

The clinical management of patients with polycystic ovarian syndrome PCOS in Pakistan: A case control study

Mehwish Rizvi¹, *Atta Abbas^{1,2} Sidra Tanwir¹, Arif Sabah¹

¹Faculty of Pharmacy, Ziauddin University, Karachi, Pakistan.

²Department of Pharmacy, Health and Well Being, University of Sunderland, England, United Kingdom.

* Corresponding author: Atta Abbas

E-mail id: bg33bd@student.sunderland.ac.uk

ABSTRACT

Polycystic ovarian syndrome PCOS is common in women all over the globe. In addition to irregular menstrual cycles and infertility, the rates of co morbidities are notably higher in women with PCOS. It has also been associated with obesity as well. The scenario of Pakistan is different from the developed countries as the reporting of the disease and disclosure by the patient is a daunting task due to the sensitivity of the issue keeping in view the society's frame of mind and overall social environment of the country. The lack of disease awareness has lead to poor reporting and managing of the disease at patients and physicians ends respectively. A pharmacist can play an important role as a physician and patient counselor and this educational intervention of a pharmacist has a pivotal role in the said regard. The present case study is based on 31 patients and their physicians and discusses the criticalities of PCOS with regards to health care system of Pakistan.

Keywords: Patient; Clinical Management; Polycystic Ovarian Syndrome; PCOS; Pakistan; Case study.

INTRODUCTION

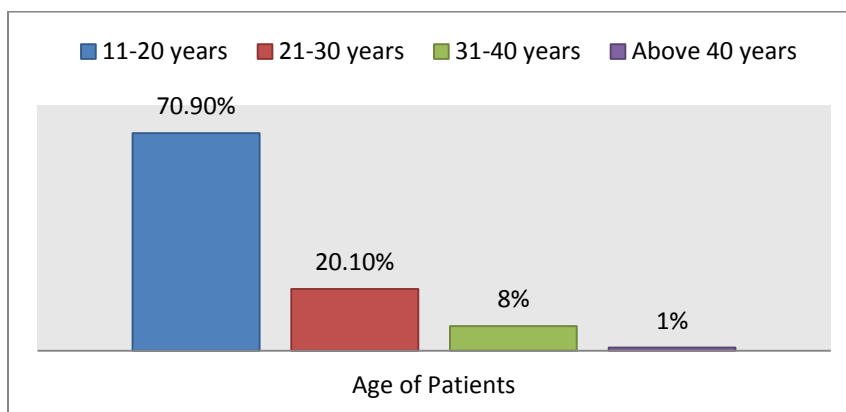
Polycystic ovarian syndrome PCOS is a very common disorder of endocrinal origin in women all over the globe. In addition to infertility (Darion et.al, 2011), the rates of co morbidities are also significantly higher in women with PCOS. The terminology polycystic syndrome refers to the presence of small, benign and painless cysts in the ovaries, which are clinically manifested by a faction of symptoms and changes in hormonal levels. The hormonal imbalance is the major underlying reason for this ailment. (Ricardo Aziz 2004). It has been associated with obesity and other metabolic abnormalities as well (Al-Azemi, 2004).

The scenario of Pakistan is different from the developed countries as the reporting of the disease and disclosure by the patient is a daunting task due to the sensitivity of the issue keeping in view the society's frame of mind and overall social environment of the country. To date, PCOS has never been reported in clinical practice of Pakistan and this case study is based on clinical aspects of PCOS patients being treated in different health care settings of the country who were suffering from the syndrome. It reports the pharmaco-epidemiological information of patients of PCOS as well as their pharmaco-therapeutics and discusses the critical

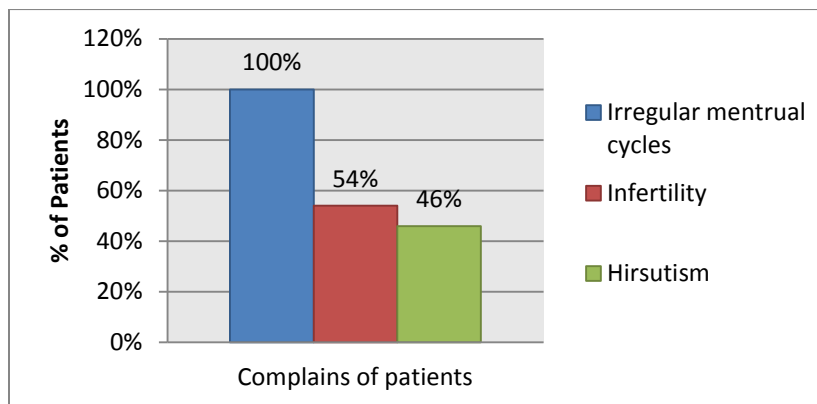
findings in the actual clinical practice. Prior to the recording of the information, the patients and physicians were informed and a written consent was obtained from them and as well as the health care facility in which the study was carried out. A number of patients of PCOS along with their physicians were included in the study to study the clinical management of the disease in context of health care environment of Pakistan.

