Results of a 4-year study on 15,447 medical abortions provided by privately practicing general practitioners and gynecologists in France

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uccess of this study was to determine: (1) whether early medical abortion at home is a reliable and safe method when provided by physicians in their private practice outside abortion facilities, and (2) whether early medical abortions at home supervised by general practitioners (GPs) in their private practice have the same efficacy rate and the same safety as those supervised by gynecologists in their private practice.

Study Design: The data are drawn from a prospective survey of 15,447 in-home medical abortions up to 49 days after the last menstrual period (LMP), provided within the Ile-de-France abortion network between privately practicing physicians and hospitals (REVHO: Réseau entre la ville et l’hôpital pour l’orthogénie), from 2005 to 2008.

Results: Approximately 150 privately practicing physicians participate in the REVHO network, and over half of them are general practitioners. Three physicians, called the main providers, performed over half the medical abortions. The overall efficacy rate was 97.43% (96.48% for the gynecologists, 96.44% for the general practitioners, and 98.31% for the three main providers). The rate was higher when abortion completion was determined by a decline in serum human chorionic gonadotropin rather than ultrasound.

Conclusion: Early medical abortion at home supervised by gynecologists and GPs practicing in their private offices is a reliable and safe method. Promoting networks such as REVHO increases local accessibility to this type of abortion in France.

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1. Introduction

Using mifepristone for early medical abortion combined with a prostaglandin has been authorized in France and in China since 1988. In 2010, 46 countries had approved the use of mifepristone for medical abortions [1]. The effectiveness, safety and acceptability of this method for early medical abortions have now been fully demonstrated and account for its widespread use [2]. In many countries early medical abortion has been simplified by home self-administration of misoprostol which has been shown to be safe and acceptable [3–6]. In the United States (US) where mifepristone became available in 2000, self-administration of misoprostol at home has rapidly become a standard practice and over one million women have used this form of administration with the supervision of specialized clinics in almost all cases [7,8]. In France, early medical abortion at home was authorized in 2001 but was possible at first only under the medical supervision of doctors working in abortion facilities in hospitals or clinics.

In 2004, legislation made it possible for physicians — both gynecologists and general practitioners (GPs) — to provide at-home medical abortions in their private practices outside abortion facilities of hospitals and clinics [9]. The conditions for private practice are (1) abortions should take place within 49 days since the last menstrual period (LMP); (2) physicians must have the required training and professional experience and a partnership with a hospital abortion center able to treat the patient in case of complications. In France, doctors can easily be supplied mifepristone at local pharmacies and providing early medical abortion does not increase rates for their professional
insurance [9,10]. As a result, in France in 2009, 10.22% of the 222,137 surgical and medical abortions and 20.97% of the 108,247 medical abortions were supervised by private physicians outside abortion facilities [11]. The method will spread all the more rapidly if many physicians adopt it in their private practice.

In 2004, physicians practicing abortions in four hospitals of Ile-de-France (a region covering the city of Paris and surrounding areas) came together to create the REVHO (Réseau entre la ville et l'hôpital pour l'orthogénie)* network with privately practicing physicians. The aim was to develop the offer of at-home early medical abortion outside the hospital [9]. REVHO has been active since 2005 and is financed by the national health insurance fund. It provides theoretical and practical training to physicians and puts them in contact with a referral hospital for establishing a contract. By 2008, 4 years after its creation, 15,447 home medical abortions had been performed within this network by private physicians. A database on these abortions was created, using standardized medical records filled out by physicians for each patient. This prospective study presents the results from the statistical analysis of this large database. The main aim of this publication is to communicate results on the efficacy and safety of home medical abortions supervised by physicians, including general practitioners, in the context of their private practice. The second objective is to analyze differences in results and practices between private gynecologists and GPs. Finally, the goal is to demonstrate the relevance of a network between private physicians and hospitals for increasing access to abortion for women and encouraging private physicians, and particularly GPs, to provide early medical abortions in France.

