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Regional differences in surgical intervention following medical termination of pregnancy provided by telemedicine

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Conflict of interests
Rebecca Gomperts is a paid consultant for Women on Web. The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Abstract

Objective. Analysis of factors influencing surgical intervention rate after home medical termination of pregnancy (TOP) by women in countries without access to safe services using the telemedical service 'Women on Web'. *Design.* Cohort study. *Setting.* Women with an unwanted pregnancy less than nine weeks pregnant who used the telemedicine service of Women on Web between February 2007 and September 2008 and provided follow-up information. *Sample.* Women who used medical TOP with a known follow up. *Methods.* Information from the online consultation, follow-up form and emails was used to analyze the outcome of the TOP. *Main Outcome Measures.* Ongoing pregnancy, reason for surgical intervention, perceived complications and satisfaction. *Results.* Of the 2 323 women who did the medical TOP and had no ongoing pregnancy, 289 (12.4%) received a surgical intervention. High rates were found in Eastern Europe (14.8%), Latin America (14.4%) and Asia/Oceania (11.0%) and low rates in Western Europe (5.8%), the Middle East (4.7%) and Africa (6.1%; p=0.000). More interventions occurred with longer gestational age (p=0.000). Women without a surgical intervention more frequently reported satisfaction with the treatment (p=0.000). *Conclusions.* The large regional differences in the rates of reported surgical interventions after medical TOP provided by telemedicine cannot be explained by demographic factors or differences in gestational length. It is likely that these differences reflect different clinical practice and local guidelines on (incomplete) abortion rather than complications that genuinely needed surgical intervention. Surgical interventions significantly influenced womens' views on the acceptability of the TOP.

Introduction

Worldwide, an estimated 42 million terminations of pregnancy (TOPs) take place annually. Approximately 21.6 million women globally still have an unsafe TOP each year, resulting in an estimated 47 000 deaths, largely among the most vulnerable women, such as the poor, the unmarried and, especially, the young women. In addition to the women who die every year due to an unsafe TOP, an estimated eight million women annually experience complications that need medical treatment (1).

Medical TOP is one of the safest procedures in contemporary medical practice, with minimal morbidity and a negligible risk of death (2). The combination of two drugs, mifepristone and misoprostol, is highly effective to induce a complete TOP. Evidence indicates that it is safe to perform a medical TOP procedure at home up to nine weeks of gestation (3–7). The risk of serious complication is exceptionally low compared with other medical interventions, and very few patients require emergency referral. Today, the clinical practice in many countries is that women administer misoprostol themselves at home. Women can safely handle

the treatment and most stages of the termination process themselves (8).

The online non-profit project Women on Web was set up in 2006 with the aim of increasing access to safe TOP and improving maternal health in countries where TOP is not available without restrictions (9). The website (womenonweb.org) refers women to a doctor online who can provide them with a medical TOP using the combined regimen of mifepristone and misoprostol, provided they fill in the online consultation form and meet the specified inclusion criteria and none of the exclusion criteria.

A previous evaluation of the service provided by Women on Web showed a surgical intervention rate of 13.6% and, after improving follow-up rates, of 6.8%. This percentage is higher than usually reported for medical TOP. Ideally, the surgical intervention rate should be less than 5% (10). Therefore, the main objective of the present study was to analyze which factors influence the outcome of a medical TOP, defined as the need for surgical intervention after use of the services of Women on Web. Moreover, we were interested in reported complications and the subjective experience of the women.

Material and methods

This cohort study consists of 2 585 women from 88 countries where access to TOP is restricted, who received medication for a TOP from February 2007 to September 2008 and provided follow-up information. Data obtained from Women on Web were collected prospectively. After completing an interactive online consultation, women who reside in countries without access to safe TOP, are up to nine weeks pregnant, wish to terminate their pregnancy and have no contraindications, will receive medication for a TOP by mail or courier. Women are advised to have an ultrasound examination before treatment to determine gestational length. Three weeks following treatment, women are advised to do a pregnancy test, have an ultrasound examination done or visit a doctor to confirm that the TOP is complete. The service has previously been described (9). It is considered a woman's responsibility to carry out this advice. Related to the online signature of the service, women receive no physical or ultrasound examination by the medical doctor of Women on Web. Information includes possible adverse effects and complications, including the risk of ongoing pregnancy, as well as increasing pain and blood loss and risk of complications in relation to increasing gestational length. The regimen used for the medical TOP is 200mg mifepristone orally followed by 800μg misoprostol buccally 24hours later and a further 400μg misoprostol buccally four hours later.

