

ORIGINAL RESEARCH ARTICLE

A Study of the Use of Primolut N Tablet as a Contraceptive in the Kumasi Metropolis of Ghana

Henry S Opare-Addo*¹, Patrick K Britwum² and George A O Ampong³

¹Department of Obstetrics and Gynaecology, School of Medical Sciences Kwame Nkrumah University of Science and Technology/Komfo Anokye Teaching Hospital, Kumasi, Ghana; ²Regional Medical Stores, Ashanti, Ghana Health Service/Brit Chemist Ltd, Kumasi; ³Youth Development Foundation, Kumasi, Ghana

*For correspondence: Email: sopareaddo@yahoo.com

Abstract

This study investigated the use of Primolut N tablet which contains norethisterone 5mg popularly called N- tablet by users as a pre-coital contraceptive by women in the Kumasi metropolis of Ghana. Clients who called at any of the twenty (20) selected Pharmacies in residential areas within the Kumasi metropolis demanding the drug, with or without valid prescriptions were interviewed using a guide. Of the two hundred and twenty (220) users interviewed, 94% demanded the drug for contraception and 6% for menstrual disorders. Sixty one percent of those demanding it for contraception were between the ages 20-25 years. Respondents preferred the use of norethisterone tablets as a contraceptive to other methods because it worked for them and they also found it easy and convenient taking a tablet just before coitus than taking daily oral contraceptive pills. Norethisterone is being used as a pre-coital contraceptive, though the efficacy, safety and reliability of the drug for that purpose is unknown. Until these are known, women must be discouraged from using the drug (*Afr J Reprod Health 2011; 15[1]: 65-67*).

Résumé

Etude sur l'utilisation de Primolut N comme un comprimé contraceptif dans la métropole de Kumasi au Ghana. Cette étude a examiné l'utilisation de Primolut N (comprimé) qui contient la noréthistérone 5mg et qui est communément connue comme le comprimé N par les usagers comme un contraceptif pré coïtal dans la métropole au Ghana. Les clients qui se sont présentées à n'importe quelle pharmacie parmi les vingt (20) pharmacies dans les quartiers résidentiels au sein de la métropole de Kumasi pour chercher le médicament avec ou sans l'ordonnance valable, ont été interrogées à l'aide d'un guide. Sur les deux cent vingt (220) usagères interrogées, 94% ont demandé le médicament pour la contraception et 6% pour les troubles menstruels. Soixante et un pour cent de celles qui le demandaient pour la contraception étaient âgées d'entre 20 et 25 ans. Les interrogées préféraient utiliser les comprimés de la noréthistérone comme contraceptif par rapport aux autres méthodes parce qu'il a marché pour elles et elles le trouvaient facile et plus convenable de prendre des pilules contraceptives orales tous les jours. La noréthistérone est utilisée comme un contraceptif pré coïtal, bien que l'efficacité, la sûreté et la fiabilité du médicament ne soient pas connues. Il faut décourager les femmes d'utiliser le médicament jusqu'à ce qu'on se renseigne sur ces détails (*Afr J Reprod Health 2011; 15[1]: 65-67*).

Keywords: Norethisterone; Primolut N tablet; Pre-coital oral contraceptive

Introduction

Primolut N tablet containing norethisterone 5mg, is a first generation progestogen¹⁻³ indicated for use in conditions such as dysfunctional uterine bleeding (DUB), primary dysmenorrhoea, endometriosis, premenstrual syndrome and progesterone challenge test as in secondary amenorrhoea³⁻⁴. Norethisterone has also been formulated in some preparations as a contraceptive³⁻⁶. These preparations which include (1) Micronor (Ortho), (2) Brevinor (Synthex), (3) Loestrin 30 (Parke-Davis), (4) Noristerat (Schering Health Care) and (5) Norigynon (Schering) are available for use in pharmacies and most family planning clinics in Ghana. Some other emergency contraceptive preparations which do not contain norethisterone such as Postinor-2 (Gedeon Richter) and Norlevo (Cipla)^{5,6} have also been introduced into the

