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Market Diffusion of Extended Cycle Hormonal Contraceptives

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Key Words: Extended cycle hormonal contraceptives, acceptance, awareness, advantages, disadvantages

Abstract

Background: Extended cycle hormonal contraceptives (e.g. Seasonale, Seasonique) when introduced in 2003 were considered a very novel approach to contraception. The idea of manipulating the menstrual cycle so that women would experience just four menstruations a year was radical and was assumed to be responsible for the slow acceptance rate among the general public.
Objective: This report analyzes two different aspects of the acceptance of this unique idea in the population. The first was the level of usage of extended cycle hormonal contraceptives in the general population, which was measured by a review of sales figures over time in the United States. The second was an examination of market diffusion as it relates to consumer perceptions regarding the characteristics of these products.
Methods: To determine the degree of usage of extended cycle hormonal contraceptives the yearly sales, in terms of units sold, were compared with that of other leading methods of hormonal contraception. Along with the data, survey answers were obtained from 65 women who volunteered to participate in the study. Participants were selected randomly to represent the target population to assess the level of awareness about the benefits, risks, and any other concerns regarding the use of extended cycle hormonal contraceptives.
Results: The yearly sales data of units sold showed a definitive increase in the sales of extended cycle hormonal contraceptives since their release on the market. The survey results showed an overwhelming awareness in the study population about the extended regimen. However, only about half of the women in the survey group were aware of its benefits. The main concern reported was the perceived significant side effect profile.
Conclusion: Though awareness about the extended cycle hormonal contraception regimen was widespread, the survey population was not well informed about the advantages and the disadvantages regarding the degree of severity of side effects. To address these knowledge deficits, these aspects should be the focus when distributing information about extended cycle hormonal contraceptive regimens. This may boost the use of a potentially advantageous contraceptive regimen by a population who would derive benefit from its usage.

Introduction

The 91 day hormonal contraceptive method, also known as extended cycle contraception, was a radical approach to the conventional 28 day hormonal contraception, which had been in use for over fifty years. The proponents of this regimen advocated that by reducing the number of menstruations per year it would be possible to improve the quality of life, productivity, and provide respite from common symptoms experienced during menstruation.

Extended cycle hormonal contraception was first proposed by Barr Pharmaceuticals in association with The Eastern Virginia Medical School, and was approved by FDA for distribution in September 2003. The extended cycle hormonal contraceptive regimen allowed women the opportunity to take a daily oral contraceptive tablet, which skipped the menstrual cycle for three months in a row. The package contains three packs of 28 active pills (compared to 21 active and 7 inactive pills in a 28 day regimen) with seven days of placebo or low dose hormone at the end of the third cycle. This course allows for the menses to occur only at the end of three months or four times a year.

Although a daily oral contraceptive is not novel, the concept of purposefully skipping menses for three months at a time has not wildly caught on yet. This paper attempts to analyze how well this new approach to contraception been accepted in the community and what future challenges may lie ahead. Before the analysis of the acceptance of this new approach, it is beneficial to understand how new concepts are typically accepted in a community. One model is the theory of "Diffusion of Innovation," which explains how, why, and at what rate new ideas diffuse throughout a culture. Everett Rogers titled his 1962 book after this theory and explained, "Diffusion is the process by which an innovation is communicated through certain channels over time among

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the members of a social system" [1]. Rogers described the S-curve of society's adoption of technology by dividing people into three groups based on their ability to adopt a change. The 'innovators' lead, the 'early adopters' are next to accept an idea, followed then by the majority until society has fully accepted the idea [1].

Acceptance itself follows the 'Innovation Decision Process,' which begins with Stage 1: Knowledge, Stage 2: Persuasion, Stage 3: Decision, Stage 4: Implementation, and Stage 5: Confirmation. These stages correlate to the evolution of a person gaining knowledge of the innovation, forming an opinion, and then leading to the acceptance and confirmation of the innovation [1].

