Women's experiences and acceptability of medical termination of pregnancy

Results of an introductory study in Thailand

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Abstract

Purpose – The purpose of this paper is to understand women's experiences, acceptability and outcomes of using the medical termination of pregnancy (MTP). The study is conducted at nine reproductive health and family planning clinics at university hospitals as well as regional and provincial hospitals located in Bangkok and the locations within Thailand.

Design/methodology/approach – This is a descriptive research recruiting healthy women with pregnancy up to 63 days since the last menstrual period (LMP) who opted for MTP during 2012–2014.

Findings – A total of 443 women who were referred from the reproductive health networks voluntarily participated in the study. Overall, 92.6 percent of participants had a complete abortion. No serious adverse events were found for cases using misoprostol at home or at clinic. More than 98.3 percent of the women felt satisfied or very satisfied with the method. More than 80 percent of participants thought that the side-effects of the method were as expected or less than expected. More than 95 percent of the women recommended having MTP available in Thailand.

Originality/value – The introduction of MTP that uses a mifepristone and misoprostol regimen (Medabon®) in pregnancies up to 63 days, since LMP demonstrates that misoprostol can be safely used by women at home or at clinic. The administration of misoprostol at home reduces the number of hospital visits, which saves time and costs for traveling from home to the facility. In addition, women have more privacy and control over their bodies by self-administering misoprostol. The MTP's introductory results also show that MTP service provision is well integrated into reproductive health and family planning services. It is useful for stakeholders who would be involved in design and planning of health system services before the MTP is made broadly available throughout the country.

Keywords Abortion pills, Medical abortion, Medical abortion introduction, Medical termination of pregnancy, Mifepristone, Misoprostol

Paper type Research paper

Introduction

In Thailand, the issue of termination of pregnancy (TP) is often controversial and emotional and has significant socio-cultural and religious implications. Thus, women who have faced this situation have often hidden the issue and sought various means to terminate an

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unplanned or unwanted pregnancy[1]. One of the most commonly sought ways has been with medical abortion products. Illegal in Thailand, the products have become known and available throughout the country largely via the internet. They are now obtainable, albeit in diverse regimens and at significant cost to consumers. Due to the danger of self-medication resulting in complications, the rapid and widespread uptake of medical abortion products created an issue that required urgent attention.

The provision of safe TP within the full extent of the law is an important component of reproductive health services. Providing women with a choice in TP methods improves satisfaction, and some health care providers find it easier to provide medical termination of pregnancy (MTP) than to perform aspiration. The provision of MTP can also improve access to TP services as various types of health care professionals can be trained to provide MTP.

The most effective regimen for early TP consists of the use of 200 mg of mifepristone (Mf) followed 24–48 h later by 800 μg of misoprostol (Ms). Mifepristone is an antiprogestin that blocks the action of progesterone so the uterus cannot sustain a developing pregnancy. Mifepristone also makes the uterus more sensitive to prostaglandins and softens and dilates the uterine cervix. Prostaglandin analogues, such as misoprostol, cause uterine contractions which lead to the expulsion of uterine contents. As of 2017, mifepristone is licensed in 65 countries for the termination of early pregnancy[2]. In 2005, the World Health Organization (WHO) included mifepristone and misoprostol for early TP on its Model List of Essential Medicines[3]. The regimen used in this study is the same regimen as listed in the latest WHO clinical practice handbook for safe abortion in 2014[4].

Expected normal effects of MTP during and after administration include vaginal bleeding and cramping. Vaginal bleeding from MTP, often accompanied by the passage of clots, is usually heavier than during a menstrual period. Bleeding sometimes begins after taking mifepristone, but most often starts 1–3 h after misoprostol is taken. The amount and duration of bleeding vary: bleeding is generally heaviest for a few hours during the actual abortion and has the general pattern of diminishing over time, often lasting up to two to three weeks. Cramping is typically strongest in the hours after misoprostol is taken, and then eases off after the pregnancy has been expelled[5, 6]. During MTP, women may experience what feels either like an intense, crampy and long menstrual period, or like a spontaneous miscarriage. After the pregnancy passes – which the woman may not be able to differentiate from other blood and/or clots – she will likely experience a persistent decrease of bleeding and cramps until the bleeding ends. Uterine contractions can be painful, and some women will experience side-effects including nausea, vomiting, diarrhea, headache, chills, shivering and transient fever lasting less than a day[7]. There are no long-term health effects of MTP, nor will the medication impact any future pregnancies[8].

