EFFECTIVENESS AND SIDE EFFECTS OF SYANAPRESS (SUBCUTANEOUS DEPOT MEDROXYPROGESTERONE) IN FEMALES OF REPRODUCTIVE AGE GROUPS

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ORIGINAL ARTICLE

ABSTRACT

Background: Sayana Press® (injectable contraceptive) is associated with a high level of contraceptive efficacy. It is fascinating that effectiveness of Sayana press is sustained even if the time period of injection is prolonged from usual three to four months. **Objective:** To study the effectiveness and side effects of Sayana press in the females of reproductive age, in order to change existing contraceptive practice. **Methodology:** This descriptive case series was done in six-month duration (01-04-2023 to 30-09-2023) at department of obstetrics and gynecology Lady Aitchison hospital which enrolled 96 females after informed consent and followed up for study duration. Ethical approval and informed consent were taken before study conduction. SPSS-v26 was used for data analysis.

Results: Total 96 females of reproductive age group were selected for this study. Mean age of the patients was 31.95±5.06 year. Among 96 patients, 22(22.9%) were nulliparous, 35(36.5%) were primiparous and 39(40.6%) were multiparous. According to the efficacy of Sayana press, it was efficacious in 66(68.7%) patients and 30(31.3%) had side effects. **Conclusion:** The findings of the study revealed that Sayana Press, was deemed satisfactory by the women within our specific demographic. The information provided by this study is of importance as it not only provide significant perception to the government, but also serves as a pivotal milestone towards the potential implementation of Sayana Press.

INTRODUCTION

Injectable contraceptives are efficient, safe and utilized all over the globe for pregnancy prevention and convenience. The regulatory agencies of about 40 international countries have approved Sayana Press® (depot medroxyprogesterone acetate subcutaneous injection (DMPA-SC), as a three-monthly contraceptive injection.[1] It is Uniject™ progestin-only, all-in-one injectable contraceptive, which contain both drug and needle within same device. The seamless application of Sayana Press due to its light weight, compact size and user-friendly design, necessitate minimal training for smooth use. [2]

In 2012, 57% of reproductive-age women expressed a desire to not have a child. But birth control was inaccessible to almost 222 million women; 97 million of them were in Asia and 53 million were in sub-Saharan Africa. For those areas which have access to education, training, and support, the use of, Sayana® Press is advocated by the World Health Organization (WHO). Sayana Press is studied by PATH, along with the help of the health ministries in Senegal and Uganda through 2017 for self-injection, so that they can find out how safely, efficiently and successfully they can help women in these countries to do it.[3-4]

For people at risk of hematoma because of bleeding disorders or anticoagulation, Sayana Press could be better than intramuscular DMPA. Headaches (8.9%), menorrhagia (7.1%), increased weight (6.9%), amenorrhoea (6.3%), and injection site responses (6.1%) were the most often reported adverse medication events (>5%).[5] The first-year failure rate of injectable progestin is 0.2% in ideal usage and 6% in common use. Estimates show that the use of contraceptives has reduced maternal mortality by 40% in poor nations and, if demand for birth control were to be fully addressed, could avert 70% of fatalities. Subcutaneous DMPA was well-tolerated and produced comparable results in terms of contraceptive efficacy and bone mineral density as DMPA-IM, according to a randomized, evaluator-blinded study that compared the two methods over two years with an optional third year involving 225 women from Brazil, Canada, and the US.[6-7] Sayana Press is a subcutaneous injectable contraceptive offering the advantages of ease of use, self-administration and long-acting efficacy. However, limited local data exist on its effectiveness and side effects profile among women of reproductive age. This study aims to evaluate the contraceptive efficacy and common adverse effects of Sayana Press to support informed contraceptive counseling and expand safe reproductive choices. [8-9]

MATERIALS AND METHODS

Study Design: Descriptive case series study

Study Setting: Department of Obstetrics and Gynecology, Lady Atchison Hospital, Lahore.

Duration of Study: Six months 1-4-2023 to 30-9-2023

Sample Size: Total 96 patients were included in this study. Sample size of 96 patients was estimated by using 95% confidence level, 10% absolute precision with expected percentage of no side effects of Sayana Press in females of reproductive age group as 48.2%.[11] Using formula

$$n = \frac{Z^2 1\frac{\alpha}{2}.p(1-p)}{d^2}$$

$Z^2_{1-\alpha/2}$ = confidence interval = 1.96| p = prevalence = 48.2%| q = 1-p| d = absolute precision = 10%

Sampling Technique: Non-probability consecutive sampling

SAMPLE SELECTION

Inclusion Criteria:

- All females in reproductive age group presenting to the department of gynecology for family planning.
- Females having age 18-40 years.
- Females of reproductive age group of any parity.