CASE PRESENTATION

A total of 31 patients and their physicians consented and were available for their clinical data to be recorded. The majority of patients lied in the age range of 11-20 years (70.9%) and all presented with complain of irregular menstrual cycle (100%) and infertility for most part (54%), hirsutism was also observed in half of the patients (46%) in combination with the primary complain.



Graph 1.1 Age of patients



Graph 1.2 Patient Complain

The physicians pointed out hyperandrogenism (P value <0.01) and chronic anovulation (P value <0.05) as major findings along with others and also hinted at risk factors such as obesity (P value <0.05) and family history (P value >0.05). The physicians further reported that the family history of patients also revealed obesity and emotional disturbance and to some extent inadequate dietary intake. The

complications which were usually seen were abnormal uterine bleeding (P value <0.01) and endometrial cancer (P value >0.05). According to the physicians, co morbidities include diabetes mellitus DM (P value >0.05) and to some extent hypertension HTN (P value >0.05). The physicians usually preferred a combination of medication therapy along with lifestyle modifications.

DIAGNOSIS AND MANAGEMENT

It was reported that the patients suffered oligomenorrhea/ amenorrhea along with infertility and few incidences of miscarriages in first trimester. The other diagnostic features as reported by the physicians were obesity and hirsutism. In addition to these features, male pattern alopecia along with acne is considered as hallmark clinical features of PCOS. (Micheal T.S., 2004). The diagnostic test used apart from noting down the salient clinical features of PCOS was pelvic ultrasonography. It was used in diagnosis. However, the physicians did not feel the need of conducting an adreno-corticotrophic hormone ACTH stimulation test for differential diagnosis i.e. to rule out other causes of irregular menstrual cycles observed in their patients (Richard SL et.al, 2013). The management strategy focused on the lifestyle modifications and medication therapy of PCOS along with pharmacotherapy of associated co-morbidities. However, clinicians identify four goals of therapy of PCOS with addressing the infertility issue in the first place if the patient is trying to conceive a baby, however if getting pregnant is not the priority of the patient then the issue of irregular menstrual cycle becomes the priority. The other goals of therapy are to treat acne, hirsutism and male pattern alopecia and the last one being the prevention of cardiovascular and endocrinal complications such as any heart disease and diabetes mellitus (RMA of Connecticut©, 2013).

TREATMENT AND PHARMACOTHERAPY

The study reported that the 1st line treatment option was usually opted in combination with 2nd line i.e. lifestyle changes coupled with medication therapy. However, the most commonly prescribed medications in patients with PCOs were Metformin 500mg BD and OD followed by Progesterone + Estrogen for hormonal therapy. Clomiphene found its place as a 3rd line medication option with dose and duration of therapy of 50mg for 5days respectively. Progesterone for irregular menstrual cycles were comparatively less common among all but was prescribed anyhow. Surgical intervention was not considered for any patient.

The non-pharmacological treatment mainly encompassed patient education and was done by

physician treating the said condition or sometimes by a female nurse depending upon the patient's comfort.

