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ORIGINAL RESEARCH ARTICLE

Effectiveness and acceptability of home use of misoprostol for medical abortion up to 10 weeks of pregnancy

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Abstract

Introduction: The administration of mifepristone, followed by misoprostol, is widely used for medical abortion. Many studies have demonstrated home abortion to be safe in pregnancies up to 63 days of gestation, and recent data support its safety when extended to more advanced pregnancies. We studied the efficacy and acceptability of home use of misoprostol up to 70 days of gestation in a Swedish setting and compared the outcomes between pregnancies with a gestational age of up to 63 days and pregnancies with gestational age 64–70 days.

Material and methods: This prospective cohort study was performed between November 2014 and November 2021 at Södersjukhuset and Karolinska University Hospital, Stockholm, and some patients were also recruited from Sahlgrenska University Hospital, Göteborg and Helsingborg Hospital. The primary outcome was the rate of complete abortions and was defined as complete abortion without any need for surgical or medical intervention and assessed by clinical assessment, pregnancy test and/or vaginal ultrasound. Secondary objectives were assessed by daily self-reporting in a diary and included pain, bleeding, side effects and women's satisfaction and perception of home use of misoprostol. A comparison of categorical variables was made with Fisher's exact test. The significance level was set to a p-value ≤0.05. The study was registered at Clinicaltrials.gov on July 14, 2014 (NCT02191774).

Results: During the study period we enrolled 273 women opting for medical abortion with home use of misoprostol. In the early group, up to 63 days of gestation, 112 women were included with a mean gestational length of 45 days and in the late group, 64–70 days of gestation, 161 women with a mean gestations length of 66.3 days were included. Complete abortion occurred in 95% (95% CI 89–98) of women in the early group and in 96% (95% CI 92–99) in the late group. No differences were found regarding side effects and acceptability was similarly high in both groups.

Conclusions: Our results show high efficacy and acceptability of medical abortion when misoprostol is administered at home up to 70 days of gestation. This supports

Abbreviation: GA, gestational age

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previous findings about maintained safety when misoprostol is administered at home even past a very early pregnancy.

KEYWORDS
abortions, acceptance, first trimester, home use, medical abortion, mifepristone, misoprostol

1 | INTRODUCTION

Medical methods for pregnancy termination have become the method of choice for many women worldwide. The possibility of administering misoprostol at home instead of at a clinic has given women an option to terminate their pregnancy during less stressful conditions.[1]

By 2020 the World Health Organization recommended self-administration of medical abortion including both drugs—mifepristone and misoprostol at home. Medical abortion can be self-managed without the supervision of a healthcare provider, provided accurate information and support are given and women have access to a healthcare provider to contact if needed.[2,3] Reports show no significant difference in effectiveness or satisfaction between in-clinic and home use of misoprostol or both drugs.[4–10] In 2004, home use became an option in some European countries[11,12] and, in 2012, the U.S. Food and Drug Administration removed the requirement of limiting misoprostol to in-clinic provision.[13]

The rapid development of internet technologies gives further options for the provision of abortion treatment nowadays. Mobile internet coverage has increased in all countries in the world and given access to telemedicine options. Web applications developed by doctors, web application engineers and non-governmental organizations provide effective counseling on contraception and safe and effective medical abortion.[14,15]

The provision of self-medication and medical services at home has become more in demand during 2020 due to the pandemic of coronavirus. Due to lockdowns, visits to the gynecological clinics to receive abortion treatment in time became difficult or impossible.[16]

Studies aimed to increase access to medical abortion at home have been performed in different settings with different legislation and health systems. The vast majority are limited to 63 days of gestation, but more recent studies also include more advanced pregnancies with gestational lengths up to 77 days, and the World Health Organization confirms that home abortion is safe in first-trimester gestation.[3] However, reports on efficacy beyond 63 days indicate a slightly lower efficacy compared with pregnancies up to 63 days[17–19] and information on satisfaction of home use of misoprostol is frequently lacking. We aimed to evaluate the efficacy and acceptability of home use of misoprostol in medical abortion among women seeking induced abortion in gestational age (GA) up to 63 days and from 64 to 70 days.

