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Impact of the French 3rd and 4th generation pill scare in women seeking termination of pregnancy

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Abstract

Introduction: The aim of this study was to evaluate changes in the contraceptive profile of women seeking termination of pregnancy following the debate on 3rd and 4th generation pills in France in 2012.

Materials and Methods: Single-center case-control study comparing the attitude to contraception before (between 02/15/2012 and 07/16/2012) and after the debate (between 02/25/2013 and 06/24/2013).

Results: A total of 291 patients consulted before and 601 after the debate. We showed that there were more students (+9.5%), more single women (+8.3%) and fewer working women (-7.7%) in the cohort after the debate. After the termination procedure, prescriptions for long-acting reversible contraceptive (LARC) methods increased (+7.8%, p=0.03), in particular in patients aged 25 or younger including nulliparous (+12.6%, p=0.02).

Conclusion: The media alert about the pill led to a change in the contraceptive standard in the post-abortion period and altered patient profiles. An increase was notably observed in certain vulnerable populations (high school students, unemployed and single women). It remains to be seen whether these changes are transient or permanent.

INTRODUCTION

France is characterized by a model of contraception that is heavily medicalized in which the pill holds a dominant place (1). The French contraceptive landscape shows a high level of theoretical efficiency, yet the number of pregnancy terminations is high, amounting to 14‰ (2) (3). Since 2007, the French National Authority for Health (HAS) has recommended that 3rd and 4th generation pills no longer be prescribed due to increased risk of thromboembolism compared with second-generation pills (4). However, 3rd and 4th generation pills have been partially reimbursed since 2009. At the end of 2011, the increased thromboembolism risk associated with 3rd and 4th generation pills was confirmed twice by Lidegaard *et al.* (5) and HAS proposed to stop reimbursing these pills in September 2013. Besides, on December 14, 2012, a leading daily newspaper published the headline "Warning about the pill" following a complaint lodged by a young woman who suffered a stroke due to the use of 3rd generation pills (6). There was subsequently intense debate in the French media about the risk with these last-generation pills. The decision to stop reimbursing 3rd and 4th generation pills was brought forward to March 2013, leaving women with less than 6 months to see their healthcare professional in order to change contraception.

The FECOND survey was repeated in 2013 (7) to examine the latest trends in contraception in France and particularly to assess the impact of the pill scare on the contraceptive practices of the general population. In particular the survey reported a change in the contraceptive model. The number of terminations increased by 5% following the debate (8) and it is interesting to consider the change in the contraceptive profile of the population seeking to terminate their pregnancy. Our main objective was to study the impact of the debate about 3rd and 4th generation pills on the contraceptive practices of women seeking termination of their pregnancy by comparing their stated method of contraception before and after the debate.

MATERIALS AND METHODS

Design

We conducted a single-center case-control study in the pregnancy termination clinic at Rennes Teaching Hospital. The study group consisted of patients seeking a termination of pregnancy after the debate, between 02/25/2013 and 05/15/2013. The control group consisted of patients recruited before the debate, between 05/15/2012 and 07/16/2012. The inclusion criteria were women seeking a termination of pregnancy during the inclusion periods. The exclusion criteria were patients with missing contraceptive data. Electronic patient files were used to collect the data which was then compiled into anonymous Excel® files. The study was approved by the Institutional Review Board of the French College of Obstetricians and Gynecologists (CEROG-2011-GYN-08–03).

Collected data

Data were collected in a retrospective manner. They included: sociodemographic data (age, country of birth, marital status, professional status, education level), medical and surgical information, gynecological history (gravidity, parity, pregnancy termination history, miscarriage, ectopic pregnancy, pelvic infection, latest Pap smear, vaccination against Human Papillomavirus) and data on termination of pregnancy (term, complications, post-abortion consultation, partner's opinion). We also collected data on the contraceptive method used, which was stated before and after the termination procedure. Contraceptive methods were classified into medical and non-medical methods. The medical methods were divided into 4 categories: 1) oral contraception (combined or progestin-only pill), 2) contraceptive skin patch and vaginal ring, 3) long-acting reversible contraceptive methods (LARC) represented by the intrauterine device (IUD) and the contraceptive implant, and 4) permanent methods with tubal ligation. The non-medical methods were divided into two categories: the natural contraception (mainly withdrawal and Ogino-Knaus methods) and the barrier methods (condoms and spermicide).

Statistical analysis

Statistical analyses were conducted using Chi-Square tests or Fisher's exact tests, as appropriate, to compare proportions, while Student's *t* test was used for comparison of quantitative variables as means and standard deviations. We used R software version 3.1.2. $P \leq 0.05$ was considered significant.