2. Materials and methods

2.1. Database

A database was compiled on all abortions carried out in the REVHO network. The data were declarative and were routinely entered into the database from standardized medical records on each patient, transmitted by all private physicians involved in the REVHO network. This file included information on the patient (age, number of weeks of gestation calculated since the LMP, obstetrical history, etc.), the drug regimen used, the outcome of the abortion, any complications observed, and supplementary treatment administered. The patient data were de-identified and the database validated by the CNIL (Commission nationale de l'informatique et des libertés), the French national authority set up to protect privacy and personal data. The data were analyzed with Epi-Info™ software (6.04FR version). The statistical tests — chi-square for percentage comparisons and PROC GLM or t test for means comparisons — were carried out on SAS software (version 9.2). The differences were considered significant at p ≤ .05.

There is no need for an institutional review board approval for this study.

2.2. Physicians and abortion clinics involved in REVHO

GPs and gynecologists in the REVHO network provide abortion in their private offices outside of hospital or clinic abortion facilities. In order to obtain authorization to perform medical abortions, physicians sign a contract with a hospital practicing abortions. The network provides training for GPs. At the end of 2008, 148 physicians and 22 hospital centers (10 of which were situated in Paris and 12 in the suburbs) were members of REVHO.

2.3. Medical abortion process

The patient requests an abortion during a first consultation in the private office of the physician of her choice, who assesses her eligibility for medical abortion treatment at home, gives her information on the procedure and orders additional tests [serum human chorionic gonadotropin (hCG) measurement, pelvic ultrasound to confirm gestational age, determination of blood group and Rhesus factor, etc.]. After a legally mandated 7-day interval, the patient has a second consultation in the physician’s office where she signs an informed consent form. The physician gives the patient the mifepristone which she swallows in the presence of the doctor and the misoprostol which she self-administers at home 48 h later. In addition, the physician writes a prescription for analgesics. The patient is asked to return for a follow-up visit 14–20 days later. Should secondary surgical aspiration prove necessary, she is referred to the referral hospital center. The total cost for the patient (excluding additional routine tests and treatment for any complications) is about €200, 70% of which is covered by national health insurance.

The maximum gestation period authorized for this procedure is 49 days after LMP, including the 7-day waiting interval.

2.4. Medical abortion regimen

The most frequently adopted regimen (49%) consisted of oral administration of 600 mg mifepristone, followed 48 h later by 800 mcg misoprostol. In 28% of cases, the regimen consisted of administration of 200 mg mifepristone, followed by 400 mcg misoprostol, and in 23% of cases 200 mg mifepristone followed by 800 mcg misoprostol. Regardless of the dose, misoprostol may be taken either per os, sublingually or buccally.

Abortion completion was evaluated either by pelvic ultrasonography, or by sequential hCG blood tests (the first before mifepristone and the second 12–14 days after). In

* See the REVHO site: http://www.revho.fr/.
cases of complications, both serum hCG measurement and ultrasonography were used.

3. Results

3.1. Background characteristics

Within the first year, 2478 medical abortions were provided within the REVHO network by private physicians outside hospital and clinic abortion facilities. This number per year had almost doubled by 2008, when it reached 4843 (Table 1). In total, 15,447 abortions were performed over the 4-year period.

Physician participation also increased accordingly during the same 4-year period: the number of private physicians participating in REVHO more than doubled, from 57 (38 gynecologists and 19 GPs) to 148 (69 gynecologists and 79 GPs). Whereas gynecologists accounted for two thirds of the physicians in 2005 (67%), they accounted for less than half (47%) in 2008.

Wide disparities existed between physicians’ practices (Table 2). In 2008, over one third of physicians had performed fewer than five abortions, one third had performed between 5 and 19, and just over one fifth had performed between 20 and 99. GPs had performed significantly fewer abortions than had gynecologists: 44% of GPs had performed fewer than five in 2008, compared to 25% of gynecologists (p<.02).