Even though MTP has been used in several countries around the world for more than a decade, this method was first officially introduced in Thailand at five medical schools and four state hospitals. Before making MTP available in the Thai health service systems nationwide, it is important to assess the experiences of women using MTP. Therefore, the purpose of this study is to assess the acceptability, the outcomes of using MTP, and examining side-effects and service delivery. The study recruited women at gestations not later than 63 days since the last menstrual period (LMP).

Material and methods

Design of the study

This was a descriptive, observational study to understand women's experiences, outcomes from using MTP, the acceptability of side-effects and service delivery with the combination regimen of mifepristone and misoprostol (Medabon®) for TP up to 63 days since LMP.

Data collection tools included clinical data and women's acceptability record forms at admission, on day 2 or day 3, and at the follow-up visit on days 10–14.

Setting
The study was undertaken at reproductive health and family planning clinics in five medical schools and four state hospitals located in Bangkok and at provincial locations in Thailand. All of these selected sites were providing a surgical method for TP within the context of the Thai law and Medical Council's regulations.

Study volunteers
A quota sample of a total of 450 women (50 volunteers/clinic) was recruited from women requesting legal TP through the reproductive health referral network. Participants who were enrolled in the project were within the inclusion criteria, the abortion law and the Medical Council's regulation. A total of 443 healthy women voluntarily participated in the study.

Inclusion criteria and exclusion criteria
See Table I.

Description of the intervention process
The intervention consisted of the following components:

- selection of health facilities to perform MTP;
- adaptation of international MTP training curricula to the needs of the Thai health service system;
- adaptation of values clarification and materials to counsel about options, to the needs of the Thai health service system;
- training of health care providers at the selected study sites in the provision of MTP services including values clarification and counseling about options;
- development of a service protocol for MTP using international guidelines;
- development and testing of information, education and communication materials for providers and women;
- development of a recordkeeping system to be used for the study and to provide insights for recordkeeping in routine service delivery;

Inclusion criteria: women were recruited if	Exclusion criteria: women were not recruited if
Requesting abortion	Allergic to mifepristone or misoprostol
Willing and able to participate after information about the study was provided	They had history or evidence of disorders that represented a contraindication to the use of mifepristone (chronic adrenal failure, severe asthma uncontrolled by corticosteroid therapy, inherited porphyria) or of prostaglandins
Eligible for legal termination of pregnancy[9, 10]	
In good general health;	They had history or evidence of thromboembolism
Their pregnancy was not more than 63 days, verified by physical examination (PE), per vaginal examination (PV) and/or ultrasound	They experienced severe or recurrent liver disease
	Had a medical condition or disease that required regular treatment with systemic drugs, care or precaution (e.g. corticosteroid or anticoagulant therapy) in conjunction with abortion
Their pregnancy was single and intrauterine (single sac)	
And agreeing to have the abortion with a surgical method, if treatment with a combination of Mf and Ms failed	Had uterine fibroids that were likely to affect bleeding or contractility
	There was the presence of intrauterine device in utero
	Or were breastfeeding

Table I.
Inclusion and exclusion criteria for selecting study participants

- collection of data on service provision and outcomes of the treatment including adverse events;
- provision of MTP using practical guidelines;
- interviewing providers and women who have used MTP and collecting their opinions of MTP service;
- assessment of how the provision of MTP affects services and costs;
- reporting of the outcome of MTP including rates of complete and incomplete termination of pregnancies and failures and complications, if any;
- review of the experience of MTP provision in a participatory process with stakeholders for the development of a strategy for the wider availability and accessibility of MTP in Thailand;
- organization of a dissemination workshop; and
- preparation of scientific papers on the results.

The regimen for MTP to be used

The regimen for MTP used in the study consisted of one 200 mg tablet of mifepristone followed 24–48 hours later by four tablets of 200 μg misoprostol each. This protocol was based on the recommended MTP regimen by WHO and the UK Royal College of Obstetricians and Gynecologists[4, 11]. This regimen was approved in Thailand by Thai FDA in December 2014[12] (Table II).