Five weeks after a woman receives a package with the medication, a follow-up questionnaire is sent to her via email. In this form, we enquire about the outcome of the TOP, whether the woman visited a doctor or hospital because of perceived complications, if she received any surgical intervention or additional medical treatment, and how she experienced the procedure, including her feelings about carrying out the TOP through Women on Web. The analyzed data set was derived from the Women on Web database and consisted of data from the online consultation with information on gestational and demographic characteristics.

The follow-up form and email correspondence with the helpdesk provided information on the outcomes, successful termination, complications and subjective experiences. To measure acceptability, women could choose from five options: grateful to be able to do the medical abortion; stressed, but acceptable in order to do the medical abortion; if I had known before how stressful it would be, I would never have done it myself; no specific feeling; and do not want to share.

The 4 325 women who had a medical TOP resided in six regions: Western Europe (681 medical TOPs); Eastern Europe (2 303 medical TOPs); Middle East (220 medical TOPs); Africa (78 medical TOPs); Asia and Oceania (305 medical TOPs); and Latin America and Caribbean (738 medical TOPs). The respective follow-up rates in these regions were 58.4% in Western Europe, 63.9% in Eastern Europe, 64.5% in the Middle East, 50.0% in Africa, 54.1% in Asia/Oceania and 50.0% Latin America/Caribbean. The follow up between the regions differed significantly (Kruskal Wallis test, p=0.00). From the remaining cohort of 2 585 women, we excluded 240 (9.3%) who decided not to take the medication for divergent reasons, such as spontaneous miscarriage in the meantime or a wish to continue the pregnancy. In addition, 22 (0.9%) women with an ongoing pregnancy were excluded from analysis. Thus, 2 323 (89.7%) women remained in the study and provided follow-up information on the outcome of treatment. All data were recorded using AWStats (a tool that generates advanced web-server statistics). All information on the web-server is protected with an SSL certificate. Data analysis was performed using the statistical program SPSS 16.0. Chi-squared tests were used for comparing groups. Non-parametric continuous variables are presented as medians and ranges. A p-value of <0.05 was considered significant. Factors affecting surgical intervention rates were evaluated using logistic regression. Ethical permission was obtained from the regional ethics committee at Karolinska Institute, Stockholm, Sweden.

Results

Of the 2 323 women who had a medical TOP and spontaneous start of expulsion, 289 (12.4%) had an additional surgical intervention. Table 1 shows the demographic data on the womens' age, parity and other characteristics, such as gestational age, sonogram examination, region, doctors' visits and acceptibility. No blood transfusions were reported.

Table 1. Comparison of characteristics of women with or without surgical intervention.

	Total *n*	Percentage	Missing	Surgical intervention	Percentage	No surgical intervention	Percentage	χ^2 (*t*-test)	95% Confidence interval	Odds ratio	*p*-Value
Mean age	2 323		0	26.3		27.3					0.001
Children	2 323								0.69–1.13	0.88	0.36
Yes	1 075			126	11.7	949	88.3				
No	1 248	53.7		163	13.1	1 085	86.0				
Gestational age	2 323		0						1.25–2.36	1.71	0.001
<7weeks	1 944	83.7		227	11.7	1717	88.3				
7–9weeks	379	16.3		62	16.4	317	83.6				
Ultrasound confirmed	2 323		0	289	12.4	2 034	87.6		1.40–2.68	1.94	0.000
Yes	1 709	73.6		241	14.1	1 468	85.9				
No	614	26.4		48	7.8	566	92.2				
Region	2 323		0	289	12.4	2 034	87.6	31.22			0.000
Western Europe	362			21	5.8	341	94.2				
Eastern Europe	1 342			199	14.8	1143	85.2				
Middle East	127			6	4.7	121	95.3				
Africa	33			2	6.1	31	93.9				
Asia/Oceania	146			16	11.0	130	90.0				
Latin America/Caribbean	313			45	14.4	268	85.6				
Doctor/hospital visit for complication	1 917		406								
No	1 439	75.1		0	0.0	1 439	100.0	912.21			0.000
Yes	478	24.9		272	56.9	206	43.1				
Western Europe	67	22.2		20	29.9	47	70.1				
Eastern Europe	302	25.7		192	63.6	110	36.4				
Middle East	13	16.7		5	38.5	8	61.5				
Africa	5	17.2		2	40	3	60				
Asia/Oceania	24	24.0		13	54.2	11	45.8				
Latin America/Caribbean	67	29.0		40	59.7	27	40.3				
Acceptability	1 893		430	257		1 636		67.27			0.000
Satisfied	1 214	64.1		131	51.0	1 083	66.2				
Stressful but acceptable	426	22.5		66	25.7	360	22.0				
Extremely stressful	43	2.3		22	8.6	21	1.3				
No specific feeling	58	3.1		7	2.7	51	3.1				
Do not want to share	152	8.0		31	12.1	121	7.4				

