Medical versus surgical abortion efficacy, complications and leave of absence compared in a partly randomized study

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Abstract

To provide optimal information to women choosing between early medical and surgical abortion, rigorous comparisons of the two methods are warranted. We compared the outcome of 1135 consecutive women with gestational age (GA) ≤ 63 days receiving either a medical (600 mg mifepristone and 1 mg gemeprost) or a surgical abortion (vacuum aspiration in general anesthesia). One hundred eleven of these women were randomized for abortion method. Surgical interventions and complications leading to readmission within the following 15 weeks were identified through a computer system. Information about antibiotic treatment, leave of absence and number of contacts to the health care system were obtained from mailed questionnaires. The number of complications was identical after the two methods, but surgical abortion was associated with a higher success rate [97.7% (708/725) vs. 94.1% (386/410), p < .01] and also with a higher risk of antibiotic treatment [7.8% (37/467) vs. 3.7% (13/356), p < .05]. The median leave of absence was shorter in women choosing a medical (1 day) than a surgical termination (2 days), p < .05. On average, one third of all the women requested at least one extra unscheduled consultation apart from a routine follow-up visit. We conclude that the chance of a primary successful termination at GA ≤ 63 days is higher after a surgical abortion in general anesthesia compared to a medical abortion induced with 600 mg mifepristone and 1 mg gemeprost. A surgical abortion is associated with an increased risk of antibiotic treatment compared to medical abortion. The women’s need for follow-up might be higher than we expect.

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1. Introduction

Through the last decade, medical abortion has become an alternative to surgical abortion throughout the world. In countries with limited health resources and a poorly developed health care system, the medical procedure has made legal abortions safer and more accessible, and is clearly preferable to the surgical procedure. In most western countries however, both procedures are performed in safe and efficacious settings. Often, women are offered the choice between the two procedures, which requires detailed information about advantages and risks based on comparisons of the two procedures. So far, only two prospective studies have compared a high-efficacious medical regimen with vacuum aspiration [1,2]. Other comparative studies have been retrospective [3], have addressed low efficacious medical regimens using prostaglandin alone [4] or mifepristone alone [5], have administered prostaglandin the less effective oral way [6,7] or included only a small number of women [8,9].

Varying definitions of success, different intervention strategies and different attitudes toward screening, diagnosing and treatment of infectious complications furthermore hampers direct comparisons of efficacy and complications after medical and surgical abortion.

On this background, we wanted to make a rigorous comparison of the same outcome measures on efficacy and complications after medical and surgical abortion per formed prospectively by the same personnel in the same organization. We also wanted to compare the leave of absence and the number of contacts to the health care system after medical and surgical abortion.

2. Materials and methods

Women referred to Copenhagen University Hospital H:S; Hvidovre and Frederiksberg for early termination of
pregnancy in the period of August 2000 to June 2001 were considered for the study. Exclusion criteria were of the following: less than 18 years of age, gestational age (GA) >63 days (confirmed by Crown Rump Length >23 mm on transvaginal ultrasound), insufficient language skills, asthmatic bronchial requiring daily medication, lactation, suspicion of or verified ectopic pregnancy or spontaneous abortion, coagulation disorder, multiple gestation and impairment of liver or kidney function. Women were counseled as to the option of either a medical or a surgical procedure and offered a choice of randomization (performed through a centrally located telephone procedure) into one of the two procedures. If randomization was declined, the woman chose method of termination herself.

All women were screened for *Chlamydia trachomatis* (analyzed with polymerase chain reaction) in the cervix and the urethra. The screening took place at the general practitioner’s office 1 to 2 weeks before the abortion (80%) or at the first appointment in the hospital (20%). If positive, the women were treated with 1 g azithromycin prior to the abortion. The medical abortion regimen was 600 mg mifepristone at day 1 followed by 1 mg gemeprost administered vaginally at day 3. Pain and nausea were treated with morphine/metoclopramide supplemented with paracetamol/codeine if necessary. The surgical regimen was dilatation and vacuum aspiration in general anesthesia immediately followed by an abdominal ultrasonography to ensure that the uterus was empty. As prophylactic analgesia, these women received a suppository of 1 g paracetamol postoperatively. In primigravidae, cervical priming was performed with oral prostaglandin (misoprostol 0.4 mg) 8 h prior to surgery. All women were treated as outpatient

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**Fig. 1. Flow chart of the study population.**
and came for a follow-up visit, including a questionnaire after 2 weeks. Another questionnaire was mailed to both groups 8 weeks after the abortion.