market in Ghana. Despite the availability of these large range of products, there have been speculations in Ghana that, Primolut N tablet containing norethisterone 5mg and popularly called N- tablet by users, is being used as a pre-coital contraceptive by a cross-section of women in Ghana. This has come to the notice of community health nurses, midwives, medical officers, pharmacists and other family planning providers in the country. Primolut N tablet taken minutes/few hours before sexual intercourse has however, not been a conventional contraceptive.

A study was therefore undertaken to investigate into the use of Primolut N Tablet as a pre-coital contraceptive by women in the Kumasi Metropolis of Ghana. The rationale for the study was to obtain background information on the use of norethisterone 5mg (Primolut N tablet) as a pre-coital contraceptive by a cross-section of women in Kumasi. The specific objectives were to

determine the percentage demand of Primolut N tablet use as a contraceptive against its recognized uses such as in dysfunctional uterine bleeding, progesterone challenge test and endometriosis, identify the age groups and marital status of women who use the N - Tablet as a contraceptive, and the prescribers who recommend this drug as a family planning method as well as identify how long users have been on the drug as a contraceptive and reasons for preference of Primolut N as a contraceptive and some side effects that might have been encountered during its usage.

Methods

The study was a prospective cross-sectional study. Twenty (20) Pharmacies in residential areas within the Kumasi metropolis were selected. Selected pharmacists and pharmacy technicians in the 20 Pharmacies were trained to conduct the interview and assisted the respondents to fill the questionnaires. A prescriber in the questionnaire is defined as under the Ghana National Drugs Programme as anyone with a recommendation for a use of a drug and a dispenser as anyone who gives out a drug to a client⁷.

Clinical or hospital prescription implied clients came with a written prescription form. Clients who called at the pharmacy demanding Primolut N tablets with or without a valid prescription and consented were interviewed. Each client was interviewed once within the period of study. Interviews were conducted one on one with an interview guide. Privacy and confidentiality were assured before the interview, the motive of the survey was explained to the respondents and informed consent obtained.

The data collection instruments were pre-tested in two community pharmacies. Five clients in each of the pharmacies were interviewed over a period of two weeks before the actual survey started. In all 300 respondents were targeted randomly. Each pharmacy received a file with 15 questionnaires (one for each respondent). The second author distributed the files and monitored the progress of the survey, by periodic visits to the pharmacies and phone calls. At the end of the 12 weeks, the completed questionnaires were collected and analysed.

Results

Two hundred and twenty (220) users of the Primolut N-tablets responded to the questionnaire. Ninety four percent (94%) of the respondents demanded norethisterone tablets for contraceptive use as against 6% for use in menstrual disorders, such as dysfunctional uterine bleeding, progesterone challenge test in amenorrhoea and primary dysmenorrhoea. The dosage requested for as contraceptive was a total dose of 5–15mg before and/ or immediately after intercourse as a single or in divided doses. The dosage requested for treatment for

menstrual disorders ranged between a daily dose of 10–15mg in divided doses and for five or more days.

The age group with the highest usage of Primolut N-tablets as contraception were women between ages of 20 and 25years. This median age group represents 61% of the total respondents. Sixty-three percent (63%) of the respondents were single as against 37% married women. Forty three percent (43%) of the respondents had no children whilst 57% had between one and four children. Sixty-one percent (61%) of the respondents had been introduced to the drug for less than two years. Thirty-five percent (35%) had been introduced to the drug between two and four years and 4% had used the drug for over four years. The study showed that 89% of the respondents had no hospital or clinical prescription as against 11% with hospital or clinical prescription. Only 3% had received hospital or clinical prescription meant for contraception. The non-health workers prescribers (mainly by verbal prescription) included the following, hairdressers, traders, policewomen, teachers, apprentices of various trades, students, boyfriends and partners.