In all, 1 917 (82.5%) women completed the questionnaire, while data other than the outcome of the TOP were missing for 406 (16.5%) women.

The mean age of the included women was 27years, with a range of 16–49years. Women who underwent a surgical intervention were slightly younger (26.3years) than those who did not (27.3years; p=0.001). A slight majority (53.7%) of the women were nulliparous. Parity was not related to surgical intervention [relative risk (RR) 0.88; 95% confidence interval (CI) 0.69–1.13].

In all, 1 944 (83.7%) women stated that they were less than seven weeks pregnant at the time they consulted the doctor online; the remaining 379 (16.3%) were seven to nine weeks pregnant. The intervention rate in the latter group was higher (16.4%) than in the former group (11.7%; RR 1.171; 95% CI 1.25–2.36). The gestational length was confirmed by ultrasound in 1 709 (73.6%) of the women. Of these, 241 (14.1%) had a surgical intervention following the TOP, which was significantly more than the 48 (7.8%) of the 614 women who did not have an ultrasound before the TOP (RR 1.94; 95% CI 1.40–2.68).

The wide reach of the Internet created access to medical abortion for women in many countries (n=88), and to analyze the outcomes, the regions and not individual countries are reported (Table 1). There was no significant difference in outcome after TOP between countries in a specific region. The surgical intervention rate varied widely within each region, from 4.7% in the Middle-East, 5.8% in Western Europe, 6.1% in Africa and 11.0% in Asia and Oceania up to 14.4% in Latin America and the Caribbean and 14.8% in Eastern Europe (p=0.000). In the logistic regression, besides region, only confirmation of the pregnancy with ultrasound and duration of pregnancy influenced surgical intervention rates.

In total, 1 917 (82.5%) of 2 323 women reported whether they visited a doctor or a hospital for a perceived complication after the TOP. Among them, 478 (24.9%) women reported such a visit. Women in Western Europe (22.2%), Latin America and the Caribbean (29.0%), Asia/Oceania (24.0%) and Eastern Europe (25.7%) more frequently visited a doctor or a hospital than women in the Middle East and Africa (16.7 and 17.2%, respectively). Of the 478 women who reported a perceived complication, 272 (56.9%) had a surgical intervention. This happened more often in Eastern Europe (63.6%), Latin America and the Caribbean (59.7%) and Asia/Oceania (54.2%) compared with Western Europe (29.9%), the Middle East (38.5%) and Africa (40%).

Data on acceptability were collected from 1 893 women who provided information on how they experienced a medical TOP using telemedicine. Among them, 1 214 (64.1%) reported satisfaction, another 426 (22.5%) women reported acceptable stress, 58 (3.1%) women reported no specific feeling and 152 (8.0%) did not want to share their feelings. Only 43 (2.3%) of the women reported extreme stress or dissatisfaction. Women without a surgical intervention reported more frequent satisfaction (p=0.000). Of the 1 636 women who did not have a surgical intervention, 21 (1.3%) considered the TOP extremely stressful, compared with 22 (8.6%) of the 257 women who received a surgical intervention after the TOP.

Discussion

Of the women who had a medical TOP with mifepristone and misoprostol at home through telemedicine, a significant difference in surgical intervention rates after the medical TOP was found between different regions worldwide. Nearly 15% of women in Latin America and the Caribbean and in Eastern Europe had a surgical intervention. This is more than two and a half times the intervention rate for women in Western Europe, the Middle East and Africa. Country variations in success rates from 86 to 97% for home medical abortion have also been found in other studies, with an average success rate of 89.7% (11). A similar variation in regional hospitalization after unsafe TOP in developing countries was found previously, with rates of four to seven per 1 000 women for women in the Philippines, compared with two countries in Latin America with rates of almost nine per 1 000 women (12). Although the follow-up rate differed between the different regions, this seemed not to be related to the outcome.

