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Same-day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation methods

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Abstract

Introduction: Published comparisons of oral contraceptive pill (OCP) initiation methods demonstrate that OCP initiation at the office visit ("Quick Start") resulted in higher continuation rates into the second cycle. This trial was performed to investigate whether Quick Start with the contraceptive patch would provide similar results.

Materials and Methods: Sixty women were randomized to initiate use of the contraceptive patch using Quick Start (Group 1, $n=30$) or on the first day of their next menses (Group 2, $n=30$). Telephone contact at 6 weeks occurred to ensure that the second cycle had been initiated. A single follow-up visit was scheduled after completion of the third patch cycle.

Results: Continuation rates for Groups 1 and 2 were 97% and 93% ($p=1.0$), respectively, into the second cycle, and 93% and 90%, respectively, into the third cycle ($p=1.0$). Only approximately half of the subjects planned to continue using the patch after the study.

Conclusion: Quick Start for the contraceptive patch did not improve continuation rates into the second or third cycle.

Keywords: Contraceptive patch; Initiation; Quick Start; Continuation rate

1. Introduction

Conventional initiation of most hormonal contraceptives requires waiting for the start of the next menses. The two motives behind initiation with the onset or after the next menses are to avoid giving contraceptives to women who might have already conceived and to allow for a withdrawal bleed to occur approximately 4 weeks after the onset of spontaneous menses. The latter motive was to create the appearance of regular cycles. Typical instructions given to a patient are to start use of oral contraceptive pills (OCPs) on the first day of the menstrual cycle after the office visit or to wait until the Sunday following the start of menses [1,2]. Women who are told to wait for the next menses frequently do not start their method due either to confusion regarding starting instructions or to waning motivation to use contraception [3–5]. Overall, approximately 25% of patients never even start their prescribed method of contraception [4–6]. In those women who do start their contraceptive method, one of seven patients will discontinue the method of contraception two or more times over a 1-year period. Follow-up of women who discontinue use of oral contraceptives demonstrates that 20% choose to use no contraception and 70% use a less-effective method [7–9].

Because of these compliance and counseling issues related to OCP use, researchers from the Columbia University initiated a "Quick Start" protocol that allows for starting OCPs on any cycle day, usually the same day as the clinic visit. Women were recruited to compare continuation rates of OCP use with the second cycle when they were instructed to initiate use at a traditional time (i.e., on the Sunday following their next menses) versus that on the same day as the clinic visit [1]. Of the 250 women enrolled in this nonrandomized trial, 62 agreed to the Quick Start method. Fifty patients (87%) in the Quick Start group continued onto the second cycle as compared with 115 of 256 (49%) in the traditional start group.

Nonadherence to OCP taking has led to the development of new delivery systems of contraceptive hormones. The contraceptive patch (OrthoEvra®, Ortho Pharmaceuticals, Raritan, NJ, USA) is a recent addition to the contraceptive market and delivers norelgestromin and ethinyl estradiol systemically. The once-a-week dosing for

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the patch improves contraceptive compliance as compared with OCPs [10,11] regardless of a woman's age. Still, the improved compliance does not translate to a significantly lower pregnancy rate with the patch as compared with an OCP [10,12].

We designed this study as a pilot investigation of whether the Quick Start concept will also be beneficial to patch users.

2. Materials and methods

An open-label prospective randomized trial was conducted after approval by the institutional review board of the Magee Womens Hospital of the University of Pittsburgh Health System. Reproductive-aged women were recruited via newspaper advertisements and flyers. Entry criteria included the following: (1) age between 18 and 45 years; (2) request to use the transdermal delivery system as their primary means of contraception; (3) willingness to comply with the study protocol and visit schedule; and (4) willingness to answer questionnaires. Exclusion criteria included the following: (1) contraindication to use of combined contraceptive hormones as detailed in the product's package insert; (2) unprotected intercourse since their last menstrual period more than 120 h before enrollment; (3) recent abortion without having had one subsequent period; and (4) weight greater than 198 lb (90 kg).

After obtaining informed consent, each subject had her blood pressure and weight measured. Subjects were randomized to start the patch in the office at the time of the visit (Group 1) or on the first day of their next menses (Group 2). Subjects were given a 4-month supply of the contraceptive patch and written instructions on what to do in case the patch fell off or partially unrolled. Each subject was told to place a new patch as soon as she noticed that the prior patch had either fallen or rolled off as well as to call our office for further evaluation if necessary. Subjects in Group 1 were instructed to use a back-up method of contraception (such as a condom) for 7 days after starting use of the patch. All subjects were also given a prescription for Plan B® for use as emergency contraception; those women who had unprotected intercourse in the 5 days prior to the enrollment appointment were instructed to use the Plan B® immediately.

All subjects were contacted by telephone 6 weeks after initiating patch use. Information obtained at this call included the date the subjects started to use the patch (if randomized to Group 2) and assurance that those subjects in Group 1 continued to use the patch into the second cycle and placed the patch at the appropriate time. Each subject was reminded of the date of her final visit.

A final visit occurred during the first week of the fourth cycle of patch use. Each subject was asked to complete a questionnaire regarding the acceptability of the new initiation method and its impact on remembrance of use into the second month. Each subject's blood pressure was checked and medical history was reviewed to ensure that she had not developed any contraindication to use of combined hormonal contraception or suffered any severe side effect from the patch. If a subject was normotensive (systolic blood pressure, <140; diastolic blood pressure, <90) and had no severe side effects, she was provided with a 3-month prescription for the patch, if desired. Alternative methods of contraception were discussed and dispensed if the patient wished to discontinue the contraceptive patch.

2.1. Statistical analysis

The total number was selected based on continuation rates from Quick Start data on OCPs [1]. Based on the continuation rates of 87% in the Quick Start group and 65% in the traditional start group [1], a sample size of 58 women per group would be needed at a significance level of .05 and a power of 80%. We chose a smaller sample size of 30 subjects per group for this pilot study based on economical restrictions. This sample size would be large enough to determine a difference in continuation rates between 87% in the Quick Start group and 60% in the traditional start group.

Fisher's Exact tests were used to analyze data. Data are reported as mean, ±SD and ranges.

3. Results

Sixty women were enrolled from September 2003 to January 2004. Table 1 summarizes the demographic data of the subject pool. Two subjects in Group 1 and one subject in Group 2 required emergency contraception before study initiation; all three subjects received and took Plan B® before medication initiation.

One subject from Group 2 was lost to follow-up; based on an intent-to-treat analysis, we considered this subject to

Table 1
Demographic data

	Group 1 ($n=30$)	Group 2 ($n=30$)	Total ($N=60$)
Age (years; median)	21	20	20
Gravidity [*n* (%)]			
0	23 (77)	25 (83)	48 (80)
1	5 (17)	4 (13)	9 (15)
≥2	2 (7)	1 (3)	3 (5)
Parity [*n* (%)]			
0	26 (87)	28 (93)	54 (90)
1	2 (7)	2 (7)	4 (7)
≥2	2 (7)	0 (0)	2 (3)
Marital status [*n* (%)]			
Single	28 (93)	26 (87)	54 (83)
Married	1 (3)	3 (10)	4 (6)
Separated	1 (3)	1 (3)	2 (3)
Living with partner	3 (10)	2 (7)	5 (8)
Race [*n* (%)]			
White	23 (77)	23 (77)	46 (77)
Black	7 (24)	4 (13)	13 (21.7)
Hispanic	2 (7)	1 (3)	3 (0.05)

Group 1= 'Quick Start'; Group 2= Traditional Start (first day of menses).