Key message

Home use of misoprostol in medical abortion can safely be made available for women with a gestational age up to 70 days. The expanded possibility of home use of misoprostol with maintained efficacy and satisfaction means increased access to safe abortion.

2 | MATERIAL AND METHODS

This pragmatic non-inferiority prospective multicenter open-label cohort study was planned to run in five units but was mainly performed at three clinics in Stockholm, Södersjukhuset, and at two separate clinics at Karolinska University Hospital. Some patients were also recruited from Sahlgrenska University Hospital, Göteborg and Helsingborg Hospital. We enrolled women seeking medical abortion up to 70 days of gestation from November 2014 to November 2021.

Due to slow recruitment, the inclusion of patients was stopped in November 2021.

The inclusion criteria were ultrasound-confirmed intrauterine pregnancy up to 70 days of gestation, willingness to administer misoprostol at home, age 18 years or older, hemoglobin >100 g/L, ability to understand the instructions, and absence of any known health problems or clinical findings that could affect the patient's safety during the study. Concerning own choice, the study was not designed as a randomized trial. Exclusion criteria were any contraindication to receive mifepristone or misoprostol (anemia, breastfeeding, liver disease, bleeding disease) and pregnancy length of >70 days of GA. Women declining to participate in the study were not recorded.

All women included in the study were allocated into two groups by GA. The first group included women pregnant with a GA up to 63 days and the second group included women with a GA between 64 and 70 days.

2.1 | Procedure

Specially trained midwives provided information, and doctors were responsible for the inclusion of women in the study in all clinics. During the first visit to the abortion clinic, women swallowed 200 mg of mifepristone (Mifegyne®, Exelgyn®) on

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site and were provided with 1200 μg of misoprostol (6 tablets of 0.2 mg of misoprostol Cytotec®, Pfizer), pain medication and a subject diary to log bleeding, pain and side effects that occurred during the treatment. Women were instructed to fill in the diary daily, starting on the day of mifepristone intake, to avoid recall bias. The participants were instructed to take four tablets of misoprostol vaginally at home 24–48 hours after mifepristone administration. If bleeding had not started within 3 hours after misoprostol administration, women were instructed to take an additional two misoprostol tablets sublingually.

All women were scheduled for a second visit to one of the study sites approximately 4 weeks after the first appointment. For this visit, women were asked to return unused misoprostol tablets and/or empty blisters and the diary. Women were asked about ongoing bleeding, any other symptoms and possible adverse events. Complete abortion was assessed using a low-sensitivity urine pregnancy test (1000 mIU/mL human chorionic gonadotropin) or transvaginal ultrasound examination to evaluate the treatment outcome. Ongoing pregnancy, heavy uterine bleeding or retained products of conception were treated according to the local guidelines of the study site. At follow-up, all women were asked to fill in questionnaires regarding satisfaction and their perceptions about the abortion procedure and preferred method of contraception. The questionnaire included seven statements on satisfaction such as: "I am satisfied with the treatment" and "I was given enough information before the procedure", where participants were to indicate their experience on a 5-point Likert Scale: 1—Very unsatisfied, 2—Unsatisfied, 3—Neutral, 4—Satisfied, and 5—Very satisfied. The statements in the questionnaire were analyzed individually and divided into three categories: 1 and 2 represented "not agreeing with the statement", 4 and 5 "agreeing with the statement" and 3 was considered neutral. In addition there was also one yes-or-no statement: "I would recommend home abortion to a friend in the same situation". The worst pain experienced during the abortion procedure was assessed on a scale from 1 to 10.

The primary objective of the study was to study efficacy in gestations up to and above 63 days with home use of misoprostol. Efficacy was defined as a complete abortion without any need for surgical or medical intervention due to incomplete abortion or ongoing pregnancy. Secondary objectives included pain, bleeding, side effects and women's satisfaction and perception of home use of misoprostol.

2.2 | Sample size

Complete abortion without any additional intervention occurs in more than 88% of medical abortions performed in early pregnancy.[20] If the true difference in efficacy is 8.7%, then with a power of 95% the upper limit of one-sided 95% confidence interval will exclude a difference in treatment of more than 1.05% to achieve non-inferiority. To compensate for possible drop-out we planned to include 660 women in total, stratified into 330 days up to 63 days and 330 days between 64 and 70 days of gestation.