RESULTS

During the study periods before and after the debate, 910 patients seeking abortion consulted with the pregnancy termination clinic. Eighteen patients were excluded from the study due to incomplete contraception data. A total of 892 patients were included of which 291 patients for the first period before the media debate on the 3rd and 4th generation pill (control cohort). There were 619 patients for the second period after the debate (study cohort).

Description and comparison of populations (Table 1)

The average age was 27.6 years (+/-0.4) and 27.0 years (+/-0.3) before and after the pill debate respectively (NS). We found a greater number of single women in the cohort after the debate, rising from 40.1% to 48.4% (p=0.02) and a fall of 8% for women who were married or with partners (p=0.002). In the case of working women, 58.7% were employed before the debate as against 51% afterwards (p=0.04). The number of students rose after the debate: 17.4% versus 26.9%, respectively (p=0.003). Primigravida and nulliparous women were similar in the two groups: 36.3% versus 37.8% and 49.8% versus 50.6%, respectively. The proportion of primigravida women was higher after the debate: 20.1% as against 15.2%, marking a significant trend (p=0.1). The previous abortion rate was similar in the two groups: 31% versus 35.9% before and after the debate, respectively (NS). The average term of abortion was 8.8 (+/-0.1) weeks' gestation before and after the debate: 18.2% versus 23.9%, although the statistical significance threshold was not reached (p=0.08).

Contraceptive method used before and after pill debate

Data on contraceptive methods used before abortion are shown in Table 2. Before the debate, 58.4% of patients used contraception versus 52.4% after the debate (p=0.1). Among the women using medical contraception, the rate of pill users declined after the debate: 32.6% versus 26.2% (p=0.1).

Data on contraceptive methods used after abortion are shown in Table 3. Almost all women used contraception before and after the debate: 98.2% and 97.2% of patients, respectively. The proportion of women choosing effective medical contraception did not change: 96.5% before and 95.4% after the debate (p=0.5). Among the women using medical contraceptive methods, there was a significant decline in pill use: 48.8% before the debate and 41.6% afterwards (p=0.05). There were mainly fewer combined oral contraceptive pill users (45.4% versus 38.8%). On the other hand, the number of LARC users increased from 42.9% to 50.7% (p=0.03). The majority of post-abortion patients opted for a LARC method after the debate. The proportion of IUDs (intrauterine devices) immediately post abortion increased from 27.8% to 32.6% (p=0.2) before and after the debate respectively. The proportion of contraceptive implants increased by 3% after the debate (p=0.3).

Analysis of the subgroup of patients using LARC post abortion (Table 4)

The increase in the number of LARC users in the post-abortion period involved mostly patients under 25 years of age. The proportion of women under 25 years of age using LARC increased from 28% to 40.6% (p=0.02), when comparing before and after the debate, respectively, particularly in nulliparous women (rising from 29% to 41.6% (p=0.017)). We also observed an increase in IUD use among women having their first abortion: from 53.6% to 64.9% (p=0.03), when comparing before and after the debate.

DISCUSSION

To our knowledge, this is the first study to examine the impact of the debate over the 3rd and 4th generation pill (referred to as the French “pill scare”) on the contraceptive use of patients seeking abortion. We showed that there was a diversification in contraceptive practices after the debate about the 3rd and 4th generation pill, particularly after abortion. After the debate, the use of pill-based contraceptive methods declined by 7.2% (p=0.05) to the benefit of LARC methods which

increased by 7.8% (p=0.03) after abortion, especially the IUD. This was the option chosen in particular by women of 25 years or younger (+12.6%, p=0.02) including nulliparous women (+12.6%, p=0.01). The French pill scare about 3rd and 4th generation pills led to a change in contraceptive practices in young and/or nulliparous women. We showed a higher proportion of patients aged 20 to 29 years (+7%, p=0.03) and also of patients with no steady partner (+8.3%, p=0.02). These findings seem logical because this population is used to taking combined oral contraceptive pills according to the French model (7) and, following the pill scare, use of these oral contraceptives fell, exposing the patients to unintended pregnancies.

