

A Survey on Low-Dose Oral Contraceptive Transactions at Pharmacies

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Low-dose oral contraceptives (OCs) were approved by the Japanese Ministry of Health, Labor and Welfare in 1999. However, few women use low-dose OCs (married 1.9%, unmarried 0.7%). A survey of pharmacies was conducted to determine the current status of OC transactions. Of the 449 pharmacies randomly selected from each prefecture in Japan, 408 agreed to be interviewed. The survey results indicated that few pharmacies (15.1% of the total) stocked low-dose OCs. Even among pharmacies where they were available, only a few (13.5%) offered a wide variety of low-dose OCs for immediate dispensing. The price of low-dose OCs varied widely (¥1,167–¥7,000). In many pharmacies, the amount of space and interior structure were not adequate for users to seek advice on and receive low-dose OCs. The survey revealed that the current environment of many pharmacies is not adequate for users to visit, consult on OC use, and receive their prescriptions. To promote wider use of low-dose OCs, the facilities of pharmacies as well as the behavior of pharmacists need to be improved to safeguard the privacy of users.

Key words—low dose pill; pharmacy; stock; price; privacy

INTRODUCTION

Japanese are becoming sexually active at younger ages, and currently the mean age of the first sexual activity is approximately the same as that in the West. The results of one survey indicated that 37.3% of third-year high school boys and 45.6% of girls had engaged in sexual activity.¹⁾ There are concerns about how young women prevent pregnancy and the care they receive if they do become pregnant.

Combined estrogen and progesterone oral contraceptives (OCs) were introduced in Japan in 1957 for the treatment of menstrual disorders and were used off label for contraceptive purposes. Low-dose OCs, which contain much smaller amounts of the two components, were finally approved by the Japanese Ministry of Health, Labor and Welfare for contraceptive use in 1999, after more than 40 years of experience had been accumulated worldwide. Although they were approved 3 years ago, one survey indicated that only 1.9% of married and 0.7% of unmarried women use low-dose OCs.²⁾ This means that many rely on condoms and other nonpharmaceutical methods for contraception. The low rate of usage reflects concerns about side effects, such as thrombosis, weight gain, etc., even though low-dose OCs have

been prescribed worldwide for many years, their long-term side effects have been studied extensively, and their safety established. The culture and perceptions relating to sexual activity may differ between Japan and the West, which may also result in the less frequent use of low-dose OCs in Japan. Insufficient knowledge of low-dose OCs and their appropriate use, not only among the general public but also among medical professionals including pharmacists, may also be a reason for their less frequent use compared with other countries.^{3–11)}

To the best of our knowledge, no previous report has been published on current low-dose OC transactions at Japanese pharmacies, including how many stock them, pricing, and methods employed to instruct women in their contraceptive use. This survey was conducted among pharmacies to determine:

- 1) the ability of pharmacies to dispense low-dose OCs immediately upon request;
- 2) the types and amounts of low-dose OCs stocked by pharmacies;
- 3) the prices of low-dose OCs dispensed; and
- 4) attitudes of pharmacists toward the confidentiality of low-dose OC users.

SURVEY METHODOLOGY

Pharmacies Candidate pharmacies to be interviewed were selected from “List of Pharmacies and

Table 1. Survey Questionnaire and Process

Q1 Do you dispense drugs?	Yes→Q2	If no, end
Q2 Do you stock low-dose OCs?	Yes→Q3	If no,→Q5
Q3 Which brands of low-dose OCs do you stock?	→Q4	
Q4 What is the price of low-dose OCs at your pharmacy?	→Q7	
Q5 Can you order low-dose OCs if none are in stock?	Yes→Q6	If no, end
Q6 How long does it take from order until delivery?	→Q7	
Q7 How do you maintain the privacy of customers during consultations and giving instructions on drug use?	End	

Drugstores in Japan” (Zenkoku-Yakkyoku-Yakuten-Meikan, Higashinohon 2001,¹²⁾ Nishinohon 2000¹³⁾). Approximately 1% of candidate pharmacies were selected from each prefecture in Japan by random sampling based on a table of random numbers. Four hundred and forty-nine pharmacies were selected from among 45,019 registered. There were some variances among prefectures in the number sampled because of rounding off to one decimal place.