Data on baseline characteristics were obtained from the hospital records. Data on the use of antibiotics, leave of absence and return to normal physical activity were obtained from the 2-week questionnaire, while both questionnaires provided data on number of contacts to the health care system. Leave of absence included student’s leave from school but excluded unemployed women and women on maternity leave. Complications requiring contact to a hospital within the country, such as subsequent surgical intervention or readmission for any other reason during a 3-month period, were identified in a national database. Success was defined as complete abortion achieved by the initial abortion procedure, while failure was defined as an unscheduled surgical intervention within 3 months or switch of method. The indications for surgical intervention were categorized as ongoing pregnancies, bleeding problems, patient requests not related to bleeding or switch of method.

Sample size was estimated to detect a 3.5% difference in success rates. Based on the existing literature, the success rate after medical abortion was set at 95% [10–12] and the success rate after surgical abortion at 98.5% [13–15]. With at least 401 women in each group, the study should have 90% power \( (p^{<.05}) \) of detecting a difference of 3.5% in success rates. Power calculations were made on the expectation of the majority of the population being randomized. The results were compared with chi-squared test, Mann–Whitney test and Fisher’s Exact Test, where appropriate. The local Ethical Committee approved the study, and all women gave informed consent.

### 3. Results

After the exclusion of 1022 women, 1135 were eligible for the study (Fig. 1). One hundred two of these women (23 medical and 79 surgical terminations) were either not approached or did not want to participate in the questionnaire study, but were included in the efficacy analysis. Among the 1033 included women, 111 (10%) accepted randomization into either medical \( (n=55) \) or surgical \( (n=56) \) termination. Nine hundred twenty-two women wanted to decide on the method of termination themselves; 36% chose medical \( (n=332) \) and 64% chose surgical \( (n=590) \). In the group of women who accepted randomization, fewer were higher educated and more had had prior induced abortions than women who chose method of termination. There were no significant differences in baseline characteristics either among women in the randomized groups, all women receiving medical or surgical abortion, or among women accepting or declining study participation. The response rate was 81% (832/1033) on the 2-week questionnaire and 73% (751/1033) on both questionnaires. Nonresponders had more often had prior miscarriages, and in the surgical group, more nonresponders than responders were smokers. Other baseline characteristics were similar (Table 1).

The overall success rate was lower after medical abortion, 94.1% (386/410; 95% CI, 91.8–96.4), than after surgical abortion, 97.7% (708/725; 95% CI, 96.6–98.3), \( p^{<.01} \), and was of similar magnitude in the randomized subgroups (92.7% vs. 96.4%, respectively). The success rate after medical abortion decreased with increasing GA \( (p^{<.01}) \) but was insignificantly affected by GA after surgical abortion (Fig. 2). The success rates were identical at the two participating hospitals. Failures were identified after a longer period of time following medical than surgical abortion; median 22 (range, 3–91) days and 5 (range, 1–54) days, respectively, \( p^{<.05} \). After 2 weeks, only 29% (increasing to 79% after 5 weeks) of the medical abortion failures were identified compared to 71% (increasing to 82% after 5 weeks) of the surgical abortion failures. The failures after medical abortion were categorized as ongoing pregnancies (0.5%), bleeding problems (4.1%) and patient requests not related to bleeding (1.2%). Surgical abortion

<table>
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<tr>
<th>Table 1 Baseline characteristics for nonresponders and responders of the 2-week questionnaire after medical and surgical abortion</th>
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<tr>
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<td>GA, median (range)</td>
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<tr>
<td>Prior induced abortion (%)</td>
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<tr>
<td>Prior miscarriage (%)</td>
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<td>BMI, median (range)</td>
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<td>Smokers (%)</td>
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<td>Educated &gt;9 years (%)</td>
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<td>Married/living together (%)</td>
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Nonresponders and responders are compared with Mann–Whitney test and Fisher’s Exact Test.

Gestational age (GA) was measured by transvaginal ultrasound. BMI indicates body mass index.

* \( p^{<.05} \)

** \( p^{<.01} \).
failures were categorized as bleeding problems (1.9%), switch of method due to anatomical anomaly of the uterus (0.3%) and one case of post abortion synechia in the cervix requiring surgical dilatation (0.1%).