Women without complications tend to refrain from follow up (9). However, the two regions with relatively high intervention (Eastern Europe and Latin America) had different follow-up rates, which suggests that differences in follow-up percentages are not responsible for the high intervention rates. The relatively high rate of surgical intervention in the total group (12.3%) is probably also related to selective reporting of women with complications. Other studies showed no difference in effectiveness or acceptability between home-based and clinic-based medical abortion. (11).

The regimen used with a repeated dose of misoprostol was chosen to decrease the risk of ongoing pregnancy in the event of more advanced gestational length (13,14). Increasing gestational length increases the risk for having a surgical intervention. Women from Eastern Europe and Latin America and the Caribbean more frequently visited a doctor after the TOP because of a perceived complication and had a higher surgical intervention rate. This indicates that these women experience a lower barrier to access healthcare. In contrast, in the Middle East and Africa the percentage of women who visited a doctor or hospital after the TOP was low, as were the surgical intervention rates.

Women who live in countries with no access to safe termination of pregnancy usually choose to present with a spontaneous miscarriage if they need to seek healthcare (15). There is no way to discriminate clinically between a complete or

incomplete medical TOP or spontaneous miscarriage. It is likely that women from the Middle East avoid health professionals for cultural reasons, because they cannot present with a miscarriage when they are unmarried and not supposed to be pregnant at all. The low rate of healthcare visits in Africa is possibly also due the costs, the lack of providers and the lack of availability of ultrasound.

Although possibly contributing, the high rate of surgical interventions reported in Eastern Europe and Latin America and the Caribbean cannot be attributed only to more frequent visits to healthcare providers due to perceived complications. The rate of interventions also suggests that healthcare providers in these regions more often judge the symptoms after a miscarriage or TOP as signs of complications that need surgery. The different surgical intervention rates following the doctor's visit thus seem to reflect different clinical practice and local guidelines on incomplete TOP, rather than genuine complications that really need a surgical follow-up treatment. Expectant care or the use of misoprostol are acceptable alternatives to surgical evacuation, which are increasingly used in Western Europe and the USA (16). Neither prolonged bleeding nor the presence of tissue in the uterus is an indication for surgical intervention following medical TOP or spontaneous miscarriage, as long as the woman is well. There are several concerns about such possible unnecessary surgical interventions. Many doctors still use dilatation and curettage rather than manual vacuum aspiration or misoprostol for incomplete TOP, even though the last two are the safest, simplest and most cost-effective techniques (17). Furthermore, not all health facilities use anesthesia when performing curettage. Hospital staff have been reported to be judgmental and hostile, to handle the patients roughly and to deliberately withhold pain relievers and anesthesia (1). Our findings that the medical TOP was significantly less acceptable for women if they had a surgical intervention afterwards are of clinical importance, which also has been found in other studies (18). Fewer women in the high-intervention regions were satisfied with their TOP and more were extremely stressed.

The ongoing pregnancy rate in this study, 0.9%, was comparable to the ongoing pregnancy rates from other studies (2,4,6–8,10). It should be stressed that although the surgical intervention rate after the medical TOP provided through telemedicine was higher than reported in other studies, this alternative was highly accepted and is still much safer than other methods that are available to women in countries where there are no safe TOP services and where, as a result, one in four women undergo an unsafe TOP, and an estimated five million women every year are hospitalized for treatment of complications (11). To reduce maternal mortality due to unsafe TOP, increased access to safe TOP methods, such as medical TOP, is urgently needed, especially in those places where no safe TOP services are available. In these places, medical TOP via telemedicine may provide women with an acceptable and safe alternative to avoid unsafe TOP.

Conclusion

Large regional differences were found in surgical interventions after medical TOP provided by telemedicine. This is likely to reflect factors such as (outdated) local treatment guidelines after spontaneous and incomplete TOP and seems to indicate that at least some of the surgical interventions are medically unnecessary. This does not benefit women, because medical TOP was less acceptable for women if they had a surgical intervention. Increased knowledge on medical or expectant treatment of incomplete miscarriage might help to improve this practice.

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