nurses is usually not included in the management protocols of H. (Brody et al., 2013). Studies on the nursing role for health education for H cases are lacking. This study aims to test impact of nursing health education for women with unexplained persistent H not responding to therapeutic prolactin-normalizing drugs.

**Subjects and Methods:**

The trial is demonstrated in technical, administrative, operational, and statistical designs. Technical Design covered the study design, setting, study sample, and tools of data collection. Study design was a prospective randomized controlled trial done at Infertility and Gynecologic outpatient clinics between April 2019 to March 2020 and was approved by the ethics committees of the Faculties of Nursing and Medicine. It was registered at The Clinical Trail.gov (Registration Number: NCT04262024). It comprised infertile women with a lab diagnosis of persistent pathologic H measured by ELISA (enzyme-linked immunosorbent assay) at the institutional lab. Normal serum PRL was considered between 2-20ng/ml. Administrative design included informed consent taken from each woman involved in the study, confidentiality was assured. Inclusion criteria were pathologic H not responding to standard doses of cabergoline (1.5-2 mg/week i.e., half tablet at bedtime during meal day after day) taken regularly for at least one month. Physiologic H was excluded from the study. Other exclusion criteria included women on receiving proton pump inhibitors in combination with prokinetics, first or second generation anti-psychiatric drugs or oral contraceptives, antidepressants, antihypertensives or opioid analgesics (Venkatanarasu et al., 2021). Patients with a systemic disease like uremia or suspected pituitary adenoma or pituitary stalk lesions were excluded based on routine investigations and clinical absence of neurologic symptoms, visual impairment, or headache. In suspected cases (14 cases) a coned-down plain X-ray was ordered to exclude pituitary fossa lesion. MRI was not requested in any case.

The sample size was calculated using the Epi info program with a 95 % confidence coefficient, 10% tolerable error, 50 % predicted frequency. The sample was divided into study and control groups (50 cases each). The researchers created a structured interview questionnaire tool after conducting a review of the relevant literature which comprised 3 parts. Part1 involved questions related to personal characteristics and sociodemographic data. Part 2 included history of present illness, obstetrics, medical diseases, or treatment histories to exclude an evident underlying cause like drugs or pituitary adenoma. Part 3 included infertility history as years of infertility, type of infertility, causes. In all cases enquiry about lifestyle factors, sexual behavior and feeding habits that may contribute for resistant H was made (discussed latter). Lastly, a follow up sheet to be filled in after treatment was included. Operational design was presented into two phases, pilot study and field work. A pilot research was conducted on 10% (10 women) of the sample to check that the tools were clear and thorough, as well as to calculate the amount of time needed to complete the questionnaire. The pilot study's findings indicated that no more improvements or modifications were required; hence the pilot study's women were included in the final sample. Field work data collecting took twelve months, commencing in April 2019 and ending in March 2020. This was divided into three stages: pre-intervention, intervention, and follow-up. Pre intervention phase: In both groups, the researchers interviewed each couple individually in a separate room to maintain confidentiality. Intervention phase started by randomization of cases with resistant H into two groups using labeled papers. Group A included 50 cases receiving therapeutic dose of cabergoline (1.5-2 mg/week during dinner for one month) plus health education while women in group B received the same medication without health education. General, systematic and local examinations were done for all cases. Body mass index (BMI) (weight in kilograms/ square of height in meters). was measured in all cases. All study cases were examined carefully clinically and using transvaginal ultrasonography (TVS) to rule out any associated gynecologic lesion. Chest wall and breast examination for galactorrhea (inappropriate milk secretion) were performed in all cases. TSH and routine investigations particularly creatine were requested for all cases. For group A, the researchers created supportive materials after doing a literature review. It was created in the form of a booklet, with simple and clear Arabic language and photos to facilitate health education on H for women. The definition, causes, signs, and symptoms of H, how to control H, advice for women with H were all covered in the instructions. To assess tool reliability, Cronbach Alpha (Connelly, 2011) done for both tools used and founded that Cronbach Alpha was 0.731 and 0.825 for questionnaire follow up sheet. In group A, health education included free supportive booklets, lectures, and discussions of to avoid some behaviors that may increase serum PRL like frequency and pattern of breast involvement during sexual intercourse, pressure on breast or chest, direct trauma to the breast or wearing tight brassiere. Moreover, modification of some nutritional habits was discussed in detail like avoidance excess of some foods e.g., sweets specially flour sweetness (halvah), excessive fats, high protein diet, oils or seeds specially fenugreek and sesame seeds, nuts, and some birds like chicken, and pigeons. Women were encouraged to eat vegetables, fruits, fish, vit omega 3 plus, zinc, vit B16, and proteins. Daily behaviors that may lead to H (e.g., seeing another woman breast feeding, carrying children on the chest, insufficient sleep, excessive exercise, stress, and tight clothes) were also addressed. Post intervention included follow-up by telephone every week to assure their implementation instructions given in the session. After 4 weeks of therapy, all patients came to the clinics to remeasure PRL and to enquire about adherence to the instructions and any undesirable effects. Statistical analysis was performed using SPSS for windows version 20.0. All variables with continuous data showed normal distribution and were expressed in mean ±standard deviation (SD). Categorized data were presented in number and percentage. The comparisons were determined using t-test for variables with continuous data. Chi-square and McNemar test were used for comparison of variables with categorized data. Statistical significance was considered at P-value ≤ 0.05.