The preabortion prevalence of Chlamydia infection was 4.4%, and treatment was initiated before the termination. Within the first 2 weeks following the abortion, 6% of the women received antibiotic treatment for pelvic inflammatory disease (PID). This frequency was higher after surgical (7.8%) than after medical abortion (3.7%), p < 0.01, but was independent of GA. This difference persisted after adjusting for prophylactic use of antibiotics prescribed to six women because of late surgical interventions, to two women with a history of frequent pelvic infections and to one woman with a congenital heart failure. Three of the women with pelvic infection after surgical abortion were treated during readmission in hospital.

Apart from readmission due to failure or pelvic infection, five women were readmitted after medical abortion because of bleeding; one of them required a blood transfusion day 50 (hemoglobin, 4.8 mmol/L). After surgical abortion, one woman was readmitted because of bleeding, one because of pain and one woman with an unrecognized heterotopic pregnancy presented day 15 with a ruptured ectopic pregnancy. A fourth woman had a perforation of the uterus followed by a laparoscopy with no further complications. The total number of complications (failures, infections and other readmissions) was similar after medical termination (7.3%) and surgical termination (9.2%).

Women who chose a medical abortion had a shorter leave of absence (1 day) compared to women who chose a surgical abortion (2 days), p < 0.05; fewer were absent more than 1 week; 4% and 8%, respectively, p < 0.01. Women randomized

### Table 2

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<th>Leave of absence, relative’s absence from work and time to return to normal physical activity after medical and surgical abortion</th>
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<tr>
<td><strong>Random medical</strong> (n=53)</td>
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<td>Leave of absence in days (median, 25–75% percentiles)</td>
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<td>Relative’s absence in days (median, 25–75% percentiles)</td>
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<td>Return to normal physical activity in days (median, 25–75% percentiles)</td>
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* p < 0.05 compared to “chose surgical” (Mann–Whitney test).
to medical abortion had an insignificant (p=.06) longer leave of absence than women randomized to surgical abortion (Table 2). The time taken to return to work (Fig. 3), time taken to return to normal physical activity and relative’s absence from work was similar in all groups (Table 2).

Within 8 weeks after the abortion, approximately one third of all women requested one or more unscheduled contacts to their general practitioner, a doctor on call or a hospital (Table 3). The average number of contacts was similar after medical and surgical procedures (2.6 and 2.7, respectively) and among the randomized and nonrandomized women.

4. Discussion

We have followed 1135 women with GA ≤63 days prospectively in a parallel setting 3 months after medical and surgical abortion performed by the same personnel in the same organization. Using the same definition of success, we found a higher success rate and a higher risk of antibiotic treatment after surgical than after medical abortion. Our intention to compare the two methods in a mainly randomized trial was not possible, as only 10% of the eligible women were willing to be randomized. The baseline characteristics of the women, as well as the results, however, seem comparable in the randomized and the nonrandomized subgroups. We have therefore chosen to analyze most of the results for all medical procedures and all surgical procedures together.

Comparing outcome after medical and surgical termination holds several problems. Surgical intervention after a medical abortion is traditionally defined as failure, whereas secondary surgical intervention following a surgical abortion most often is classified as a complication. If a woman requests a surgical intervention because of prolonged bleeding, this case is defined as a failure. Success rates after medical abortion might therefore reflect patient acceptability rather than true failure rates. A switch from a surgical to a medical procedure because of uterine or cervical anomalies, on the other hand, does not represent patient acceptability [16]. As the cases of failures after medical abortion are diagnosed later than surgical abortion failures, a long follow-up time is necessary to compare the efficacy of the methods. We have tried to handle this complexity by comparing the medical and the surgical procedure performed by the same personnel in a prospective design using an intention to treat analysis. Identical definitions of success and failures were applied on the two procedures, and the outcome was finally assessed after 3 months.

The chosen medical regimen is validated in other studies [10,17–19]. The overall success rate of 94% after medical abortion at GA ≤63 days in the present study is in the lower range of success rates from other series [20]. This is explained by the extended follow-up time in this study, which has shown to correlate with a decrease in success rate [21,22]. At 2 weeks, the success rate was 99%, decreasing to 95.4% at 5 weeks and 94% at 3 months. Comparing success rates after medical abortion in the literature is complicated, though, because of the many variables that may affect the outcome — as the dose of mifepristone, dose and administration of the prostaglandin, duration of the follow-up period, GA and threshold for surgical intervention. When the present study was planned, we chose the most efficacious prostaglandin, gemeprost, for our medical abortion regimen. It has later been shown that 0.8 mg misoprostol vaginally appears to be superior to 0.5 mg gemeprost [23], but the efficacy of 1 mg gemeprost seems comparable to that of 0.8 mg misoprostol, although there are no direct comparisons [24]. When effective prostaglandins are used, the success rate can be maintained after reduction of the mifepristone dose from 600 to 200 mg [24,25].