2.3 | Statistical analyses

Continuous data were presented as means ± SD, range, and discrete data were presented as median and range. The normality of distribution was tested with the Shapiro–Wilk test. A comparison of means between groups was performed using a Mann–Whitney *U* test. A comparison of categorical variables was made with Fisher's exact test. The significance level was set to a *p*-value ≤0.05. Statistical analyses were calculated in R 4.2.1 (R Core Team 2021. R: A language and environment for statistical computing. Vienna: R Foundation for Statistical Computing; https://www.R-project.org/).

2.4 | Ethics statement

This project was approved by the Regional Ethical Review Board in Stockholm on January 22, 2014 (Reg. No. 2013/2160-31/2). The study was registered at Clinicaltrials.gov on July 14, 2014 (NCT02191774). The case report forms from which data were extracted were anonymous and could not be used to track individual

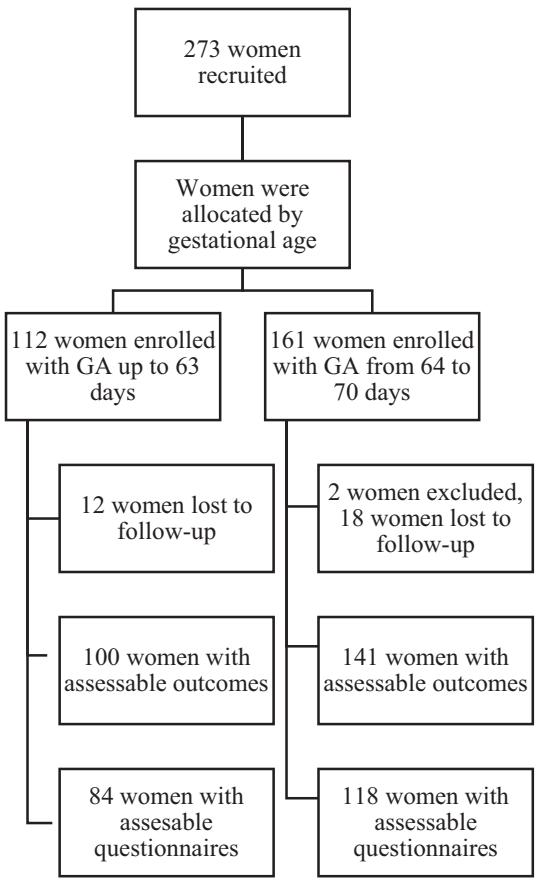

FIGURE 1 Participant flow. GA, gestational age.

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patients; hence, personal integrity was preserved during the study. The women were given oral and written information about the study's aim and procedures before obtaining their informed consent. Patients had the right to withdraw from the study at any time without giving any reason and without affecting their care.

3 | RESULTS

We recruited 273 women, who were allocated into two groups based on pregnancy length. The first group (early group) included 112 women with a length of pregnancy up to 63 days; 100 of these women had assessable outcomes and 84 of them had returned completed questionnaires. The second group (late group) included 161 women with a length of pregnancy from 64 to 70 days; 141 of these women had assessable outcomes and 118 of them had returned complete questionnaires (Figure 1).

We saw no significant differences in baseline characteristics between groups in age or parity (Table 1). The gravidity and number of previous spontaneous abortions were higher in the late group. The mean pregnancy length was 45 days in the early group, and 66 days in the late group. Among intended methods of contraception after the abortion procedure, 61 (70.1%) women from the early group had chosen long-acting reversible contraception (LARC) methods, and 58 (51.3%) women from the late group had chosen the same type of contraceptive method.

The complete abortion rate did not differ significantly between the groups. In the early group complete abortion rate was 95%, and in the late group 96% (Table 2). The need for additional treatment was based on clinical assessment, such as ongoing pregnancy diagnosed by ultrasound or heavy or prolonged bleeding. The decision on the type of method, surgical or medical, was made in agreement with the patient.

The acceptability was similarly high in both groups (Table 3). The majority of women in both groups were satisfied with the treatment. The participants were also satisfied with sufficient information received before the abortion and the pain medication. In both groups, most of the women answered that they were either very satisfied or satisfied with feeling calm and safe during the abortion, the treatment and the bleeding met their expectations.