Survey Period The survey was conducted from June 27 to July 9, 2002. During the survey period, two low-dose OCs, Ortho M-21[®] (Janssen) and Ortho 777-28[®] (Janssen) were found to contain coloring agents not approved for use in pharmaceuticals and were recalled from pharmacies. That did not influence the results of the survey, however.

Interviews The questionnaire used for the survey is shown in Table 1. Four interviewers were selected from among fourth-year undergraduate students at the Kyoritsu College of Pharmacy to conduct interviews over the telephone. The interviewers were first trained in the interview technique and were instructed to ask the same questions in the same order in a standardized manner. Each interviewer recorded the responses of interviewees on the questionnaire sheet either during the telephone interview or immediately thereafter.

RESULTS

Four hundred and forty-nine pharmacies were contacted by telephone, and 408 pharmacies (90.9%) agreed to be interviewed. Of those 408, 345 (84.6%) stated that they filled prescriptions for ethical drugs and dispensed them on-site. It was an unexpected result that 15.4% of registered pharmacies (not drug-

Table 2. Demographic Characteristics of Survey Respondents

<i>n</i> =449		
Contacted by telephone	Yes	408 (90.9%)
<i>n</i> =408		
Dispenses drugs	Yes	345 (84.6%)
<i>n</i> =345		
Occupation of respondent	Pharmacist	344 (99.7%)
	Receptionist	1 (0.3%)
Sex of respondent	Female	221 (64.1%)
	Male	124 (35.9%)

Table 3. Stock of Low-Dose OCs

<i>n</i> =345		
Low-Dose OCs in stock	Yes	52 (15.1) *
	No	293 (84.9)
<i>n</i> =293		
Low-Dose OCs can be ordered	Yes	258 (88.1)
	Depends on circumstances	4 (1.4)
	No	31 (10.6)
<i>n</i> =262		
Time required for delivery	1 hour	23 (8.8)
	2-4 hours	7 (2.7)
	Within 1 day	3 (1.1)
	Within 1 or 2 days	90 (34.4)
	Only the next day	74 (28.2)
	2-3 days	3 (1.1)
	Depends on circumstances	52 (19.8)
	A long time	4 (1.5)
Not known	6 (2.3)	

* Nine pharmacies refused to disclose the brand names.

stores) investigated did not accept ethical drug prescriptions and did not dispense drugs (Table 2). The interviewers spoke with licensed pharmacists in all pharmacies except for one, where the person in charge of the reception desk responded because the pharmacist was “too busy” to be interviewed. Of the respondents, 64.1% were women and 35.9% men.

Only 52 pharmacies (15.1%) had low-dose OCs in stock, and 293 pharmacies (84.9%) did not usually stock them (Table 3). When questioned on the proprietary names of low-dose OCs stocked, nine interviewees refused to disclose them. The 293 pharmacies that did not stock low-dose OCs were asked what they did when women requested a prescription for them to be filled. The majority (258 pharmacies, 88.1

Table 4. Price of Low-Dose OCs (Numbers Represent Numbers of Surveyed Pharmacies)