The surgical regimen included European tradition of general anesthesia, which is associated with an equivalent risk of failure as surgical abortions performed in local anesthesia [14,26]. Priming of the cervix with misoprostol prior to the surgical abortion needs to be 3 h minimum before the procedure [27,28]. Due to practical reasons, the women were informed to administer misoprostol the night before the procedure.

Efficacy is one aspect of the termination procedures, another aspect are complications. Pelvic inflammatory disease is associated with an increased risk of chronic pelvic pain and tubal damage leading to infertility and ectopic pregnancy [29,30]. We found a significantly reduced risk of antibiotic treatment after medical compared to surgical abortion, which confirms other comparative studies [31]. The same difference has been described at GA 10–13 weeks, although not significant [1]. The majority of cases treated with antibiotics were not associated with a secondary surgical intervention, and the use of antibiotics were unaffected by GA. Antibiotics prescribed in the hospital were based on a diagnosis of PID confirmed by objective signs of infection. Other women were treated at the discretion of the general practitioner. We do not know how many of these presumed infections were confirmed by laboratory or microbiological analysis. In an optimal study setting, the doctors would be blinded to the method of termination, but this was not possible in the present study. There is on the other hand no reason to assume that the type of termination procedure affects the prescription of antibiotics.

After medical as well as surgical abortion, 7–9% of all women had one or more complications. Included in this frequency are 0.2% or 0.3% major complications. These frequencies are a little higher than the frequencies reported in other studies (5–5.8%) [15,19,32,33]. This difference can be explained by a longer follow-up period and an inclusion of complications diagnosed outside the hospital in the present study. The risk of complications is similar [14] or slightly higher [34] when surgical abortions are performed under general compared to local anesthesia.

We found a median time to return to normal physical activities of 2 days after both procedures, and an average leave of absence of 1 day after choosing a medical and 2
days after choosing a surgical abortion. These figures are equivalent with earlier findings [1]. We did not, however, include time lost from work before the abortion, which might influence the total length of leave of absence [35]. The data in the present study were obtained from the 2-week questionnaire including time lost from work in direct relation to the abortion procedure. Since the majority of failures after medical abortion were diagnosed after 2 weeks, the total leave of absence is probably underestimated — primarily in the group of women having a medical abortion. We did not give any recommendations about leave of absence in connection with the abortion.

During the study period, all women came for a follow-up visit at the hospital 2 weeks after the abortion. One third of all women had one or more additional unscheduled contacts to the health care system within 8 weeks after the abortion. These contacts equal almost one extra unscheduled contact per abortion. The number of women requesting extra consultations was similar after medical and surgical abortion and in randomized and nonrandomized groups. The contacts after medical abortion occurred later than the contacts after surgical abortion, which probably reflects the longer duration of bleeding and the later diagnosing of failures after medical abortion. Whether some of the consultations reflect sociopsychological problems rather than medical problems is unknown.

Women who choose a medical termination represent a selected population on sociodemographic characteristics [36], which also is illustrated in the present study. This selection bias may have an impact on satisfaction, leave of absence and number of contacts to the health care system. Since failure after medical abortion is associated with patient acceptability, efficacy might also be affected. To overcome this potential bias, women should be randomized for abortion method. In agreement with other studies, we found no major differences in efficacy and complications in the randomized and in the nonrandomized groups [2]. The randomized group, however, was very small confirming the general reluctance in Denmark toward randomization [37]. Patient preference was probably the major reason to decline randomization. Another explanation can be various clinician barriers as time constraints, concern for patients and worry about impact on the doctor–patient relationship [38]. The advantage of the present study is the inclusion of the whole population, thus being representative of the total abortion seeking population. This ensures a high external validity of the results, which could have been a problem, if only randomized women were included.

The group of nonresponders of the questionnaires might represent a slightly more vulnerable group of women compared to the responders. This is a well-known problem in studies of women seeking termination of early pregnancy [39]. We have no reason to believe that this affects the use of antibiotics, but whether the differences had an impact on leave of absence and consultations to the health care system is not known.

In summary, the total number of complications is similar after early surgical and medical abortion, but medical termination is associated with a higher risk of failure and a lower risk of antibiotic treatment. After both procedures, about one third of the women request one or more extra unscheduled contacts to the health care system. Whether this need for extra consultations is founded in insufficient information to the women needs to be explored.

References