Sequence	Procedure and data collection process	Treatment
Admission, day 1		
Day 1 at clinic	Vaginal examination (PV) and/or ultrasound exam (if judged necessary) to verify the length of pregnancy and check that pregnancy is intrauterine Medical and gynecological exam, height, weight and blood pressure (BP) according to hospital's practice Medical, obstetrical and gynecological history taken and recorded	Mf 200 mg orally (1 tablet)
Day 2 or 3 (24–48 h) at clinic or at home	At clinic Brief interview Measurement of BP and pulse rate Physical examination Hourly record of temperature, noting possible side-effects and noting any medication given during the 3-h clinical observation period Recording exact time of expulsion At home Daily record form for bleeding, signs and symptoms after using Ms	Ms 0.8 mg vaginally or sublingually (4 tablets of 0.2 mg)
End of study		
Day 10–14 follow-up visit at clinic	Medical and perception interview and review of diary card recorded Pelvic examination Ultrasound examination if judged necessary from clinical findings	If the subject is still bleeding at this visit, she must be examined and a follow-up appointment made

Notes: Mf, mifepristone; Ms, misoprostol; BP, blood pressure

Table II.
Treatment plan and study process

Statistical analysis

The data were analyzed centrally at the Concept Foundation in Pathumthani, Thailand. The statistical analysis was done using SPSS 17.0 software for Windows. Descriptive statistics were calculated for all baseline characteristics for all study subjects, to describe characteristics of the population, efficacy, side-effect by routes and place of administration. The main efficacy analysis included all subjects from nine hospitals for whom the treatment outcome was known. The safety and acceptability analyses were assessed during the follow-up visit and included all women.

Ethics and independent ethics committee

The study was approved by the ethical committee of the institutional at all participating hospitals before each center starts recruitment of the study participants. Only Health Promotion Hospital, region 6 Khon Kaen, implemented the study based on the Department of Health's policy on safe abortion in 2012. Followings are the listed certificate ethical committee approvals:

- Chulalongkorn medical school, Chulalongkorn University, IRB No. 227/54, dated June 7, 2011.
- Siriraj Medical medical school, Mahidol University, EC No. Si 061/2012.
- Ramathibodi medical school, Mahidol University, EC No. MURA2011/252 dated July 4, 2011.
- Srinakarind hospital, Khon Kaen University, IRB No. 00001189, dated August 7, 2013.
- Sonklanakarind hospital, Prince of Songkla University, EC: 56-223-12-1-1, dated May 20, 2013.
- Health Promotion Center (HPC), region 6 Khon Kaen, implemented under the Department of Health's policy in 2012.
- Chiangrai Prachanukroh regional hospital, Chor Roe 0032.102/22566, dated July 29, 2013.
- Nan provincial hospital, EC No., Nor Nor 0032.2/1679, dated May 23, 2013.
- Phrae provincial hospital, EC No., EC 3/2556, dated July 2, 2013.

The women who chose medical abortion were informed about the study and invited to join. All potential volunteers were informed about the aims and procedures of the study, side-effects that may occur as a result of the treatment and the alternative method(s) of pregnancy termination that was (were) available. They were also informed about the measures taken to ensure confidentiality and their right to withdraw from the study at any time without prejudice to their further medical care. Women who decided to participate in the study were asked to sign the consent form before enrollment into the study; the consent form was written in the subject's own native language. For women who were under 18 years, investigators requested parent(s) and women to provide consent after they received information about the study.

Results

Recruitment started in March 2012 and finished in November 2014. A total of 446 women were recruited. Three women were excluded from the analysis due to their gestational age of more than nine weeks. In total, 443 healthy pregnant women with 63 days or less of gestation were enrolled in the study. Eight women were lost to follow-up and excluded from the analysis. Therefore, 435 women were included for efficacy, safety and acceptability analysis. Protocol violation happened in the cases of two women who received only mifepristone.

Details of the brief outcome of participants are shown in Figure 1.