Finally, three physicians (one GP and two gynecologists), who we refer to as the main providers, had each performed over 200 medical abortions in 2008. One of them, the GP, had performed more than 400. Over the four-year period, close to half of all abortions had been supervised by these three physicians.

The patients’ average age was 28.9 years (standard deviation 6.4 years), with a range of 14–58 years. Three quarters of the women were between 20 and 34 years old, about 7% were 40 or over. Minors (under 18) accounted for fewer than 1% of abortions.

The physicians declared the amenorrhea duration in entire weeks. With this calculation, the average period was 6.12 weeks of amenorrhea (standard deviation 0.8 week). In total, three out of four abortions were performed between 6 and 7 weeks after LMP (Table 3). A very small percentage (1.6%) of abortions exceeded the recommended interval of 7 weeks of amenorrhea. More than one in five abortions took place before at least the end of the fifth week after LMP.

3.2. Efficacy

Patients were advised to visit their physician in his/her private office two to three weeks after the abortion. Out of 15,447 patients, 2985 (19.3%) did not return for this follow-up visit.

Ultrasonography was the method most frequently used by private physicians in REVHO to check successful completion of medical abortion (Table 4). In 2005, close to 87% of all abortions were evaluated by ultrasound, but in 2008 this had dropped to 68%. At the same time, we found an increase in the use of two serial serum hCG measurements at 2 week interval from 8.7% to 28.3% in four years. hCG and ultrasound were used for 4% of abortions: in the majority of these cases there was a reported diagnosis of a complication (not shown). In general, gynecologists used ultrasound more (68% of abortions) and GPs used hCG testing more (65%). Evaluation of pregnancy termination by post procedural hCG decline nevertheless increased significantly among gynecologists, from 12% in 2005 to 34.5% in 2008 (p<.001).

3.3. Complications and supplementary treatments

Results are available for those patients who came for their follow-up visit (n=12,462). The rate of complications was calculated on the basis of physician notifications.

Irrespective of the drug regimen used, 90.66% abortions within the REVHO network between 2005 and 2008 were

Table 1
Early medical abortions within the REVHO network

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
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</thead>
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<tr>
<td>Medical abortions n</td>
<td>2478</td>
<td>3882</td>
<td>4244</td>
<td>4843</td>
</tr>
<tr>
<td>Private gynecologists n</td>
<td>38</td>
<td>49</td>
<td>49</td>
<td>69</td>
</tr>
<tr>
<td>Private general practitioners n</td>
<td>19</td>
<td>39</td>
<td>60</td>
<td>79</td>
</tr>
</tbody>
</table>

Table 2
Number of early medical abortions per privately practicing physician in 2008

<table>
<thead>
<tr>
<th>Early medical abortions in 2008</th>
<th>1</th>
<th>2–4</th>
<th>5–19</th>
<th>20–49</th>
<th>50–99</th>
<th>100–199</th>
<th>200–399</th>
<th>&gt;400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private physicians n*</td>
<td>18</td>
<td>34</td>
<td>54</td>
<td>20</td>
<td>12</td>
<td>7</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>%**</td>
<td>12.2</td>
<td>23.0</td>
<td>36.5</td>
<td>13.5</td>
<td>8.1</td>
<td>4.7</td>
<td>1.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

* Number of physicians.
** % of physicians.

Table 3
Number of early medical abortions in relation to period of amenorrhea

<table>
<thead>
<tr>
<th>Gestation (weeks of amenorrhea)*</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>≥8</th>
</tr>
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<tbody>
<tr>
<td>Early medical abortions n</td>
<td>3418</td>
<td>6458</td>
<td>4959</td>
<td>242</td>
</tr>
<tr>
<td>%</td>
<td>22.7</td>
<td>42.8</td>
<td>32.9</td>
<td>1.6</td>
</tr>
</tbody>
</table>

* The duration of the gestation is calculated by the physicians as entire weeks since the LMP.
reported to have had no complications and the rates of reported incomplete abortion and ongoing pregnancy were, respectively, 6.74% and 0.79% over the 4 years.