No significant difference was observed in experienced pain and duration of bleeding (Table 4). However, no further information after the follow-up was available.

No significant difference in pregnancy-related symptoms was found between the groups. These symptoms were reported after the mifepristone administration (day 1 in the diary). The median duration of nausea was 1 (0–14, interquartile range [IQR] 3) days in the early group and 1 (0–15, IQR 1) days in the late group ($p = 0.9$). Women in the early group reported 0 (0–2, IQR 1) days median duration of vomiting vs 1 (0–6, IQR 1) days in the late group ($p = 0.109$). The median duration of pelvic pain in the early group was 3 (0–22, IQR 5) vs 4 (0–23, IQR 5) in the late group ($p = 0.111$). In the early group, the median duration of fever/chills was 0 (0–8, IQR 1) days vs 1 (0–15, IQR 1) days reported by women in the late group $p = 0.241$.

TABLE 1 Patient characteristics.

Characteristic	Gestational age	
	≤63 days	64–70 days
Age in years, median (range, IQR; no. of women)	28 (18–46, 8; $n = 110$)	29 (18–47, 8; $n = 156$)
BMI, mean ± SD (no. of women)	22.62 ± 3.55 ($n = 108$)	24.01 ± 3.78 ($n = 137$)
Parity, median (range, IQR; no. of women)	0 (0–3, 2; $n = 112$)	0 (0–5, 2; $n = 149$)
Gravidity, median (range, IQR; no. of women)	2 (0–9, 2; $n = 112$)	3 (0–10, 2; $n = 152$)
Pregnancy length, mean ± SD (no. of women)	44.96 ± 6.93 ($n = 111$)	66.31 ± 1.7 ($n = 159$)
Number of previous abortions, median (range, IQR; no. of women)	0 (0–5, 1; $n = 100$)	1 (0–7, 2; $n = 143$)
Miscarriage, median (range, IQR; no. of women)	0 (0–5, 0; $n = 93$)	0 (0–2, 0; $n = 127$)

Abbreviations: BMI, body mass index; IQR, interquartile range; SD, standard deviation.

TABLE 2 Primary outcome.

Success rate	≤63 days ($n = 100$)	64–70 days ($n = 141$)	p	OR
Complete abortion, n (%)	95 (95)	136 (96)	0.745	0.7 (0.16–3.13)
Incomplete abortion				
Treated medically, n (%)	3 (3.2)	2 (1.4)	0.65	0.46 (0.04–4.16)
Treated surgically, n (%)	2 (2.1)	2 (1.4)	1	0.7 (0.05–9.8)
Ongoing pregnancy				
Treated surgically, n (%)	0 (0)	1 (0.7)	1	

Abbreviation: OR, odds ratio.

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TABLE 3 Secondary outcome—experience and perception of the abortion treatment.

Gestational age	≤63 days (*n* = 84)*	64–70 days (*n* = 118)*	*p*
Satisfied with the chosen treatment			
Agreeing with the statement, *n* (%)	77 (91.6)	102 (85)	
Neutral, *n* (%)	5 (6)	12 (10)	
Not agreeing with the statement, *n* (%)	2 (2.4)	6 (5)	
Total score 1–5, mean ± SD	4.6 ± 0.76	4.42 ± 0.98	0.247
Feeling calm and safe during the abortion			
Agreeing with the statement, *n* (%)	68 (81)	87 (72.5)	
Neutral, *n* (%)	9 (10.7)	22 (18.3)	
Not agreeing with the statement, *n* (%)	7 (8.4)	11 (9.2)	
Total score 1–5, mean ± SD	4.11 ± 0.98	3.92 ± 1.11	0.233
Provided with sufficient information before the abortion			
Agreeing with the statement, *n* (%)	78 (92.8)	106 (88.4)	
Neutral, *n* (%)	5 (6)	9 (7.5)	
Not agreeing with the statement, *n* (%)	1 (1.2)	5 (4.2)	
Total score 1–5, mean ± SD	4.62 ± 0.66	4.48 ± 0.9	0.473
Treatment matching patient's expectations			
Agreeing with the statement, *n* (%)	68 (81.9)	90 (75.6)	
Neutral, *n* (%)	10 (12)	14 (11.8)	
Not agreeing with the statement, *n* (%)	5 (6)	15 (12.6)	
Total score 1–5, mean ± SD	4.19 ± 0.99	3.95 ± 1.14	0.136
Experienced bleeding matching patient's expectations			0.1
Agreeing with the statement, *n* (%)	31 (36.9)	60 (50)	
Neutral *n* (%)	33 (39.3)	39 (32.5)	
Not agreeing with the statement, *n* (%)	20 (23.8)	21 (17.5)	
Total score 1–5, mean ± SD	3.19 ± 1.25	3.48 ± 1.11	0.1
Experienced pain matching patient's expectations			
Agreeing with the statement, *n* (%)	31 (36.5)	66 (55)	
Neutral, *n* (%)	24 (28.2)	29 (24.2)	
Not agreeing with the statement, *n* (%)	30 (35.3)	25 (20.8)	
Total score 1–5, mean ± SD	2.98 ± 1.35	3.52 ± 1.15	0.01
Provided with sufficient pain medication			
Agreeing with the statement, *n* (%)	74 (89.2)	102 (85)	
Neutral, *n* (%)	7 (8.4)	11 (9.2)	
Not agreeing with the statement, *n* (%)	2 (2.4)	7 (5.8)	
Total score 1–5, mean ± SD	4.55 ± 0.84	4.47 ± 1	0.805
Recommendation of home abortion to a friend in the same situation			0.467
Agreeing with the statement, *n* (%)	76 (95)	109 (92.4)	
Not agreeing with the statement, *n* (%)	4 (5)	9 (7.6)	