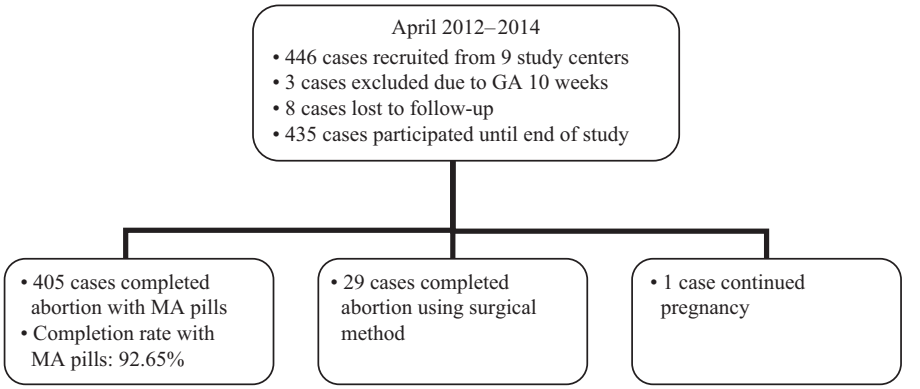

Figure 1.
Outcome of study participants from the nine study clinics

Baseline characteristics were similar among the nine study centers. The mean age was about 26.5 years old (SD ± 7.6), between 13 years and 45 years. A total of 221 women (or 50.2 percent of all women recruited) had been pregnant before. The mean gestational age was 46.5 days (SD ± 8.6) with minimum 28 days and maximum 63 days. In total, 70.2 percent of the women had gestational age (GA) at ⩽ 49 days and 4.7 percent with GA 57–63 days (Table III).

Misoprostol at home or at clinic

After the women took a tablet of mifepristone at the clinic, they needed to administer misoprostol 0.8 mg vaginally or sublingually at home or in the clinic on day 2 or day 3 (24–48 h) to complete the course of MTP. The results revealed that 65.3 percent of women preferred to use misoprostol at home. The rest (or 34.7 percent) administered misoprostol at the clinic. This was true both in Bangkok and up-country (Table IV).

End results after complete MTP (Medabon®)

In total, 383 women of the 435 completed abortion with the original one pack of Medabon®. Therefore, the success rate of using the original regimen (one pack of Medabon®) was 88.1 percent, including both routes of administration of Ms. If 20 women who received additional

Table III.
Number and percentage of age group and gestational age distribution among the women enrolled from nine study clinics

Characteristics	Number	%
Age (years) mean ± SD = 26.5 ± 7.6, min 13: max 45		
< 18	53	12.0
18–29	234	52.9
30–39	127	28.7
⩾ 40	28	6.3
Total	442	100.0
Pregnancy history		
Ever pregnant	221	50.2
First time	219	49.8
Total	440	100.0
Gestational age (days) mean ± SD = 46.48 ± 8.6, min 28: max 63		
⩽ 49	311	70.2
50–56	111	25.1
57–63	21	4.7
Total	443	100.0

misoprostol at the first follow-up visit were included, the success rate of complete abortion was 92.6 percent. A total of 29 women completed abortion using surgical methods after using MA (Table V). Since the MTP process may feel similar to spontaneous miscarriage, some of the women became worried and requested to interrupt the MTP process and use a surgical method.

Experiences of side-effects and complications

In general, there were no severe complications reported in this study. Nausea related to pregnancy and/or related to the use of misoprostol sublingually was reported at 58.8 percent. Of drug-related side-effects, diarrhea was also commonly found at 71 percent.

There was one case report of a maculopapular rash appearing on a participant's chest, abdomen and both hands about 2–3 h after the administration of mifepristone. The woman felt itching for 1–2 days and visited a hospital where she was treated with an oral antihistamine and she recovered fully.

The degree of abdominal pain was classified on a scale from 0 to 10. The mean degree of pain reported was 2.9 (SD ± 2.97). There were two cases reported at a perceived "10" degree of abdominal pain.

Table VI reveals the women's subjective assessment of MTP experience at the follow-up visit on days 10–14 as well as their perception of privacy of services. Overall, 76 percent (328/433) of the women had experienced less pain or the same pain as expected. 65.4 percent (281/430) of the women reported either less bleeding than expected or the same as expected.