Exclusion Criteria:

- Females with known or suspected pregnancy
- Female with undiagnosed vaginal bleeding
- Female with Severe liver dysfunction
- Female with Known hypersensitivity to MPA or any component of the drug
- Female using Additional Contraception(s) for Specific Use
- Female with Known or suspected malignancy of the breast
- Patients not willing to be included in the study

DATA COLLECTION PROCEDURE

A total of 96 females who fell into the reproductive age group were selected to participate in this study, all of whom sought family planning measures through the Department of Obstetrics and Gynecology. For comprehension, insight and voluntary participation, informed consent was taken from each patient prior to their inclusion in the study. Study was done after approval from hospital ethical committee (496/ RC/KEMU). Variables such as age and parity which are confined in baseline patient demographics were collected for thorough understanding of the participants.

Efficacy was defined when there were no side effects, and side effects were reported as given bellow. Self-reported discomfort in abdomen once per week and lasting for 30 minutes was considered as abdominal pain, nausea was considered when there was sensation of feeling the urge to vomit once per week and more than 30 minutes and forceful expulsion of stomach contents through mouth once in a week was defined as vomiting. Any episode of vaginal bleeding that requires changing a tampon more than 2 hours for 1 day per cycle was taken as heavy vaginal bleeding and self-reported pain in head twice a month and not attributed to neurological condition was defined as headache.

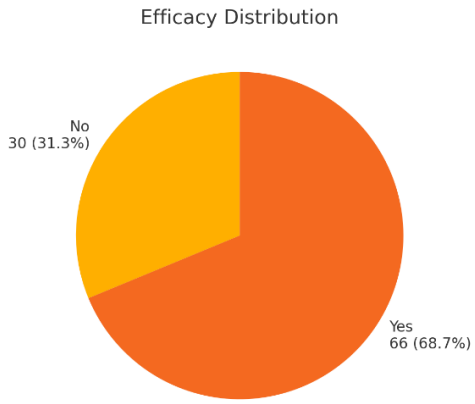
Pain at the site of Sayana Press injection was considered when they reported within 7 days of administration and lasted more than 24 hours is injection site pain. Amenorrhea was considered when there was absence of menstrual bleeding for 90 constructive days following the injection. Pain localized to lumbar region once a week interfering with daily activities was taken as backache.

Weight change was defined of there was a change of more than 2 kg in body weight from baseline over 3 months period. Decreased libido was defined as self-reported reduction in sexual desire for 4 weeks impacting quality of life. Other aches or pains are nonspecific body pains occurring at least twice per month. Effectiveness is absence of pregnancy in women using Sayanapress over six months period following the initial injection. Follow up of the patients who participated in study was vigorously done after their inclusion in the study, till the period they wanted to conceive again. The statistical software SPSS-v26 was used for data analysis. In order to effectively present the quantitative variable of age, the mean and standard deviation were utilized, enabling a more accurate depiction of the data. Conversely, qualitative variables such as parity and side effects were represented through frequency and percentages.

RESULTS

Total 96 females of reproductive age group were selected for this study. Mean age of the patients was 31.95±5.06 year. According to the efficacy of Sayana Press, it was efficacious in 66(68.7%) patients and 30(31.3%) had side effects **(Fig-1)**. According to the side effects distribution, 13(43.3%) had abdominal pain, nausea or vomiting, 11(36.7%) had irregular or heavy bleeding, 9(30.0%) had headaches, 7(23.3%) had injection-site pain or irritation, 7(23.3%) had amenorrhea, 6(20.0%) had backaches, 4(13.3%) had weight changes, 9(30.0%) had decreased

libido and 18(60.0%) had other aches or pain. **Fig-2.** Stratification of side effect with respect to age and parity has been in tables and showed insignificant difference (p>0.05) **(Table-1)**



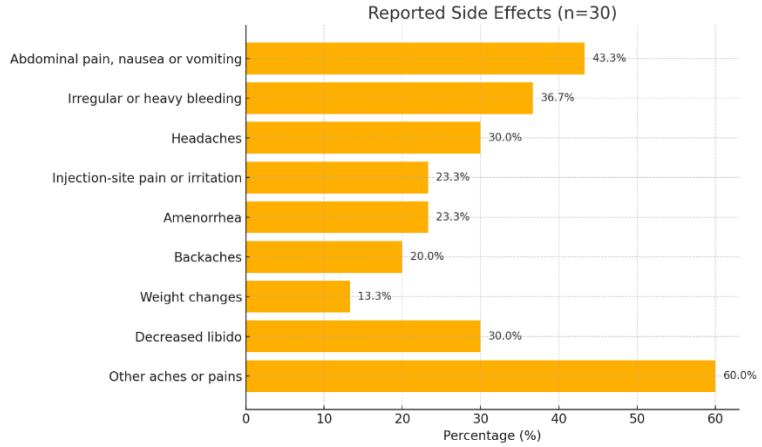


Fig-1: Efficacy of treatment **Fig-2: Frequency distribution of reported side effects**