There were, however, significant differences between the three groups of private physicians: gynecologists reported fewer complications (6%) than did GPs (9%) and the three main providers (11%) (p < .001) (Table 5). Reported excessive bleeding, as evaluated by physicians, which was around 0.5%, was significantly higher for GPs than for gynecologists or the three main providers. Only four patients needed blood transfusion, which corresponds to 0.03% of all abortions. Statistically, the occurrence of secondary infections was also slightly more frequently by GPs than by gynecologists or the three main providers (p < .04). Lastly, incomplete abortion was more frequently declared to be present by the main providers than by GPs and gynecologists (p < .001).

Over the 4-year period, four cases of extra-uterine pregnancy (0.03%) were reported, without any major consequences. No deaths occurred during the four-year period.

In 86.6% of cases, no additional treatment was given after the abortion, apart from analgesics or anti-D globulin for Rh-negative women. An additional dose of misoprostol was administered in 10.93% of cases (n = 1362) and treatment with antibiotics was given in 0.57% of cases (n = 71).

3.4. Efficacy rate

The efficacy rate over 4 years, defined as no secondary surgical intervention, was 97.4%, for all private physicians, which corresponds to the best international results for medical abortions before 49 days LMP[2,14]. A lack of precision remains, however, in so far as close to 20% of women did not attend their post-abortion visit. This percentage corresponds to findings elsewhere[15,16], and it is difficult to speculate on the outcome of the corresponding abortions. Current data do not allow us to say whether women who do not attend the follow-up visit are at a greater risk, and the necessity of a systematic follow-up visit remains an open issue[17,18].

Abortions in the REVHO network are usually performed early during pregnancy: the average time from LMP is 6.12 weeks.

Table 4

<table>
<thead>
<tr>
<th>Evaluation method</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial hCG alone, n*</td>
<td>108</td>
<td>411</td>
<td>564</td>
<td>975</td>
<td>2058</td>
</tr>
<tr>
<td>%</td>
<td>8.7</td>
<td>13.6</td>
<td>18.0</td>
<td>28.3</td>
<td>19.0</td>
</tr>
<tr>
<td>Ultrasonography alone, n*</td>
<td>1071</td>
<td>2512</td>
<td>2391</td>
<td>2357</td>
<td>8331</td>
</tr>
<tr>
<td>%</td>
<td>86.6</td>
<td>83.3</td>
<td>76.1</td>
<td>68.4</td>
<td>76.9</td>
</tr>
<tr>
<td>Ultrasonography + hCG, n*</td>
<td>58</td>
<td>91</td>
<td>186</td>
<td>112</td>
<td>447</td>
</tr>
<tr>
<td>%</td>
<td>4.7</td>
<td>3.0</td>
<td>5.9</td>
<td>3.3</td>
<td>4.1</td>
</tr>
<tr>
<td>Total</td>
<td>1237</td>
<td>3014</td>
<td>3141</td>
<td>3444</td>
<td>10,836</td>
</tr>
</tbody>
</table>

* Number of abortions.

4. Discussion

The REVHO network was created to facilitate the development of at-home early medical abortions provided by private physicians in Ile-de-France. The results obtained by analyzing the REVHO database on 15,447 cases show that this method is effective and safe. The efficacy rate, defined by the absence of secondary vacuum aspiration [12,13], was 97.4%, for all private physicians, which corresponds to the best international results for medical abortions before 49 days LMP [2,14]. A lack of precision remains, however, in so far as close to 20% of women did not attend their post-abortion visit. This percentage corresponds to findings elsewhere [15,16], and it is difficult to speculate on the outcome of the corresponding abortions. Current data do not allow us to say whether women who do not attend the follow-up visit are at a greater risk, and the necessity of a systematic follow-up visit remains an open issue [17,18].