**Results:**

This study comprised 100 infertile women with unexplained persistent pathologic H despite proper treatment. They were divided into two groups of proper cabergoline therapy with (group A) or without (group B) health education. There was no statistically significant difference between both groups regarding sociodemographic data, infertility details, medical and obstetric histories. All cases had high PRL level at the start of the study (Mean ±SD was 75.9±38.1 and 77.16±26.9 in both groups respectively) without any significant difference. Irregular menstrual cycles were encountered in 11(22.0%) and 14(28%) in both groups respectively without any significant difference. Table1 shows some possible contributing factors for resistant H in all cases in both groups without any statistically significant difference. Figure (1) shows that 48% of studied women in study group and 36% in control group were overweight without statistically significant difference. As shown in figure 2, there was no statistically significant difference between both groups regarding clinical detection of galactorrhea while figure 3 demonstrates a statistically significant difference regarding PRL values after therapy.

**Discussion:**

Pathologic H should be thoroughly evaluated as it has a direct impact on women’s health (Darwish et al., 2012). A careful history and examination and TVS followed by laboratory tests and diagnostic imaging of the Sella turcica are mandatory prerequisites to rollout an underlying cause ( AbdElghani et al., 2013) as shown in this study. Serious causes were excluded in this study by absence of neurologic symptoms, visual impairment, or headache and normal coned-down plain X-ray. Moreover, a detailed drug history was taken from all cases to exclude any possible link with H. In this study, not all cases of H had galactorrhea but there was a high prevalence of galactorrhea among studied patients (70% and 65% in both groups respectively) as reported by others ( Basama and Kuruluşunda, 2020, Zargar et al., 2005). Its incidence may reach up to 90% of women with H.  The marked variability is likely a result of the difference in how the milk is expressed and how galactorrhea is defined (Huang and Molitch, 2012). Others found that only 15-68% of patients with excessive PRL secretion develop galactorrhea that can be attributed to differences in examination techniques, the investigator's definition of galactorrhea, and the patient population studied (Sakiyama and Quan, 1983).  Emotions and stress are important contributing factors for development of galactorrhea (Dissanayake, 2014). Another explanation is heterogeneity of PRL hormone (bioactive and immunoactive forms) so patients can have all the features of H with normal serum prolactin levels (Verma, 2016). The predominant form is monomeric PRL (little PRL, MW: 23 kDa) accounting for 80–95% of the total PRL. Other forms include dimeric PRL (big PRL, MW: 48–56 kDa) representing <10% and macroPRL (big-big PRL, MW: >150 kDa) accounting less than 1% of the total PRL (Melmed and Kleinberg, 2003).   Monomeric PRL is biologically and immunologically active while macroPRL is of limited bioactivity in vivo as it is confined to the vascular system and has limited access to the PRL receptor of target organs resulting in asymptomatic H.  It will persist in serum despite disappearance of monometric PRL (Bonhoff et al., 1995, Hattori et al., 2010). This issue should be included during follow-up visits and better to be excluded by sophisticated tests (unfortunately not available at out institution) like gel filtration chromatography (GFC), immunoassay of serum PRL before and after removal of macroprolactin by ultrafiltration, immunoadsorption of IgG species with protein A, protein G, or anti-human IgG and precipitation with polyethylene glycol (PEG) (Che Soh et al., 2020). Nevertheless, the decision to treat patients with galactorrhea should be based on the serum prolactin level, the severity of galactorrhea, and the patient’s fertility desires (Che Soh, 2004).