Table-2: Comparison of side effects with respect to parity

Parity	Side effect		Total	p-value
	Yes	No		
Nulliparous	5 (22.7%)	17 (77.3%)	22 (100.0%)	0.406
Primiparous	10 (28.6%)	25 (71.4%)	35 (100.0%)	
Multiparous	15 (38.5%)	24 (61.5%)	39 (100.0%)	
Total	**30 (31.3%)**	**66 (68.7%)**	**96 (100.0%)**	

DISCUSSION

The utilization of injectable contraceptives has experienced a surge in popularity within the realm of contraceptive users, effectively curbing the occurrence of unintended pregnancies.10 Over the course of recent decades, there has been a gradual rise in the percentage of women of reproductive age who have successfully satisfied their need for family planning through the employment of modern contraceptive methodologies, including injectable contraceptives. This proportion has witnessed a notable increase, ascending from a value of 73.6% in the year 2000 to a percentage of 76.8% in the year 2020. Remarkably, within the span of a mere ten years, the usage of injectable contraceptives has witnessed a twofold augmentation, subsequently providing comprehensive protection for over 42 million women globally on an annual basis.[11-12] In particular, community health workers (CHWs) have emerged as a highly effective option for the provision of contraceptive services, particularly in rural areas where access to healthcare might be limited.[13] Consequently, this situation presents a substantial obstacle in effectively addressing and fulfilling the needs and preferences of women who desire family planning. As a

result, it is of utmost importance for health policymakers to critically reassess the various options for delivering injectable contraceptives, as it has increasingly become the favored method among women, thereby overshadowing other contemporary contraceptive methods.[14-15]

In the context of this particular study, the findings pertaining to the efficacy of Sayana Press revealed that it was successful in achieving the desired outcome in 66 individuals, which accounted for approximately 68.7% of the study population. Conversely, it is important to note that 30 individuals, constituting roughly 31.3% of the sample, experienced side effects as a result of using Sayana Press.[16] In a comprehensive study, it was found that a total of seventy-three participants, accounting for 9.7% of the overall population, encountered adverse events (AEs). The occurrence of two serious adverse events was documented, whereby one participant suffered from a stroke, which was considered possibly linked to the study product, and another participant experienced a leg fracture, which was determined to be unrelated to the study product. It is noteworthy that bleeding irregularities were reported by approximately 5.2% of the individuals among the frequently reported adverse effects by the participant included in the study.[17] However, a rising trend of case of amenorrhea was witnessed as the research progressed. It is fascinating that when follow up of these participants was carried out during the study, there was detectable trend showing that there is decrease in number of participants with heavy bleeding as compared to baseline. This implies that chance of heavy bleeding in the participants decrease as the study advances. For management and treatment of bleeding irregularities, this detection plays significant influence among the individuals involved in this study. This implies that among the participants of this research project, a significant variation in weight is encountered. In addition , at the month 12 visit a significant proportion of 69.4% participants experienced weight gain. This concluded that the study product is responsible for increase in weight gain of any significance among the individuals of study group.[18] Moreover, this research study also provide significant information regarding bleeding irregularities and weight gain which are beneficial in developing potential side effect and health association. In order to better understand the adverse effects of study product and its implication in health of individuals, it is important that further research should be conducted.[19]

Furthermore, an additional 4.9% of the subjects opted to discontinue the treatment due to their earnest endeavor to conceive a child. Moreover, a minuscule fraction of 0.7% reported the occurrence of irregular menstruation, while an identical percentage experienced the unpleasant sensation of pain at the injection site. In a subsequent study, an overwhelming majority of 71%

who underwent the Sayana press injection did not encounter any untoward side effects. It is worth noting that the findings of the current study are fully aligned with the outcomes of previously conducted research endeavors.[20]

Moving forward, it is imperative for future research endeavors to delve into the identification of steps that can be taken to effectively implement this practice on a larger scale. Additionally, further investigations should be conducted to explore the potential of administering alternative medications to enhance adherence and improve the overall health outcomes of individuals residing in local settings.

CONCLUSION

The findings of the study revealed that Sayana Press, a contraceptive method, was deemed satisfactory by the women within our specific demographic. This information is of great significance as it not only offers valuable insights to the government, but also serves as a crucial steppingstone towards the potential implementation of Sayana Press. Furthermore, it prompts the government to contemplate the prospects of future research focusing on self-injection methods, thereby ensuring a comprehensive understanding of the topic.

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