In France, oral contraceptive use is still predominant with 50.6% of users in 2012. LARC methods are the second favorite methods with 20.7% of IUD users, mainly women over 35 years of age (9) (10). Two thirds of induced abortions occur in women using contraception. In 2010, the FECOND survey assessed issues of reproductive and sexual health, showing a slight shift away from oral contraception (-4.6%) between 2000 and 2010. In the survey repeated in 2013, this effect was shown to be greater after the debate. In our study, the number of post-abortion pill users fell after the pill scare. In our population, LARC use increased by 7.8% (p=0.03) with a majority of IUDs (64.2%) after induced abortion. This is in line with the observation of a 22% rise in IUD sales by the French National Agency for Medicine and Health Product Safety (ANSM) (11). Contrary to the FECOND survey, we did not find an increase in non-medical methods, probably due to the limited power of our study (7). The sharp increase in LARC use among women aged under 25 and nulliparous women showed a personal move to a less burdensome contraceptive method. The FECOND survey also observed this increase in LARC use in younger women: +8% in women of 25 to 29 years and +3% in those of 20 to 24 years. The French contraceptive model (condoms at sexual debut, pill until wanted pregnancies, and IUD after all wanted pregnancies) remains predominant in France. This model failed particularly among younger and single women and women with no steady partner (12) (13). LARC methods seemed suitable for this population with a continuation rate of 85% as against 68% for the pill (14). The debate appears to have changed the French contraceptive

landscape and increased the number of abortions. Whether this increase will be transient or not remains to be seen. This change also came after several years of reluctance on the part of healthcare professionals to prescribe IUDs to nulliparous women (15) (16). Despite the national HAS guidelines, IUD prescriptions did not increase until 2010 (7) although the devices were recommended as first-line contraception like combined oral contraceptive pills. Fear of pelvic inflammatory disease and painful insertion limited the use of LARC methods in nulliparous women (17). Many publications have reported the lack of any risk of infection or infertility with IUD use (18) (19) (20). Moreover, LARCs are an attractive option for reducing the number of unintended pregnancies and therefore the number of induced abortions (21). According to a recent American prospective study known as the Contraceptive CHOICE Project, IUD use reduced the proportion of unintended pregnancies from 15.8% to 3% and voluntary terminations from 4.1% to 0.9% (22). In our study, physicians' attitudes towards contraception seemed to be changed: they prescribed more IUDs after the debate according to the increased sales figures (+22%) in the French general population (ANSM) (11).

In 1995, numerous articles accused the 3rd generation pill of increasing thromboembolic risk compared to second-generation pills. Despite ANAES (French national health accreditation and evaluation agency) guidelines advocating the use of IUDs, the pill remained the first line of prescription (23) (24), with more than 2 million French users towards the end of 2011. In 2010, one in two women was prescribed a 3rd or 4th generation pill that was partly reimbursed in 2009 (7) (23). The pharmaceutical laboratories continued to promote it, arguing that these pills caused less weight gain and treated acne. Danish publications on 3rd and 4th generation pills stimulated the debate. However, the change in contraceptive behavior occurred only after a highly publicized lawsuit over a stroke in a young woman in December 2012. The decision promptly taken by the French government to stop reimbursing 3rd and 4th generation pills heightened women's anxiety whereas thromboembolic risk was lower for pill users than for pregnant women: 6/10000 as against 4/10000 (23) (25) (26). The French Department of Health advised not to panic or suddenly

discontinue contraception just one month after the lawsuit was filed (27). Pozzi *et al.* examined the impact of the "pill alert" on the number of elective abortions in four pregnancy termination clinics in Paris (8). From February 2013 to April 2013, they observed a 4% increase in the number of induced abortions, an observation also confirmed by a national survey (7). The French government made the same mistake as was made during the 1995 British "pill scare" when elective abortions rose by 8% during the following year, particularly in women under the age of 20. In our study, the debate mainly had an impact on patients of 20-29 years old with 7% (p=0.03) more patients seeking induced abortion. At the sexual debut of these women, the pill was central to the French contraceptive model (7). Moreover, women in disadvantaged social groups (pupils, students or women in vocational training) were the most exposed (28). In our study, the proportion of women who sought to terminate their pregnancy was already high before the debate but it increased to a worrying level after the debate (+9.3%, p=0.003). Public acceptance appeared to differ between social groups, as N. Bajos (7) and I. Nisand (25) reported that the information seemed to have been perceived as clearer but also more alarming by the less affluent socioprofessional categories. The emergency measures taken by the health authorities caused much anxiety which was disproportionate to the real risk. The message advising users not to discontinue contraception had not been heard and came too late. Induced abortion was considered less of a risk than contraception. Although national advertising campaigns did not change the French contraceptive landscape in 2007 and 2010, the French pill scare led to a change in contraceptive use (fewer combined contraceptive pills and more LARC) in France but with a higher number of induced abortions, particularly among the most vulnerable (26).

