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Can women determine the success of early medical termination of pregnancy themselves? ♣,♣ ★

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Abstract

Objective: To determine the outcome of early medical termination of pregnancy (TOP) among women who choose a "self assessment" follow up comprising a self-performed low sensitivity urine pregnancy test with instructions on signs/symptoms that mandate contacting the TOP service.

Study Design: A retrospective review of computer databases of 1726 women choosing self-assessment after early medical TOP (<9 weeks) in the UK. The main outcome measures were (a) number of women choosing self-assessment, (b) contact rates with TOP service and (c) time to presentation with an ongoing pregnancy (failed TOP).

Results: Ninety-six percent of women having an early medical TOP and going home to expel the pregnancy chose self-assessment. Two percent of women made unscheduled visits to the TOP service. One hundred and eighty-eight women (11%) telephoned the service about concerns related to complications or the success of treatment. There were eight ongoing pregnancies (0.5%; 95% confidence interval 0.2–0.9%). Four were detected within 4 weeks of treatment; the remainder were not detected until one or more missed menses after the procedure.

Conclusions: Most women having an early medical TOP, who go home to expel the pregnancy, choose self-assessment. Relatively few women make unscheduled visits or telephone the TOP service. Most ongoing pregnancies are recognized at an early stage, although late presentation (as with all methods of follow up) does still occur.

Implications statement: If women are given clear instructions on how and when to conduct a urine pregnancy test and on signs/symptoms that mandate contacting the TOP service, then they can confirm the success of early medical TOP themselves. Late presentation due to failure to recognize an ongoing pregnancy is rare.

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1. Introduction

It is estimated that one in three women will have a termination of pregnancy (TOP) at some point in their lives [1]. Increasingly in Great Britain, early TOP (up to 9 weeks

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gestation) is being conducted medically; 87% and 61% of those at less than 9 weeks gestation were conducted medically in Scotland and England/Wales, respectively, in 2013 [2,3]. The medical regimen at less than 9 weeks gestation usually consists of a single oral dose (200 mg) of mifepristone followed 24–48 h later by 800 mcg of misoprostol (usually administered vaginally) [4]. In most countries where early medical TOP is legal (e.g., USA, Sweden, France and Portugal), women are able to administer the second part of this treatment regimen (misoprostol) at home, and this has been shown to be safe and preferred by women [5]. In Great Britain, legal restrictions mandate that misoprostol must be administered on licensed premises, although women may then go home to expel the pregnancy [6,7]. This has sometimes been termed *early medical discharge*. With early medical

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TOP, the risk of ongoing pregnancy is small—approximately 0.5–1% [4]. For women in whom expulsion of the pregnancy has not been confirmed by a clinician before, follow-up traditionally has involved a routine clinic visit for ultrasound. While ultrasound will reliably exclude an ongoing pregnancy, its use can lead to unnecessary medical or surgical intervention due to detection of blood clot or products of conception that are visible but not clinically important [8,9]. Reliance on ultrasound is also costly and requires highly skilled staff, and for some services, the volume of repeat appointments may limit the number of new referrals that can be seen. Observational studies report high loss to follow up when women are scheduled for a routine clinic follow-up, which is a waste of resources [6,10]. The most studied alternative method of follow up to exclude ongoing pregnancy is that of a telephone follow-up from the TOP provider combined with a self-performed pregnancy test conducted by the woman herself at home [11,12]. Although telephone follow-up has been shown to be an acceptable method of follow-up [11,12], a survey of women showed that more than half would have preferred no routine telephone call but rather simply to contact the service themselves if there was a problem [11].

The TOP service in Edinburgh, which is part of the National Health Service (NHS) Scotland and provides free treatment, introduced telephone follow as routine in 2011. However, by 2012, staff of the TOP service, reported that there were increasing requests from women not to receive a routine call, and that several attempts had to be made before most women were successfully contacted. Furthermore, staff reported that women had often forgotten to perform the pregnancy test on the day of the scheduled call necessitating a second call at a later date for results of the pregnancy test. In response to this in April 2012 the TOP service introduced "self assessment," permitting women having early medical TOP and going home to expel the pregnancy, to opt out of receiving this routine telephone call provided that they understood how to conduct and interpret the urinary pregnancy test and signs and symptoms that indicated the need to contact the TOP service. The quality improvement team for gynecology for the region approved the new service.

We wished to evaluate the self-assessment option in terms of (a) proportion of women choosing this, (b) contact rates with the TOP service and (c) time to presentation with an ongoing pregnancy (failed TOP).

2. Methods

2.1. Self-assessment

All women attending the TOP service in Edinburgh had an ultrasound to assess gestational age, and the medical TOP regimen used was 200 mg mifepristone followed 24–48 h later with 800-mcg misoprostol. From September 2012, clinics for women requesting a TOP were held both in a hospital outpatient clinic and a city centre community sexual and reproductive health (SRH) clinic, 3 mi away. The same

clinical lead was responsible for both sites, and the same clinic protocols were used at both NHS sites. Women were provided with a low sensitivity pregnancy (LSUP) test (detection limit 1000 IU Human Chorionic Gonadotrophin) at the clinic visit for administration of misoprostol and were instructed by clinic staff on when and how to conduct the LSUP test (Baby Duo, Quadratech diagnostics, UK). This was supplemented with both written and pictorial instructions on how to perform and interpret the test together with and signs/symptoms that might indicate an ongoing pregnancy [13] and for which they should contact the service on the dedicated number provided. All women who chose to have self-assessment were required to sign a form stating that they wished to opt out of receiving a routine telephone call, that they accepted the responsibility for contacting the TOP service if the pregnancy test was positive or invalid or they were not certain of the result or that even if the LSUP test was negative that they should still contact the service if they had less than 4 days of bleeding, had persisting symptoms of pregnancy or if their next period failed to arrive by 1 month after treatment (Fig. 1). In this way, ongoing pregnancy should in theory be detected at the latest when the next menses following treatment were missed (after 4 weeks).

The TOP service also provided free ongoing contraceptive supplies (pills, patch, ring) to women to start on the day that they received misoprostol. Progestogen-only injectables and implants were also administered/inserted at this visit before the woman was discharged home. Women wishing intrauterine contraception (intrauterine device or system) were given an appointment for insertion at a later date at the SRH service [14].

A retrospective review of the TOP service databases was conducted for all women choosing self-assessment during the period of study. Demographics that are routinely recorded include reproductive history, deprivation category based upon Scottish postcodes [15], body mass index (BMI) and method of contraception supplied to women at discharge from the service. For all women, the regional hospital computerized database was also checked to determine if women made an unscheduled visit to either the hospital or SRH site with a complication of treatment within 3 months of TOP or to the maternity service with an ongoing pregnancy. The TOP service telephone call registers were also checked to determine if women made telephone contact and reason for this. The chair of the local ethics committee confirmed that formal ethical committee approval was not required for this retrospective database review.

2.2. Statistical analysis

Statistical analysis was conducted using International Business Machines (IBM) Statistical Package for Social Sciences (SPSS) software Version 18 (SPSS, Chicago, IL, USA). Descriptive statistics were performed for demographics, and groups were compared by chi-squared test of significance.

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