*Number of completed questionnaires.

4 | DISCUSSION

Our results showed high efficacy of medical abortion at home with a success rate exceeding 95% even at extended GA and no significant differences in ongoing pregnancy or incomplete abortion rate compared with home abortions in an earlier pregnancy.

The numbers of incomplete abortions or ongoing pregnancies were low in both groups, which is a reassuring similarity to the results from previous studies.

For pregnancies up to 63 days of gestation, there is convincing data to support the home use of misoprostol. In 2011, a systematic review and meta-analysis revealed that when comparing early

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TABLE 4 Pain and bleeding: median, range and IQR.

	Gestational age		
	≤63 days (*n* = 73)*	64–70 days (*n* = 114)*	*p*
Pain intensity 1–10	7 (3–10, 4; *n* = 55)	7 (0–14, 4; *n* = 91)	0.34
Bleeding days	14 (2–28, 6; *n* = 73)	15 (4–31, 8; *n* = 114)	0.1
Duration of heavy bleeding, days	2 (0–10, 3; *n* = 69)	3 (1–14, 3; *n* = 109)	0.37
Duration of moderate bleeding, days	5 (0–19, 4; *n* = 70)	5 (1–27, 5; *n* = 110)	0.71
Duration of spotting	7 (1–20, 5.5; *n* = 71)	7 (0–24, 7; *n* = 96)	0.21

*Number of returned diaries.

medical abortion, up to 56 days of gestation, performed at home or at a clinic, there were no differences in effectiveness, safety and acceptability.[4] Recently, this review was updated and incorporated 10 more studies, including three randomized controlled trials. No difference was found between home-based and facility-based medical abortion when women with a GA up to 63 days were included in the analysis, further evidence that home-based abortion in early pregnancy is safe.[10] Home-based abortion was defined as a medical abortion where mifepristone, misoprostol or both were administered at home.

Lately, more data on home administration of misoprostol in the late first trimester has become available. In a recent systemic review with a meta-analysis aiming to identify the potential "cut-off" in gestational length when benefits still outweigh the risk, it was shown that pregnancies up to 63 days of gestation were as safe as pregnancies 64–70 days of gestation.[21] Data on the safety in more advanced pregnancies were, however, not possible to include due to a lack of high-quality studies. There are, however, small prospective and retrospective studies on home abortion also in more advanced pregnancies up to 84 days of gestation showing a high rate of complete abortion.[22]

A decline in efficacy with more advanced pregnancy has been reported, as well as an increased rate of ongoing pregnancies. In pregnancies up to 63 days, the risk of ongoing pregnancy is approximately 1%, whereas in pregnancies exceeding 64 days, the risk was reported to be almost threefold higher.[23,24] In many settings nowadays, the treatment regimen therefore includes additional doses of misoprostol for pregnancies with a gestational length of over 63 days.[25]

In our study, home abortion was very well accepted. A high proportion expressed that they were very satisfied or satisfied with the chosen treatment, and there were no significant differences between the two study groups. The definition of acceptability varies between studies, and there are several factors influencing women's perception of abortion. Duration of bleeding is an important factor that might affect satisfaction and acceptability of the procedure. Medical abortion is associated with a few more bleeding days than surgical abortion,[24] and it might be expected that more advanced pregnancy length could increase the duration of bleeding. In our study, there was no significant difference in the duration of bleeding.