Similarly, Coleman, Katz and Menzel studied the diffusion process of ideas, but through the impact of societal influence. *Medical Innovation* demonstrated the influence of interpersonal relationships at certain stages of the decision-making process. Their 1966 study illustrated both individual and social variables affecting the adoption of new ideas and the influences existing from social or professional ties to the adopters [2].

Ratna, et al. tested the willingness of doctors to adopt a new drug based on differing levels of influence, modeled their study after that of Coleman, Katz and Menzel. The first group studied was the Baseline Scenario, where only one innovator or one journal was influential in the decision. Another group was the Heavy Media Scenario, where influences involved several individuals and journals. Finally, the third group, the Integration Scenario, involved no outside influence. The results showed that those in the Heavy Media Scenario group adopted the new drug in the least amount of time as compared to that of Baseline or Integration Scenario, the slowest adopters [3]. Essentially, the more influence from others who have adopted the idea or media showing its efficacy, the more willing they were to adopt the use of the new drug themselves.

Viewing this information in light of acceptance of the extended cycle hormonal contraception, it can be assumed that the society consists of women who would be willing to accept the new idea more rapidly when recommended by sufficient numbers of peers. This represents a traditional scenario of diffusion of innovation, and also is comprised of women who would be willing to try a new idea when influenced by the media. When hormonal contraceptives were originally introduced in the early 1960s the acceptance was slow, as the primary methods of diffusion was personal recommendations. However, today the growing media campaigns and public reliance on the internet as a reliable source of information has made the diffusion of ideas much faster. As a result, we would expect that overall the acceptance of this new regimen of hormonal contraception should be faster than that of the traditional 28 day contraception products.

Contraceptive options now range from patches, intravaginal rings, depot injections, and birth control pills. In general, hormonal birth control has not changed profoundly in the past five decades, with only the real innovations in dosing. Over the years, studies have shown that women require much lower doses than originally thought for contraception, and that dosing varies from woman to woman. An example of multiple dosing strengths was the introduction of Yaz shortly after Yasmin. Yaz contains the same active ingredients as Yasmin, but with a lower dose of ethinyl estradiol (drospirenone 3 mg/ ethinyl estradiol 20 mcg and drospirenone 3 mg/ ethinyl estradiol 30 mcg, respectively).

Even with the lower doses, some females were experiencing hormone withdrawal symptoms during the week of their menses. For such occurrences, there was the innovation of low dose hormones during the week of menses. Doses were low enough to allow menses to occur, but they did not deprive the body of hormones completely. An example, Seasonique (levonorgestrel 0.15 mg/ ethinyl estradiol 0.03 mg/ and ethinyl estradiol 0.01 mg), allows for a small amount of ethinyl estradiol to be delivered during menstruation in order to prevent withdrawal symptoms such as headache. Another advantage is its extended cycle allowing women to only experience four periods a year, therefore they have less cramping, headaches, and fatigue. The 91 day regimens are a middle ground between the monthly period of a 28 day regimen and an alternative form of contraception such as hormonal rings and depot injections.

Methodology

This paper attempts to analyze the primary question of the level of diffusion or acceptance of this new approach to hormonal contraception via two methods, sales data and survey results. To mark the diffusion of this innovation for extended cycle hormonal contraception, the sales of units of 91 day regimens versus other leading birth control regimens currently on the market were interpreted. Sales data of the six leading hormonal contraceptive methods were analyzed to determine if the extended cycle hormonal contraceptive regimen is something that the public has accepted as compared to the typical 28 day tablet regimen. The products included 91 day tablet Seasonale and Seasonique regimens; 28 day tablet regimens of Yasmin, Yaz, Loestrin 24 FE; and Nuvaring. The sales data that were used to compare the sales of the above mentioned formulations were obtained from

Wolters Kluwer Pharma Solutions, a leading firm in the pharmaceutical market research space.