Price (yen)	One-phase			Three-phase							Total
	Ortho M-21®	Progesterone increases mid-cycle, estrogen unchanged		Ortho 777-28®	Progesterone increases stepwise, estrogen unchanged		Estrogen increases mid-cycle, progesterone increases stepwise				
		Synphase T28®	Norinyl T28®		Ange 28®	Tridiol 21®	Tridiol 28®	Triquilar 21®	Triquilar 28®	Libian28®	
1,000-1,499	1	1	0	1	1	1	0	1	0	0	6
1,500-1,999	0	0	0	0	0	2	0	2	1	0	5
2,000-2,499	2	1	1	1	6	4	1	0	1	3	20
2,500-2,999	3	0	0	3	2	3	0	1	0	0	12
3,000-3,499	3	0	1	3	4	0	1	1	1	1	15
3,500-3,999	0	0	0	0	0	0	0	0	0	0	0
4,000-4,499	0	0	0	0	1	0	0	0	1	0	2
4,500-4,999	0	0	0	0	0	0	0	0	1	0	1
7,000	0	0	0	0	0	0	0	0	0	1	1
No response	0	0	0	0	1	1	1	1	1	0	5
Minimum	1,430	1,167	2,000	1,430	1,430	1,420	2,100	1,400	1,624	2,000	1,167
Maximum	3,000	2,100	3,160	3,000	4,000	2,730	3,000	3,000	4,800	7,000	7,000
Total	9	2	2	8	15	11	3	6	6	5	67

Note: Low-dose OCs indicated for contraception are not covered by national health insurance.

%) stated that they could obtain low-dose OCs on request and dispense them without significant difficulty. Four pharmacies (1.4%) answered that they would have difficulty in supplying low-dose OCs and that they could only do so when the stock center of the pharmacist community (*Yakuzaishi Senta*) had sufficient stock to supply them.

When queried about the time required for delivery, 90 pharmacies (34.4%) said that they could dispense low-dose OCs to users within 1 or 2 days even when they did not have them in stock. Seventy-four pharmacists (28.2%) answered that they could supply them on the next day following a request.

The variations in prices of low-dose OCs are summarized in Table 4. The two main types of low-dose OCs available in Japan are based on one-phase and three-phase dosage regimens. In the one-phase OCs, the amounts of estrogen and progesterone remain unchanged throughout the menstrual cycle. Ortho M-21® (Janssen) is the only currently available one-phase formulation. There are three subtypes of three-phase OCs. In the first, the dosage of progesterone is increased during the mid-menstrual cycle while that of estrogen remains unchanged (Synphase T28® (Tsumura) and Norinyl T28® (Kaken Pharmaceutical)). In the second, the dosage of progesterone in-

creases stepwise while that of estrogen remains unchanged throughout the menstrual cycle (Ortho777-28® (Janssen)), while in the third, the dosage of estrogen is increased during the mid-menstrual cycle and that of progesterone increases stepwise (Ange 28® (Teikoku hormone), Tridiol 21® (Wyeth), Tridiol 28® (Wyeth), Triquilar 21® (Shering), Triquilar 28® (Shering), and Libian 28® (Yamanouchi)).

Ortho M-21® (Janssen) was sold at only nine pharmacies and its price for a package covering one menstrual cycle varied from ¥1,430 to ¥3,000. Ange 28® (Teikoku Hormone) was sold by 15 pharmacies and in 14 of them the price varied from ¥1,430 to ¥4,000 for one menstrual cycle (one pharmacy did not state the price). For most brands, the price was in the range of ¥2,000 to ¥2,499 at 20 pharmacies, from ¥2,500 to ¥2,999 at 12 pharmacies, and from ¥3,000 to ¥3,499 at 15 pharmacies. The cheapest brand sold was Synphase T28® (Tsumura), at ¥1,167 for one menstrual cycle, and the most expensive was Libian 28® (Yamanouchi), at ¥7,000.

The variety of low-dose OCs stocked by the surveyed pharmacies is shown in Table 5. Thirty-six pharmacies had only one type in stock. Of those 36, four pharmacies dealt only in the one-phase type. Two pharmacies dealt with the first subtype of the

Table 5. Types of Low-Dose OCs Stocked by Surveyed Pharmacies

In stock	No. of pharmacies	Total
One type	a)	4
	b)	2
	c)	4
	d)	26
Two types	a) + c)	2
	a) + d)	2
	b) + d)	1
Three types	a) + c) + d)	1
	b) + c) + d)	1
Total	43	

a) One-phase low-dose OC. b) Three-phase subtype in which the dosage of progesterone increases mid-cycle while that of estrogen remains unchanged. c) Three-phase subtype in which the dosage of progesterone increases stepwise while that of estrogen remains unchanged. d) Three-phase subtype in which the dosage of estrogen increases mid-cycle and that of progesterone increases stepwise.

three-phase OC, four dealt with the second subtype, and 26 dealt with the third subtype. Five pharmacies dealt with two types of three-phase OCs and two dealt with all three types of three-phase low-dose OCs. Five pharmacies had one-phase and three-phase OCs in stock.