Abortions in the REVHO network are usually performed early during pregnancy: the average time from LMP is 6.12 weeks.
weeks. In 22.7% cases, the abortion was performed before 42 days after LMP. More than one in five abortions is declared to take place before the end of the fifth week after LMP. Several hypotheses can explain this very short delay: the use of over-the-counter sensitive pregnancy tests by the women at the time of expected menses, an approximate calculation of the period of amenorrhea by the doctors and finally, in a certain number of cases, the non respect of the mandated 7-day interval between the first consultation and the uptake of mifepristone. The respective part of these various hypotheses is not known at present. In any cases, the results illustrate the ability of private physicians to meet women’s needs quickly.

Training provided by REVHO has made it possible to include private GPs who, since 2007, have been the majority of abortion providers. On average, GPs perform fewer abortions annually than gynecologists. Three private physicians, the main providers, performed over half the medical abortions, and one of them, a GP, performed over 400 per year. Apart from those performed under the supervision of the three main providers, where the overall efficacy rate was particularly high (98.31%), abortions had the same efficacy rate whether they were provided by private gynecologists (96.48%) or GPs (96.44%). The differences observed according to drug regimens are not discussed here because the specific routes of misoprostol are not known.

A significant difference was observed according to whether the termination was confirmed using ultrasound or a decline in serum hCG, except for known cases of complications where both examinations were usually carried out. Thus, secondary surgical aspiration was significantly more frequent when ultrasound was used (2.05%) than when serial hCG blood tests were used (0.94%), and this difference increased when the ultrasound was ordered by GPs (rate of secondary vacuum aspiration 6%). The same results were found with regard to the repeat dose of misoprostol after a follow-up ultrasound, which was 15.26% in the case of GPs, compared to 5.04% when hCG testing was used (data not shown). Our hypothesis is that the private GPs who were not familiar with ultrasound had difficulties interpreting normal post-abortion images. The results of the main providers, who performed follow-up ultrasonography themselves, confirm that expertise reduces the diagnosis of failure [5,19]. The use of two sequential hCG measurements (the first one before administration of mifepristone and the second one 2 weeks later) as a reference method [20,21] is currently recommended by REVHO as good practice and is increasing with time, including among gynecologists, which should contribute to decreasing the number of secondary surgical aspirations. Taking into account all drug regimes, there were no reported complications in 90.66% abortions within REVHO, and the frequency of success (97.43%) was comparable to that observed elsewhere [2]. Significant differences existed between the three groups of private physicians: GPs and main providers diagnosed incomplete abortion and gave an additional dose of misoprostol more often than did gynecologists. Likewise, the occurrence of excessive bleeding or infection as notified by the physicians was reported more frequently by GPs than by the other two groups. It is not possible to determine whether these complications were really more frequent when GPs provided the abortions or whether they were over-estimated by GPs, who, on average, performed fewer abortions per year and practiced fewer gynecological examinations than did specialists. However, blood transfusion was infrequent and less than the estimated 1 per 1000 reported elsewhere [2], which confirms the safety of early medical abortions provided by physicians in their private practice. The occurrence of uterine infection (0.25%) was within the limits of the frequencies reported in a review of the literature [22]. No case of serious infection was reported in this large series of abortions within the REVHO network.

The large size of the series indicates that home abortion, which is women’s preferred method of early abortion in France [23], is a reliable and safe method when it is practiced under the supervision of physicians, including GPs, in their private offices. The rarity of major complications reported and the high efficiency rates should encourage GPs to provide early medical abortions at home within their everyday practice. This will improve access for women who wish to abort up to 49 days LMP by increasing the pool of providers in France. We can conclude that the creation of networks between private physicians and abortion clinics...
such as REVHO offers a solution applicable to other areas in France.

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References