Secondly, to have a comprehensive view of hormonal contraceptive attitudes and opinions, surveys were administered to characterize the diffusion of this idea through various age groups and gain opinions on the concept of 91 day contraception for the female target audience. Women were anonymously, randomly surveyed with a ten-question multiple choice "Oral Contraception" questionnaire. The survey was distributed by pharmacy interns at four pharmacies in the greater Philadelphia and suburban New Jersey areas. These pharmacies represented very different demographics and diverse neighborhoods. Approximately 200 questionnaires were distributed to female customers at these selected pharmacies. The 65 returned surveys resulted in a response rate of 32.5 percent. The questions ranged from current use and type of hormonal contraception, a willingness to take a 91-day regimen, and the knowledge of side effects and benefits of both 28 day and 91 day hormonal contraception regimens. Participants remained anonymous, revealing only their age, so that women would be more comfortable sharing their true beliefs and feelings. The study was not reviewed by an IRB since the survey was anonymous and no personal, identifiable data were collected. The surveys returned produced an age range of 19 to 52 years. It was considered whether to exclude those already beyond menopause; however, by allowing all females to partake, more views were encompassed regardless if respondents were candidates for oral contraception. The majority of participants were in their 20s, and this was an acceptable representation of the population that would be most likely using oral contraceptives, as physicians may recommend alternative methods contraception for women older than 35 years.

Results

Upon comparison of the trends of popular contraception products, it was found that Seasonale's popularity rose continuously the first three years it was on the market, but then leveled out in its third and fourth years after release. With the introduction of Seasonique in 2006, Seasonale's unit sales decreased as Seasonique's increased, rising to surpass both Seasonale and Nuvaring. Seasonique's units sold was half that of Nuvaring (in its 5th year on the market), but surpassed it by three times by the end of the following year [6]. This data was consistent with the position of Seasonique acting as a middle ground for women, as to not change their method of contraception, but provide unique benefits. The 28 day hormonal contraceptive regimen still remains the most popular, but 91 day regimens are becoming more widely accepted as shown by sales data.

In the survey, a total of 65 completed responses were returned. Of this population, 40% were currently not using any form of oral hormonal contraception. Women in this group tended to be older, but ages ranged from 19 to 50+ (with 6 participants over the age 30). The most common (70%) reasons for not using oral contraception was either experiencing past side effects or having one or more contraindications to using hormonal contraception like increased blood pressure, migraines, etc. About 23% of those women were on another method of birth control (non-hormonal) such as condoms, natural family planning, etc. Despite not being on any type of hormonal contraception, 88% had heard about Seasonique and Seasonale, mostly via television advertisements.

Conversely, those who had "never heard of it" were all from women over the age of 47, leading us to believe that current television advertising for extended cycle hormonal contraception is primarily targeted toward a younger audience. Another interesting finding was that only one respondent out of this group showed a willingness to try an extended regimen oral contraceptive in the future. The rest of that group was evenly split between being somewhat willing, not willing, or not having enough information to make that decision.

Women who were currently using oral contraceptives ranged in age from 20 to 28 years of age. This seemed to be a representative portion of the general population who may use hormonal contraception, as women younger may not be on any contraception, and older women may be thinking about having children. The respondents who were currently taking hormonal birth control were overwhelmingly (87%) on 28 day regimens (Figure 1). Only one person surveyed was currently on a 91 day regimen, while three others had been on it, but had switched to another method with no reason given. Interestingly, of that group who had never taken a 91 day regimen, 53% were willing to try an extended cycle regimen in the future (Figure 2). Most of the respondents in this group had heard of Seasonale or Seasonique, and less than 10% felt they needed more information before trying it in the future.

Regardless whether participants were using hormonal contraception, the responses were similar in the concerns with using a 91 day regimen. The occurrence of side effects (e.g. spotting, weight gain) was the primary concern, followed by the belief that it is unnatural to skip menstrual cycles, the fear of missing signs of pregnancy followed closely behind (Figure 3). Only a little more than half of the respondents were aware of the benefits of an extended cycle regimen with the percentage being 54% among women using oral

contraception and 58% of those not on hormonal contraception (Figure 4).