Table IV. Number and percentage of place where women administered misoprostol

	Place of misoprostol administration					
	Bangkok		Other provincial locations		All	
Place	*n*	%	*N*	%	*n*	%
Clinic	61	14.0	90	20.7	151	34.7
Home	93	21.4	191	43.9	284	65.3
Total	154	35.4	281	64.6	435	100.0

Table V. Number and percentage of women with end results of MTP from nine study clinics

	Method used									
	Original regimen		Original regimen+ additional Ms		MVA		Others surgical methods		Total	
End results after complete MTP	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Complete abortion	383	88.1	20	4.6	1	0.2	1	0.2	405	93.1
Incomplete abortion	0	0.0	0	0.0	27	6.2	2	0.5	29	6.7
Continuing pregnancy	0	0.0	0	0.0	1	0.2	0	0.0	1	0.2
Total	383	88.1	20	4.6	29	6.7	3	0.7	435	100.0

Table VI. Number and percentage of overall experiences of MTP procedure of the women from nine study clinics

	Rating compared to expected								
	Less		Same		More		No comment		
Experiences	*n*	%	*n*	%	*n*	%	*n*	%	Total
Pain	197	45.5	131	30.3	98	22.6	7	1.6	433 (100.0)
Bleeding	103	24.0	178	41.4	142	33.0	7	1.6	430 (100.0)
Duration of abortion procedure	183	42.3	166	38.3	71	16.4	13	3.0	433 (100.0)
Privacy	30	7.0	166	39.0	215	50.5	15	3.5	426 (100.0)
Other side-effects	260	61.5	82	19.4	65	15.4	16	3.8	423 (100.0)

In total, 80.6 percent (349/433) of the women reported that the duration of bleeding was shorter than or as expected, whereas 51.4 percent of the women expressed that the duration of bleeding was long but acceptable (Table VII). A total of 61.5 percent (260/423) revealed that other side-effects were less than expected (Table VI).

Acceptability

As per Table VII, 49.9 percent (214/429) of the women revealed that "none" of the features of the method could be considered the worst. When asked what the worst feature of the MTP procedure was, women responded that the following effects from using MTP were considered the worst: pain, nausea/vomiting and bleeding at 19.1, 13.1 and 7.5 percent, respectively.

When asked whether they were satisfied with the medical abortion method, 98.3 percent (425/432) reported being satisfied or highly satisfied (Table VIII).

Discussions

The MTP regimen used in the early TP (less than or equal to 63 days) consisted of 200 mg mifepristone orally followed 24–48 hours later by 800 μg misoprostol vaginally or sublingually. Then, the women need to come for follow-up on days 10–14[13, 14]. Protocol violation happened in the cases of two women who received only mifepristone. Of the two women who only received Mf and not Ms, one woman who completed abortion was confirmed on the follow-up visit. The other woman had a continuing pregnancy confirmed by ultrasound. This case had a twin pregnancy. When the first fertilized embryo expelled, the provider thought that the woman had had a completed abortion, so the provider decided by herself to ignore the remaining tablets of Ms. These results suggest that whether abortion is completed or not, providers need to administer the full course of Mf and Ms based on the study protocol.

The characteristics of the study participants in Table III showed that nearly 80 percent of the women terminated their pregnancy at the ages of 18–39 years. This result suggests that

Table VII.
Number and percentage of features of the MTP and bleeding perception of women from nine study clinics

Feature of the method considered the worst

None		Pain		Bleeding		N/V[a]		Too long		Discomfort[b]		Others		
n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	Total
214	49.9	82	19.1	32	7.5	56	13.1	20	4.7	19	4.4	6	1.4	429 (100.0)

Duration of bleeding

Too long		Long but acceptable		As expected		Less than expected		Very little		Other		
n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	Total
24	5.6	222	51.4	109	25.2	72	16.7	4	0.9	1	0.2	432 (100.0)

Notes: [a]Nausea/vomiting; [b]vaginal examination discomfort

Table VIII.
Number and percentage of acceptability of women with MTP from nine study clinics

Satisfaction with medical abortion								
Highly satisfied		Satisfied		Not satisfied		No opinion		
n	%	*n*	%	*n*	%	*n*	%	All
284	65.7	141	32.6	1	0.2	6	1.4	432 (100.0)

unwanted/unplanned pregnancy can occur to women at any time during their reproductive age, and not only among teenagers who have less experience with birth control.