The interviewers asked the 345 pharmacies that filled ethical drug prescriptions about their efforts to safeguard the privacy of users during consultations and while giving instructions on drug use. Only nine pharmacies (2.6%) had rooms set aside for consultation (Table 6). Sixty-three pharmacies (18.3%) had specified spaces in which pharmacists could speak privately with users, although no special precautions were taken to safeguard privacy. Thirty-three pharmacies (9.6%) explained that the interior structure did not allow them to maintain privacy and that they relied mainly on printed instructions.

Among the 52 pharmacies that usually stocked low-dose OCs, only two (3.8%) had a separate room specifically for consultation, and 11 (21.2%) had specified spaces for consulting with OC users. Two pharmacies (3.8%) indicated that the interior structure did not allow them to maintain user privacy.

DISCUSSION

The results of the present survey on low-dose OC transactions in 345 Japanese pharmacies indicate room for improvement in several areas.

Table 6. Measures to Maintain Customer Privacy during Consultation and Instructions on the Use of Drugs

Measure	All pharmacies (%) (n=345)	Pharmacies stocking low-dose OCs (%) (n=52)
Separate room available	9 (2.6)	2 (3.8)
Specified space available	63 (18.3)	11 (21.2)
No specified space but privacy maintained	150 (43.5)	20 (38.5)
Talk with OC users only at less crowded times	58 (16.8)	11 (21.2)
Instructions mainly written	33 (9.6)	1 (1.9)
Environment does not allow privacy	33 (9.6)	2 (3.8)
Not a problem because pharmacy not crowded	28 (8.1)	4 (7.7)

The room for improvement is seen in the attitude of pharmacists. The introduction of the birth control instructor system was discussed legislatively as an amendment to the Eugenic Protection Law¹⁴⁾ and introduced in Japan in 1952. Midwives and nurses can receive a birth control instructor license. At that time, the discussion included whether pharmacists should also be licensed instructors, and it was finally concluded that they should not.^{15,16)} It is assumed that the reason for this conclusion was partially because of questions about the ability of pharmacists to play that role. If pharmacists had been licensed, attitude of pharmacists of today toward oral contraception and their dealing of OCs should have been considerably different.

The separation between prescribing and dispensing drugs has long been debated in Japan. In 2001, the separation ratio reached 44.5%.¹⁷⁾ With progress in separation, the ability of pharmacists has become a topic of serious discussion. This survey found that 15.4% of registered pharmacies (not drugstores) did not accept prescriptions and did not dispense drugs. Since this survey covered only 1% of pharmacies in Japan, it may not be relevant to extrapolate the results to all pharmacies nationwide. However, if the same trend holds true in the remaining 99% of registered pharmacies, it would have serious implications, since it would mean that more than 6,000 do not actually function as pharmacies but merely as drugstores.

The present survey revealed that only 52 (15.1%) of the 345 interviewed pharmacies that dispensed drugs stocked low-dose OCs, while the remainder (84.9%) did not. The reasons for this low percentage may be because of lack of awareness of the low-dose formulations and less frequent use by Japanese women compared with their Western counterparts.¹⁸⁾ In addition, low-dose OCs prescribed by gynecologists in private clinics may be dispensed in-house. However, this was not examined in the present survey. Among pharmacies that did not usually stock low-dose OCs, 31 (10.6%) stated that they would not dispense them even if requested by users. It is irrational for a registered pharmacy not to accept prescriptions and dispense drugs when requested. A customer whose prescription is refused by one pharmacy must find another to fill it.