In this study, abnormal high BMI was encountered in 68% and 58% in both groups respectively. Obesity can lead to H and vice versa. Obesity may lead to adverse effects like insulin resistance and metabolic syndrome while H may cause an abnormal lipid profile, weight gain, and cardiovascular diseases (Ali and Mirza, 2021). In one study (Pereira-Lima et al., 2013), 65.2% were overweight or obese and they concluded that prevalence of obesity was significantly high in hyperprolactinemic patients, regardless of the degree of obesity and the cause of H. Treatment with DA has been shown to reduce body weight and improve metabolic parameters but a study failed to prove decreased weight even after 6 months of therapy, but they reported improving metabolic parameters (dos Santos Silva et al., 2010). Health education of obese women with H should include instructions for weight reduction by physical activity, exercise and decrease fat and carbohydrate diets as done in this study.

All cases of this study were infertile. Classically, H can decrease estrogen production, causing infertility directly, and affect levels of testosterone. Recent data suggest that H lowers kisspeptin production at the hypothalamus level by on kisspeptin-1 neurons expressing the PRL receptor (PRL-R) and is responsible for decreased kisspeptin-1 and GnRH secretion. As a result, decreased pituitary gonadotrophin synthesis and secretion (LH and FSH) with a loss of gonadal stimulation (hypogonadotropic hypogonadism), anovulation and infertility (Melmed et al., 2011, Kokay et al., 2011). Moreover, the persistent effect of the high levels of serum PRL on the endometrium at the proliferative phase in the presence of E2 may induce abnormal proliferation of the endometrial glandular cells via enhanced ER and PRL-R in hyperprolactinemic women (Munekage et al., 2020). At peripheral level, PRL plays a direct inhibitory effect on estrogen and progesterone synthesis. Defective [luteal phase](https://www.sciencedirect.com/topics/medicine-and-dentistry/luteal-phase), inconstant ovulation and chronic [anovulation](https://www.sciencedirect.com/topics/medicine-and-dentistry/anovulation) are the final results of H (Crosignani, 2012).  More recent studies highlighted a central role of PRL on the reproductive system as they described two types of PRL: pituitary and peripheral ([Auriemma](https://www.frontiersin.org/people/u/653045) et al., 2020). In a different pathway than pituitary PRL, peripheral PRL is directly synthesized by the endometrium under the stimulatory action of progesterone and the myometrium that directly promotes uterine smooth muscle cell growth and proliferation. H was reported in patients with cervical or endometrial cancers, as well as uterine premalignant lesions, so it can be used as a discriminative biomarker in patients with uterine cancers. Potential application of DA in the therapeutic algorithm of women with malignant, premalignant, and benign uterine lesions has been suggested (31). All these findings send message to health care providers that H should be meticulously evaluated and ruling out of any associated gynecologic lesions suggestive of malignant or premalignant lesion should be a priority by detailed clinical and sonographic assessments in all cases as done in this study.

Role of nursing in H was addressed in scare studies (32). Nurses must be able to identify and provide initial assessment of women with possible H. Once the cause of the hyperprolactinemia is determined, the nurse practitioner can inform women about management options appropriate to their specific needs (33). In this study, nurses played a central role to detect an explanation of persistent H despite proper treatment. Nurses expressed great interest and offered the patients ample time to discuss some hidden causes of H ignored by the patients and usually not addressed by the busy physicians. To the best of our knowledge, this is the first detailed study highlighting the crucial role of nurses in the management of H. Thanks to preintervention questionnaire, booklets, lectures and kind discussions, women were cooperative and described their related life’s style, dietary habits and sexual behaviours that may contribute in persistence of H. For instance, our results found that some sexual behaviours like nipple suckling would be an important contributing factor for H. The best-known physiological stimulus for prolactin secretion is breast suckling, that results in a reduction of dopamine release into portal blood (34) reaching the anterior pituitary gland (35), thus essentially relieving the lactotrophs from tonic inhibition. Nipple suction leads to sharp rise of PRL within 1 to 3 minutes of the act. This study showed that health education seems to be a very essential cofactor for success of H treatment and the role of nurses should be addressed in all busy centers interested in the management of H. Nevertheless, this study has some limitations including small sample size and short duration of therapy, short follow-up period and non-reporting of pregnancy rate after full course of treatment. All these limitations would be overcome on construction of a large sample sized, better to be multicentric, study in the future. From this study, it is concluded that lifestyle factors, sexual behaviors and feeding habits would affect the response of H to treatment. Adding health education of the couple by a nurse would improve efficacy of treatment of unexplained persistent H.

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