Discussion

The survey results showed that though there is an overall awareness of the availability of extended cycle hormonal contraception regimens, but not as much awareness of its benefits. Participants were more aware of the drawbacks/side effects of the extended regimen. This has been the case with other innovative therapeutic modalities such as Lasik eye surgeries, which achieved much notoriety in the initial years for their possible complications rather than the advantages it provides. With improvement in technology and better outcomes of the surgery there was a drastic increase in their subsequent acceptance in the population. The same may be considered when analyzing an extended cycle hormonal contraceptive regimen, which currently faces much skepticism due to its perceived complications, such as breakthrough bleeding or the unnaturalness of skipping menses [8]. It would be advantageous if physicians and media could disseminate the many benefits provided by this extended regimen when counseling patients about these products, so that women would be more aware of all aspects of the 91 day regimen.

In conclusion, changing the public's views is a constantly evolving process that requires years and an eventual tipping point to diffuse throughout society. Innovations such as Lasik eye surgery may be often slow to take off, but eventually infiltrate common ideology. Traditional 28 day oral contraception has been widely used for many decades; however, new formulations and dosing schedules allow women fewer periods a year with an overall improvement in the quality of life. Although initially slow to gain popularity, based on the surveys and sales data, 91 day oral contraceptive regimens have progressed steadily into the mainstream and may be on their way to becoming an accepted and widely used form of birth control.

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Figure 1. Use of Oral Contraceptive Types by Respondents