The results of the survey showed that finding sufficient space to stock prescription drugs in general, and low-dose OCs in particular, is an issue. OCs require relatively more shelf space than other drugs, because they are usually accompanied by numerous accessory items, such as bags or cases for carrying them, instruction pamphlets, etc. Furthermore, there is no guarantee that a single user will visit the pharmacy repeatedly to fill a prescription, and therefore the shelf space for low-dose OCs is apt to become a dead space in pharmacies. Some new measures may be necessary to enable pharmacies to stock, dispense, and give instructions for the use of low-dose OCs without concerns over inventory. Co-utilization of the stock center of the pharmacist community may be one solution to this problem.

The pricing of low-dose OCs is another issue. They are not covered by national health insurance if prescribed for contraception, and users must bear the entire cost. Several publications have pointed out that the prices of low-dose OCs are around ¥3,000 per menstrual cycle.^{19–28)} However, the present results showed that there is a wide variation in price depending on the pharmacy, with the cheapest being Synphase T28® (Tsumura) (¥1,167) and the most expensive Libian 28® (Yamanouchi) (¥7,000), which is felt to be too expensive by most users. Most common price range is between ¥2000–2499. Ever though, this price range seems to give an impression to OCs users that oral contraception is relatively expensive and this may be the one reason for their low rate of use among Japanese women.²⁹⁾

The dosage regimen of low-dose OCs is more complicated than those of other drugs, because it must be based on the individual's menstrual cycle. They must also be taken every day, although users sometimes fail to comply. It is recommended that women always have a second package of low-dose OCs so that they can adjust the dosage when a day is missed without disrupting the physiological hormonal cycle. Therefore a woman must pay about ¥30,000 for a clinical visit and laboratory tests and purchase a minimum of two packages when initiating low-dose OC use, which represents a considerable financial outlay.

Only five pharmacies interviewed stocked both one-phase and three-phase formulations, and only one stocked all three subtypes of three-phase low-dose OC. It would be preferable for a pharmacy to maintain an inventory of both types because they have different profiles of activity and, after consultation with a gynecologist, the user should select the one more appropriate for her physiological and hormonal condition. Administration of the more appropriate type also results in better compliance. Pharmacists should learn more about the interrelation between low-dose OC type and the physical condition of the user.

OCs are so common in the West that people do not consider their use a private matter. However, oral contraception is a relatively new concept in Japan, the general public perceives the use of OCs somewhat differently, and it is still a sensitive matter. Therefore Japanese pharmacists need to maintain confidentiality in their dealings with users of OCs. This survey found that few pharmacies have a separate consultation room to protect the privacy of drug users. Regulations governing the structure and facilities of pharmacies³⁰⁾ require a floor space of 19.8 m² or more. However, this amount of space may not be sufficient for a pharmacist to talk with users who want to safeguard their privacy, such as users of OCs. The present results showed that some pharmacists found it difficult to maintain strict confidentiality of OC users under current conditions. Gynecologists suggest that special care is necessary on the part of pharmacists when consulting on the use of OCs and giving instructions on their use.²⁹⁾ The same report also described the hesitancy women feel when visiting a pharmacy to receive OCs because of the open layout. Women prefer to receive OCs directly from their physician or gynecologist.

CONCLUSIONS

The present survey revealed that the current environment of many pharmacies is not adequate for users to visit, consult on OC use, and receive their prescriptions. To promote wider use of low-dose OCs, the facilities of pharmacies as well as the behavior of pharmacists need to be improved to safeguard the privacy of users. Analysis of the results of the present survey showed that:

- 1) Approximately 15% of pharmacies (not drug-stores) interviewed did not accept prescriptions and dispense drugs.
- 2) Few pharmacies stocked low-dose OCs.
- 3) Even among pharmacies that stocked low-dose OCs, only a few had a variety available for immediate dispensing.
- 4) The prices of low-dose OCs varied widely.
- 5) The space and structure of many pharmacies were not adequate for the needs of users of OCs.

Thus there is much room for improvement in pharmacies in Japan. In addition, pharmacists should give further consideration to privacy issues when consulting and giving instructions on the use of low-dose OCs.

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