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# Quality of life and acceptability of medical versus surgical management of early pregnancy failure<sup>\*</sup>

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# Abstract

**Objective**—This study compares quality of life (QOL) and acceptability of medical versus surgical treatment of early pregnancy failure (EPF).

**Design**—A randomised clinical trial of treatment for EPF compared misoprostol vaginally versus vacuum aspiration (VA).

**Setting**—A multisite trial at four US Urban University Hospitals.

Population—A total of 652 women with an EPF were randomised to treatment.

**Methods**—Participants completed a daily symptom diary and a questionnaire 2 weeks after treatment.

**Main outcome measures**—The questionnaire assessment included subscales of the Short Form-36 Health Survey Revised for QOL and measures of wellbeing, recovery difficulties, and treatment acceptability.

**Results**—The two groups did not differ in mean scores for QOL except bodily pain; medical treatment was associated with higher levels of bodily pain than VA (P < 0.001). Success of treatment was not related to QOL, but acceptability of the procedure was decreased for medical therapy if unsuccessful (P = 0.003). Type of treatment was not associated with differences in recovery, and the two groups reported similar acceptability except for cramping (P = 0.02), bleeding (P < 0.001), and symptom duration (P = 0.03).

Details of ethics approval

<sup>\*</sup>This research was presented in part at the joint 2005 Annual Meeting of the Association of Reproductive Health Professionals and the Society of Family Planning, Washington, DC.<sup>1</sup>

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Contribution to authorship

The authors have met all of the criteria for authorship for this manuscript and consent to its submission for publication. They conceived the research question and the study design, participated in data collection, performed the data analysis, and drafted and revised this manuscript.

The institutional review boards of the NICHD, Columbia University, the University of Miami, the University of Pennsylvania, the University of Pittsburgh, and the Clinical Trials and Surveys Corporation approved the study. All subjects provided written informed consent prior to any study procedure.

**Conclusions**—Despite reporting greater pain and lower acceptability of treatment-related symptoms, QOL and treatment acceptability were similar for medical and surgical treatment of EPF. Acceptability, but not QOL, was influenced by success or failure of medical management.

#### Keywords

Early pregnancy failure; misoprostol; quality of life

# Introduction

Early pregnancy failure (EPF), commonly diagnosed as miscarriage, anembryonic gestation, embryonic/fetal demise, or miscarriage, is common in clinical practice. Fully 15% of clinically apparent pregnancies do not develop past the first trimester, and women have a 25% lifetime risk of experiencing at least one EPF.<sup>2–4</sup> Surgical treatment has been the standard therapy for EPF, making vacuum aspiration (VA) one of the most common procedures performed. However, as our understanding of the risks of expectant management has improved and methods for medical evacuation of the uterus for an undesired pregnancy have been developed and practised, the options for treatment of EPF have increased.<sup>4</sup> Investigations of misoprostol for the medical evacuation of the uterus for EPF have proven that medical management of EPF is a safe and effective alternative to VA.<sup>5,6</sup>

The safety and efficacy of medical treatment is expected to improve with advances in the medical regimen, leading to new and better medical treatment options for EPF.<sup>7</sup> As access to and efficacy of medical treatment regimens increases, it is likely to become more widely offered by clinicians and increasingly chosen by women. Findings from one study indicate that misoprostol treatment for EPF would be preferred to VA by a majority of women with a diagnosis of EPF if its efficacy was greater than 65%.<sup>8</sup>

However, efficacy is not the only important factor in the selection of a treatment option for EPF. The experience of each treatment is widely different in terms of timing, setting, and expected symptoms, which may affect the experience of symptoms and the recovery from each. For example, VA is performed in an office or operating room by a trained clinician and has a defined procedure start time and a defined time when complete evacuation is confirmed. In contrast, misoprostol treatment is a patient-controlled procedure that may begin the process of expulsion of the gestation at an unpredictable time and over a longer period of time than a VA. A qualitative study highlighted themes regarding the impact of differences in the experience of the procedures on the acceptability of the treatment and mental health state of the woman. <sup>9</sup> However, the effect of the EPF treatment regimen on measures of acceptability, QOL, and the mental health state of the woman is poorly understood.