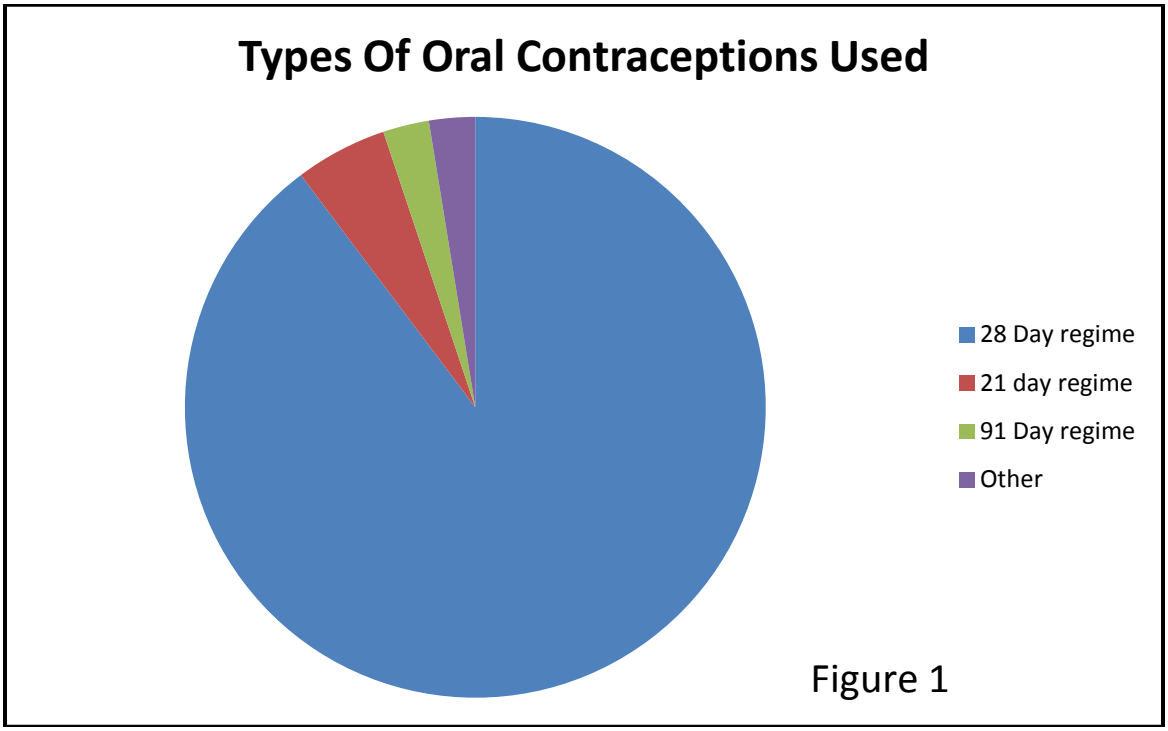

Figure 2. Respondent Willingness to Try Extended Cycle Contraceptives Opinions

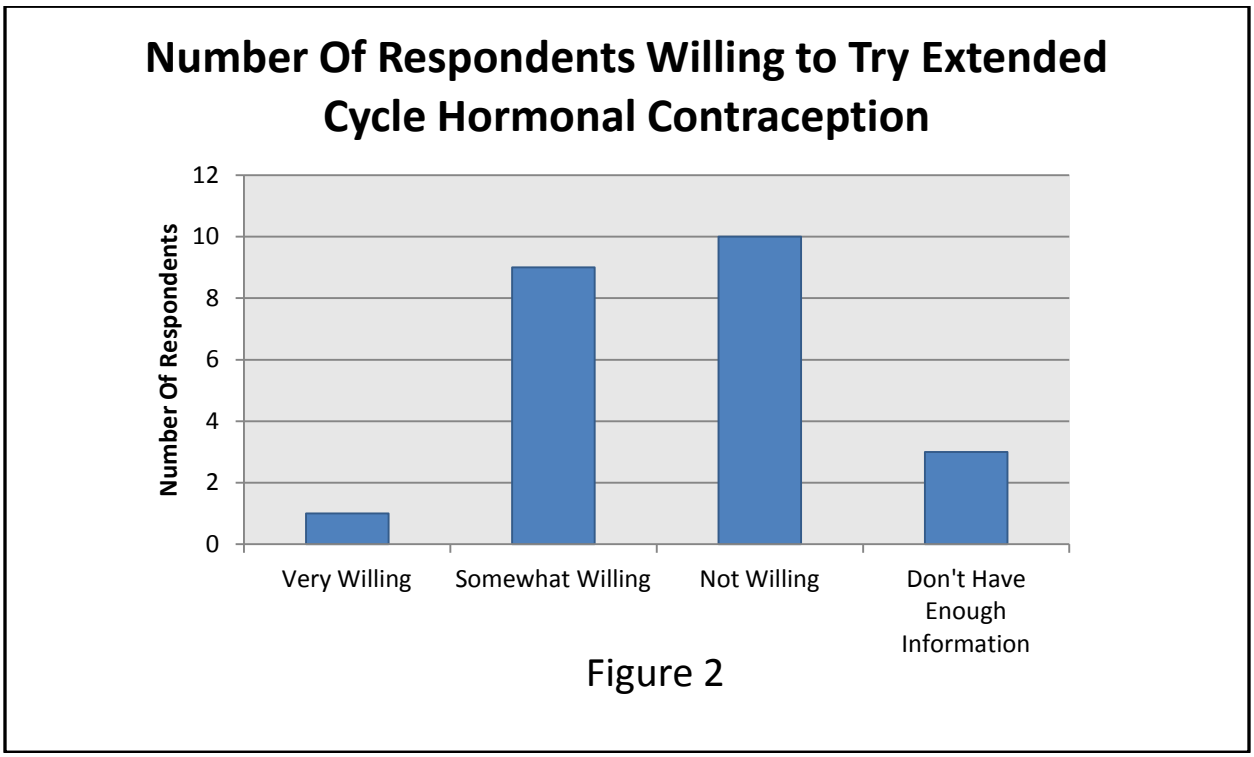