Previous studies on acceptability show similar findings to our study; however, there are only a few studies that include pregnancies with a gestational length exceeding 63 days. In a study from Mexico, 960 women pregnant up to 70 days were included.[26] In the range 64–70 days of gestation, 148 participants were analyzed; 74.8% would prefer the same method if in need of a future abortion and 76.4% found the treatment to be "not at all difficult" or "slightly difficult".

The data on the acceptability of the procedure itself and recommendation of the procedure to a friend in the previous studies was almost the same as in our study.[27]

High satisfaction with home use of misoprostol in medical abortion has been shown in early gestation. In a study from Singapore, including pregnancies up to 70 days of gestation, satisfaction was reported as very high (94.4%) and successful abortion was observed in 100% of women; however, only 11 women were in the gestational age range 64–70 days.[28]

Nowadays, sufficient data is available to change the limit for home abortion up to 10 weeks of GA. However, the treatment result needs to be evaluated. That could be done by a self-performed pregnancy test or a follow-up visit at the clinic.

The strength of our study is the prospective design and the acceptability data showing women's perception of medical abortion at home even in more advanced pregnancies. Although we included participants over a long period, there was no change in management, such as treatment regimen, pain relief or service delivery during the study period.

The limitation is the sample size, making it difficult to state that home abortion between 64 and 70 days of GA is as safe as up to 63 days. Our intention to recruit 300 participants in each group was more difficult than anticipated when the study was planned. In Sweden, with increasing access to abortion care made possible by medical abortion and accelerated by home use of misoprostol, fewer abortions are done at a GA beyond 7 weeks and only very few beyond 9 weeks[29] This shift resulted in slow recruitment and the premature end of the trial. It is also possible that the decreasing number of abortions in late pregnancy can have affected the awareness among staff regarding the study, and thus they might have failed to inform eligible women. In some of the clinics, other ongoing studies were given higher priority and recruitment were stopped. Another reason might have been that some women still prefer surgical abortion when the pregnancy exceeds 9 weeks.

However, considering available data on home abortion, our results strengthen the assumption that the efficacy is high also in pregnancies exceeding 63 days of gestation.

Due to a discrepancy in the methods of misoprostol administration in different countries and a different number of additional doses of misoprostol for medical abortion, it was essential to conduct a prospective, observational real-life study in a Swedish setting.

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5 | CONCLUSION

The high and similar success rate of medical abortion up to 70 days before and after 63 days in both groups, irrespective of GA, supports the use of misoprostol at home for women who chose this option even at the extended gestational length of 64–70 days. This is further supported by the high satisfaction reported in both the early and later gestational strata.

As medical abortion is proven to be safe and effective for home use, further development of the online provision of abortion drugs will allow women to have better access to abortion services. However, we strongly support some type of follow-up confirming this result to avoid potential complications.

AUTHOR CONTRIBUTIONS

VP, LLM and KG-D were responsible for the conception and design of this study. Data collection and data management were done by VP, LLM, Lena Marions, and Kristina Gemzell-Danielsson. VP, LLM, LM and KG-D conducted the analyses. VP drafted the initial paper, which was reviewed and revised by all authors. All authors approved the final draft of this article.

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CONFLICT OF INTEREST STATEMENT

KG-D has served occasionally on advisory boards for Bayer Healthcare and Gedeon Richter, and lectured at educational events connected with these companies and given lectures/served on advisory boards for Organon, MSD, Obseva, Natural cycles Cirqle, Medincell, Norgine and Medicine360. LM is a member of a data safety monitoring board for BayerPharma AG Berlin. VP and LLM have stated explicitly that they have no conflicts of interest in connection with this article.

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