DISCUSSION

PCOS was commonly observed in young patient usually in preliminary reproductive age of 11-20 years (70.9%) and also in middle age but less common in geriatrics which is understood considering the nature of the disease. However, the mark of PCOS as seen by physicians in their daily practice is the irregular menstrual cycles. The physicians also pointed hormonal changes leading to hirsutism and chronic anovulation. The risk factors according to the physicians is mainly obesity which was clinically and statistically significant (P value <0.05) and family history of obesity, emotional disturbances and inadequate diet which although seen clinically significant but not statistically significant (P value >0.05). This is understandable in the context of Pakistan as there is no health promotion activity for females. Moreover, recreational facilities such as fitness centers and weight loss clinics are negligible which is adding to the disease burden of obesity in females in Pakistan. The emotional disturbance and irregular dietary habits are mainly to do with the patient's personal life. The complications reported by physician that the disease leads to are abnormal uterine bleeding (P value <0.01) and endometrial cancer (P value >0.05). The co morbidities seen were metabolic disorders, DM and HTN. The latter did not prove to be statistically significant, but risk of such complication does exist. The co –morbidity were not significant as the majority of patient population resides in the range of 11-20 years of age and it is unlikely to be diagnosed with a major ailment like DM and/or HTN at such as age. Perhaps a larger sample size might have proven the statistical significance. However, further study is recommended with a larger sample size. The diagnostic test used apart from noting down the salient clinical features of PCOS was pelvic ultrasonography. It was used in diagnosis. However, the physicians did not feel the need of conducting an adreno-corticotrophic hormone ACTH stimulation test for differential diagnosis i.e. to rule out other causes of irregular menstrual cycles observed in their patients (Richard SL et.al, 2013). The reason behind this can be the fact that in the absence of an educational intervention of pharmacist,

the physicians rely heavily on their personal practices and years dealing with the issue. The economic status of patients is also a major decisive factor; Pakistan is a country where a patient has to pay direct medical expenses (Liaquat A Khowaja et.al, 2007). This is a major issue when it comes to expensive diagnostic testing.

It is evident that PCOS cannot be cured. However, the condition can be treated with lifestyle changes and medication therapy. (Mehwish Rizvi et al, 2014) The 1st line treatment option is lifestyle changes which include weight management, exercise and dietary modifications followed by medication therapy as 2nd line treatment option. (Richard SL et.al, 2013). The medication therapy is formulated in accordance to the sign and symptoms associated with PCOS i.e. for treating irregular menstrual periods, the oral contraceptive find their place in the first spot while Clomiphene and Metformin come first in treating fertility problems associated with the disease (NHS, 2013).

The focus of the investigators in the case study was limited to the two aforementioned conditions as they were the ones being mostly observed in patients during the study period. The study reported that the 1st line treatment option was usually opted in combination with 2nd line i.e. lifestyle changes coupled with medication therapy. Coming on to the 2nd line option of medication therapy oral contraceptives are the drugs of choice followed by Clomiphene and metformin. However, the most commonly prescribed medications in patients with PCOs were Metformin 500mg BD and OD followed by Progesterone + Estrogen for hormonal therapy. Clomiphene found its place as a 3rd line medication option with dose and duration of therapy of 50mg for 5days respectively. Progesterone for irregular menstrual cycles were comparatively less common among all but was prescribed anyhow. Surgical intervention targeting restoration of ovulation is usually placed at the last option. (Richard SL et.al, 2013). No clinical indication was provided and the physicians banked on their personal practice using the aforementioned medication therapy regimen. A pharmacist was not consulted in the treatment plan. However it is reported on various occasions that inclusion of a pharmacist and the educational interventions he or she performs has promoted

benefit to the patient (Alicia Pol et.al, 2012). The non-pharmacological treatment mainly encompassed patient education and it was done by a physician or sometimes by a female nurse depending upon the patient. Contrary to this, in developed countries a pharmacist usually performs this role. (Azhar et.al, 2009). One of the reasons is the hesitation of the patient, as mentioned earlier the disclosure of the disease and discussion with a physician of opposite gender is considered as a red line which should not be crossed. However, patients feel comfortable with same gender. In some cases, the physician's information is not updated as it should be as was the case in this study, the physician did not know the 1st line therapies. Such adversary highlights the need of an educational intervention by a pharmacist to update the physician's knowledge and counsel the patient.

CONCLUSION

The absence of disease awareness has lead to poor reporting and managing of the disease at patient's and physician's end respectively. A pharmacist similar to the developed countries can assume the role of disease educator and/or patient counselor. Since obesity is a major risk factor, health promotion activities and campaigns regarding obesity awareness must be a part of health care system. An education intervention by a pharmacist has a pivotal role in the said regard.

STATEMENT OF CONSENT

An informed written consent was obtained from the patients and the physicians prior to recording the information.

CONFLICT OF INTEREST

The authors declare no conflict of interests exists.

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AUTHOR'S CONTRIBUTION

All authors contributed equally in all aspects of the study.

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