Figure 3. Respondent Awareness of Extended Cycle Regimen Benefits

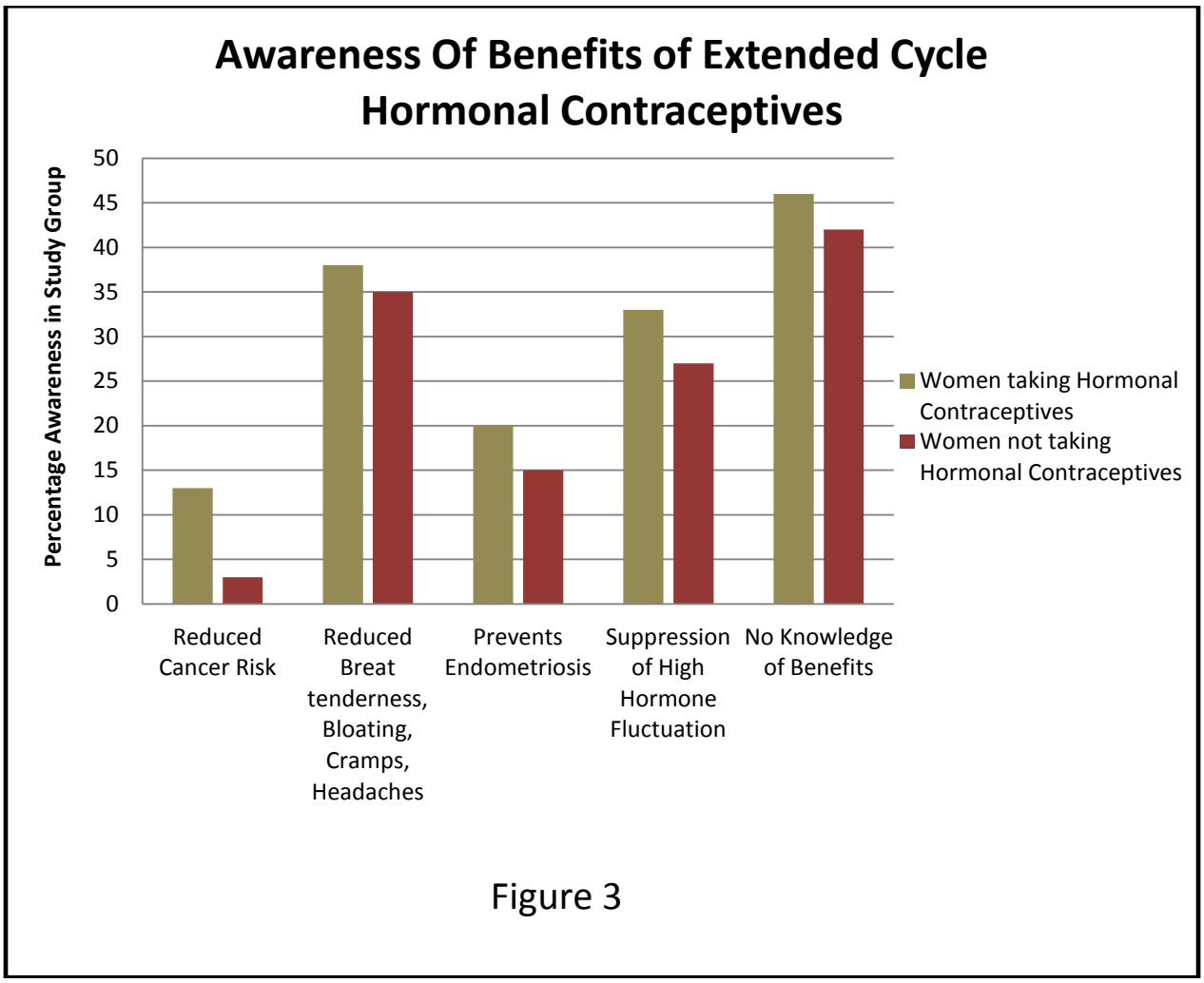

Figure 3

Figure 4. Respondent Concerns About Extended Cycle Product Use