Study limitations

Our study has certain limitations. First of all, this is a retrospective case-control study that is limited by its lack of information and heterogeneous data gathering methods. However, it reflects the daily reality of a pregnancy termination clinic and shows the positive and negative impact of the media debate over 3rd and 4th generation pills. There appears to be a negative impact on the population

that used combined oral contraceptive pills: mostly single women of 20-29 years. These women had unexpectedly discontinued their contraception, resulting in a higher rate of induced abortion. On the other hand, there was a change in the use of LARC methods, notably IUDs, following a medical discussion after induced abortion. We also believe that the French pill scare will result in a change in physicians' contraceptive prescription habits.

CONCLUSION

The French pill scare caused anxiety that led to an increase in the abortion rate, in particular among women in vulnerable situations, such as students (+9.5%, p=0.03) and single women (+8.3%, p=0.02). Our study showed a 7.8% (p=0.03) increase in LARC prescription in post-abortion patients after the debate. IUDs were preferred, notably by women aged 25 or younger, including nulliparous women, for whom an increase of 12.6% (p=0.02) was seen after induced abortion. After the French pill scare, patients and health practitioners opted for contraception with no thromboembolic risk and less risk of unintended pregnancy. Nevertheless, it is unfortunate that the first elective abortion was necessary for these patients to be prescribed appropriate contraception. Serious consideration of an effective primary prevention strategy for unintended pregnancy prevention should be undertaken, with a particular focus on teenagers in the hope of impacting their adult life.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

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Table 1. Comparison of population characteristics

Characteristics	Before debate n=291 (%)	After debate n=601 (%)	p-value
Age (years)			
< 20	39 (13.4%)	78 (13%)	0.9
20-24	79 (27.1%)	186 (30.9%)	0.3
25-29	56 (19.2%)	134 (22.3%)	0.4
30-35	56 (19.2%)	100 (16.6%)	0.3
35-39	43 (14.8%)	74 (12.3%)	0.6
≥ 40	18 (6.2%)	29 (4.8%)	0.6
Marital status			
Married/civil partnership	55 (19.5%)	69 (11.6%)	**0.002**
De facto union	94 (33.3%)	181 (30.4%)	0.4
Divorced or separated	20 (7.1%)	57 (9.6%)	0.3
Single	113 (40.1%)	286 (48.4%)	**0.02**
Country of birth			
France	232 (82.3%)	515 (86.6%)	0.12
Other	50 (17.7%)	80 (13.4%)	0.12
Professional status			
Employed	165 (58.7%)	304 (51.1%)	**0.04**
High school/Student/Training	49 (17.4%)	159 (26.7%)	**0.003**
Unemployed	54 (19.2%)	114 (19.5%)	1
Housewife	13 (4.6%)	16 (2.7%)	0.2
Education level			
Primary/Middle school	56 (19.9%)	143 (24%)	0.2
High school	111 (39.5%)	203 (34.1%)	0.1
University	114 (40.6%)	249 (41.8%)	0.8
Smoking			
Yes	168 (58.1%)	354 (58.9%)	0.9
No	121 (41.9%)	247 (41.1%)	0.9
Gravidity			
1	105 (36.3%)	227 (37.8%)	0.7
2	49 (17%)	118 (19.6%)	0.4
3	51 (17.6%)	98 (16.3%)	0.7
4	29 (10%)	71 (11.8%)	0.5
≥ 5	55 (19%)	87 (14.5%)	0.1
Parity			
0	144 (49.8%)	304 (50.6%)	0.9
1	44 (15.2%)	120 (20%)	0.1
2			
≥ 3			

	57 (19.7%)	104 (17.3%)	0.4
Previous miscarriage	44 (15.2%)	73 (12.1%)	0.2
No			
Yes			
	242 (83.7%)	505 (84%)	0.9
Previous voluntary termination	47 (16.3%)	96 (16%)	0.9
0			
1-2			
≥3	186 (64.1%)	412 (69.1%)	0.2
	94 (32.4%)	179 (29.8%)	0.4
Term of abortion	10 (3.4%)	7 (1.2%)	**0.038**
5-6 WG	53 (18.2%)	142 (23.6%)	0.08
7-8 WG	114 (39.2%)	236 (39.3%)	1
9-10 WG	80 (27.5%)	153 (25.5%)	0.6
11-12 WG	30 (10.3%)	45 (7.5%)	0.2
13-14 WG	14 (4.8%)	25 (4.2%)	0.8