The reproductive health referral networks are an important mechanism to help women get easy access to safe abortion services, since there are few facilities officially providing the services. In this study, the majority of the study participants were referred by the reproductive health network, suggesting that this channel could reduce the time needed for women to seek safe abortion services. This, in turn, resulted in 70 percent of women terminating their pregnancies at a low gestational age – less than 49 days since LMP (Table III).

It is important to note that in the Thai context, abortion is often controversial, emotional and has significant socio-cultural and religious implications. Therefore, by using MTP at home, women felt more comfortable to manage the final stage of fertilized fetal expulsion in a private place. However, counseling and information is given on how to use Ms at home, plus expected side-effects and abnormal signs and symptoms which are critical. These key messages are important in assisting women to better manage the MTP process. Providers need to emphasize these key messages to all women before discharging them after taking mifepristone.

The success rate of complete abortion of the present study was slightly lower than the previous study by WHO in 2010, which was revealed at 94.2 percent[7]. One of the reasons for the lower success rate in this study was that some of the women interrupted the MTP process by asking for surgical intervention. Since the MTP process is similar to spontaneous abortion and the abortion takes a few days to complete, some women felt nervous when they faced several days of bleeding after completing the MTP regimen. Additionally, some providers who were used to terminating pregnancies by manual vacuum aspiration (MVA) felt that the MTP process took longer time compared to MVA. So they could not wait until completing abortion and interrupted the MTP process with MVA. Therefore, these cases were recorded as failed MTP because we were unable to conclude whether the woman had a complete or incomplete abortion. However, the success rate of MTP depends on providers. It is like a learning curve: the more they provide MTP, the more they learn[15].

There were no serious complications reported by the women who used misoprostol at home or at the clinic. There were only three cases that had unexpected, non-serious adverse events needing a few days of treatment and ending with full recovery. Thus, the introduction of MTP for pregnancies less than 63 days since LMP can offer benefits for reproductive health service systems, since the provision of MTP requires no hospital admission as women can use misoprostol at home safely.

In the present study, the follow-up evaluation was scheduled on days 10–14 after taking mifepristone which is appropriate to assess the experiences of women using MTP and to monitor vaginal bleeding. This was based on the fact that heavy bleeding may be delayed for a few days up to a few weeks after taking misoprostol and that some women may experience prolonged bleeding[5]. For follow-up visits, we assessed satisfaction with MTP in terms of the women's experiences. The experiences of women included lower abdominal pain, bleeding, long duration of MTP process and side-effects associated with MTP. We found that the majority of the women's experiences were not that severe than what they had expected. This may have been due to the fact that the women were provided with adequate counseling during the process.

Overall, the majority of the women (98 percent of women in both rural and urban areas) were satisfied or highly satisfied with the regimen for TP, which is consistent with findings from other countries[7, 15]. In addition, 95.8 percent of the women thought that MTP should be available in Thailand.

Understanding the experiences of women who opted for abortion using MTP (Medabon®) is useful for everyone who would potentially be involved in the preparation of the health systems for MTP provision. For sustainability and to reduce stigmatization, the provision of MTP should be integrated into the reproductive health and family planning clinics of each health care facility.

As this study involved the introduction of MTP in nine hospitals, we believe that it will be important to conduct a bigger survey after MTP is listed in the National List of Essential Medicines in order to compare service provision of MTP at various levels of health care facilities and assess women's satisfaction as well as accessibility.

Conclusions

The regimen of MTP, or the combination package of mifepristone and misoprostol for TP less than 64 days since LMP[13, 14] consisting of 200 mg mifepristone orally followed 24–48 h later by 800 μg misoprostol vaginally or sublingually, has been demonstrated as effective and easy to use. Counseling and information given to women in order to use misoprostol at home by themselves is highly acceptable among women both in Bangkok and other provinces. No serious adverse events were recorded. Overall, most of the women in both rural and urban areas were either satisfied or highly satisfied with the regimen for TP. Reproductive health referral networks are an important channel to assist women to access the safe abortion services as soon as possible. To reduce stigmatization, MTP should be integrated into the Reproductive Health and Family Planning Clinic of each health facility.

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