Eighty eight percent (88%) of the respondents who demanded the drug for contraceptive use said they did not know any other uses of the drug apart from being used as a contraceptive. Whilst 12% said they know other uses apart from using it as a contraceptive and mentioned the following uses as; prescribed for menstrual disorders, to stop bleeding, timing or postponing menstruation, correcting irregular menses, and also used in certain cases of menstruation difficulties. All the respondents who demanded the drug for menstrual disorders said they did not know any other uses of the drug apart from its use for menstrual disorders.

On accessibility of norethisterone tablet, 78% of the respondents found no difficulty in accessing the drug whilst 22% found it difficult in accessing the drug for the following reasons. Seven percent (7%) felt shy to request for the drug and 14% said dispensers asked many questions before the drug was supplied. Seventy-five (75%) of users of norethisterone tablets as a contraceptive said they did not experience any side effects, while 25% said they experience side effects such as bleeding every two weeks (frequent menses) and cessation of menses.

When asked about the last two methods of contraception used before switching over to the use of norethisterone tablets as birth control pills, the respondents mentioned all the orthodox methods and some unorthodox methods such as saccharin and ergometrine and menstrogen tablets. About 5% of respondents said they used abortion as a means of addressing unwanted pregnancies until they resorted to the use of norethisteone tablets because the abortions were unsafe.

On the reasons given by respondents for choosing norethisterone tablet as a contraceptive 66% found the drug efficacious while 24% found it simple, comfortable and easy to take whenever required. However, 10% found it cheap and 2% felt it corrected their menstrual cycle and alleviated pain during menses.

Discussion

The high percentage (94%) of the respondents demanding norethisterone tablets for contraceptive use as against 6% for use in menstrual disorders confirms the suspicion of health workers that Primolut N tablet is being used as a contraceptive rather than the recommended indications. Many women are ignorant about the use of Primolut N tablets. They believe the drug as presented, norethisterone 5mg tablet, is a conventional contraceptive.

The median age group of 20 to 25years representing 61% of the total respondents is a very sexually active group and therefore can be targeted for reproductive health education. Even though Primolut N tablets is classified as a prescription only medicine in Ghana, the study showed that only 3% of the respondents had a hospital or clinical prescription. This figure therefore represents a high level of abuse of the drug in the metropolis. Dosage ranges for contraception and menstrual disorders were within the maximum dosage use of the drug, which is up to 25mg daily British National formulary, 2004⁸.

In-vitro studies⁹ have showed that norethisterone 350microg is effective in preventing sperm migrating in the cervical mucus about 12 hours after administration may support the claim by the women that the drug is effective. However, until some scientific in-vivo studies have been conducted, women have to be discouraged from the use of the drug to prevent pregnancy.

Conclusion

Primolut N tablets is being used mainly as a pre-coital contraceptive and also as post-coital contraceptive in the Kumasi Metropolis because users claim it works for them and it is easy and convenient to take a table just before or immediately after coitus. However until results of clinical investigations indicate its efficacy or otherwise as a pre-coital contraceptive, the sale of Primolut N tablet to the general public for that purpose must be discouraged.

It is also very important that public education is intensified on the use of oral contraceptives and the availability of post-coital (emergency) contraceptives such as Postinor 2 to help control the usage of Primolut N tablet as a contraceptive. The need to develop and manufacture a convenient, safe, reliable and affordable pre-coital oral contraceptive for women is necessary

since compliance is difficult with the use of daily oral contraceptives. This is a challenge to drug designers and manufacturers.

Acknowledgments

We acknowledge the co-operation of all the pharmacy proprietors too many for their names to be listed here, for allowing their premises to be used as data collection sites. We would also like to acknowledge Prof SWK Adadevoh for the encouragement given us in the preparation and for editing the manuscript.

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