WG = weeks of gestation

Table 2. Pre-abortion contraceptive methods used before and after debate

Pre-abortion contraception	**Before debate (%) n = 291**	**After debate (%) n = 601**	**p-*value***
Contraception			
Yes	170 (58.4%)	315 (52.4%)	NS (0.1)
No	121 (41.6%)	286 (47.6%)	NS (0.1)
Type of contraception			
Medical	102 (35%)	178 (29.6%)	NS (0.1)
Non-medical	68 (23.4%)	137 (22.8%)	NS (0.9)
Barrier	64 (22.3%)	125 (20.8%)	NS (0.7)
Natural	4 (1.4%)	12 (2%)	NS (0.7)
Medical contraception			
Oral	95 (32.6%)	163 (26.2%)	NS (0.1)
LARC	4 (1.4%)	10 (1.6%)	NS (1)
Patch/Ring	3 (1%)	5 (0.8%)	NS (0.7)
Other (Tubal ligation)	0	0	NS (1)
Oral contraception			
Combined	85 (29.2%)	147 (24.5%)	NS (0.1)
Progestin only	10 (3.4%)	16 (2.7%)	NS (0.6)
LARC			
IUD	4 (1.4%)	8 (1.3%)	NS (1)
Implant	0	2 (0.3%)	NS (1)

LARC = Long-Acting Reversible Contraception IUD = Intrauterine Device

Table 3. Analysis of changes in post-abortion contraceptive use before and after debate

Post-abortion contraception	Before debate n = 291 %	After debate n = 601 (%)	p-value
Contraception			
Yes	286 (98.2%)	585 (97.2%)	NS (0.5)
No	5 (1.7%)	16 (2.7%)	NS (0.5)
Type of contraception			
Medical	281	574	NS (0.5)
Non-medical	(96.5%)	(95.4%)	NS (1)
	5 (1.7%)	11 (1.8%)	
Barrier			NS (0.9)
Natural	5 (1.7%)	11 (1.9%)	NS (1)
	0	0	
Medical contraception			
Oral	142 (48.8%)	250 (41.6%)	**0.05**
LARC	125 (42.9%)	305 (50.7%)	**0.03**
Patch/Ring	9 (3.1%)	11 (1.8%)	NS (0.3)
Other (Tubal ligation)	5 (1.7%)	8 (1.3%)	NS (0.7)
Oral contraception			
Combined	132 (45.4%)	233 (38.8%)	NS (0.07)
Progestin only	10 (3.4%)	17 (2.8%)	NS (0.8)
LARC			
IUD	81 (27.8%)	196 (32.6%)	NS (0.2)
Implant	44 (15.1%)	109 (18.1%)	NS (0.3)

LARC = Long-Acting Reversible Contraception IUD = Intrauterine Device

Table 4. Individual variables associated with LARC users post abortion, before and after debate

Variables	Before debate	After debate	p-*value*
	(n=125 LARC users)	**(n= 305 LARC users)**	
Age (years)			
< 20	17 (13.6%)	49 (16.1%)	NS (0.6)
20-24	18 (14.4%)	75 (24.6%)	**0.03**
25-29	27 (21.6%)	59 (19.3%)	NS (0.7)
30-34	28 (22.4%)	56 (18 .4%)	NS (0.4)
35-39	28 (22.4%)	54 (17.7%)	NS (0.3)
≥ 40	7 (5.6%)	12 (3.9%)	NS (0.6)
Country of birth			
France	103 (83.0%)	263 (86.8%)	NS (0.4)
Other	21 (16.9%)	40 (13.2%)	NS (0.4)
Marital status			
Steady partner	76 (61.2%)	139 (45.8%)	**0.005**
Casual partner	48 (45.8%)	164 (54.1%)	**0.005**
Education level			
Primary/Middle	29 (23.4%)	123 (40.6%)	NS (0.3)
school	52 (42%)	98 (32.3%)	NS (0.07)
High school	43 (34.6%)	82 (27.1%)	NS (0.5)
University			
Professional status			
Employed	81 (65.3%)	161 (53.1%)	**0.028**
High school/	12 (9.7%)	73 (23.9%)	**0.001**
Student	31 (25%)	71 (23.4%)	NS (0.78)
Unemployed/			
Housewife			
Parity			
0	36 (29%)	127 (41.6%)	**0.017**
≥ 1	89 (71%)	178 (58.4%)	**0.017**
Previous			
miscarriage	67 (53.6%)	198 (64.9%)	**0.037**
0	50 (40%)	103 (33.8%)	NS (0.3)
1-2	8 (6.4%)	4 (1.3%)	**0.007**
≥ 3			

Term of abortion			
5-8 WG	70 (56%)	181 (59.3%)	NS (0.6)
9-14 WG	55 (44%)	124 (40.7%)	NS (0.6)
Smoking			
Yes	72 (57.6%)	182 (59.7%)	NS (0.8)
No	53 (42.4%)	123 (40.3%)	NS (0.8)

WG = weeks of gestation