Several studies demonstrate a temporary and recoverable impairment of QOL and mental health states after the diagnosis and surgical treatment or expectant management of EPF.<sup>10–13</sup> After misoprostol treatment of EPF in a small pilot study, QOL was most closely associated with symptoms related to treatment; women who experienced more symptoms had worse QOL scores.<sup>13</sup> Several studies comparing acceptability and/or QOL and psychological wellbeing associated with medical treatment compared with surgical treatment of EPF generally found no differences but were not powered for the secondary outcome measure.<sup>14–16</sup> Despite these insights into the effect of EPF treatment and its success on QOL, it is not known whether a diverse US urban population of women experience differences in QOL or treatment acceptability between medical and surgical treatment as a primary treatment for EPF. In a large multicentre randomised clinical trial of misoprostol versus VA treatment for EPF, we planned a secondary analysis of QOL and treatment acceptability. The purpose of this study was to

compare the QOL and treatment acceptability of women randomised to misoprostol versus VA for primary treatment of EPF.

### **Methods**

#### Procedures

This is a planned secondary analysis from a multicentre randomised clinical trial of misoprostol versus surgical treatment for EPF conducted at Columbia University, the University of Miami, the University of Pennsylvania, and the University of Pittsburgh. The complete description of the clinical trial and study procedures has been published with the primary outcome results of treatment efficacy and safety.<sup>6</sup> In brief, 652 healthy women diagnosed with a first-trimester pregnancy failure (anembryonic gestation, embryonic or fetal demise, or incomplete miscarriage or inevitable abortion) were randomised in a 3:1 ratio to 800 micrograms misoprostol (cytotec<sup>®</sup>; GD Searle & Co., Skokie, IL, USA) administered vaginally versus VA. The 3:1 randomisation scheme provided adequate power for the between-group comparisons (medical versus surgical treatment), while also providing more precise estimates of safety and efficacy for the medical treatment group because unlike surgical treatment, little was known about the safety and efficacy of medical treatment of EPF. Power calculations indicated a sample size of 620 was required to determine noninferiority of medical treatment efficacy compared with surgical treatment; additional subjects were recruited to compensate for expected attrition. For this secondary analysis, the sample size provided 80% power to detect a 2.9- to 3.5-point difference in each of the five Short Form-36 Health Survey Revised (SF-36R) OOL scales. Randomisation occurred on the day of medical treatment or within 24 hours of surgical treatment and was stratified both by study site and type of EPF (anembryonic gestation or fetal demise versus incomplete miscarriage or inevitable abortion). All subjects met entry criteria and provided written informed consent prior to any study procedure.

The day participants were randomised to a treatment group was considered study day 1, and both treatment groups followed up in person on day 15. Women who received misoprostol were followed for evaluation on day 3 and received a repeat dose if expulsion was incomplete. If expulsion remained incomplete on study day 8, VA was offered per protocol. Demographic information and reproductive history were collected at baseline prior to treatment during individual structured interviews. Participants prospectively completed a daily diary of any symptoms experienced for the 2 weeks after treatment. All participants completed questionnaires assessing quality of life (QOL), depression, stress, and treatment acceptability during their visit on study day 15 (2 weeks after treatment). The questionnaires were completed in private, and all participants were given instructions for completion of the questionnaires and the option of having a member of the research team to read the questions to them. If a participant did not present for the day 15 visit, the questionnaires were not completed at another time; however, every attempt was made to contact participants who did not present for follow up for main study outcome measures and to collect symptoms diaries. All questionnaires and diaries had been used and evaluated in a pilot study and were available in English or Spanish.<sup>13</sup> Interviews were conducted in either language, depending on participant preference and comfort. Participants were included in this planned analysis if they met criteria for inclusion in the study, received study treatment, and had follow-up diary and questionnaire data available for analysis.

#### Measures

QOL after treatment of EPF was measured using specific dimensions of QOL and mental health states relevant to the treatment of EPF. Five subscales of the SF-36R, a measure of health-related QOL, were administered.<sup>17</sup> Physical ( $\alpha = 0.92$ ) and emotional ( $\alpha = 0.90$ ) role functioning measures limitations on one's usual roles (work or other activities) due to physical

health and mental problems. Social functioning ( $\alpha = 0.75$ ) measures the extent and frequency to which health problems interfere with usual social activities. Vitality ( $\alpha = 0.79$ ) measures energy level and fatigue, whereas bodily pain ( $\alpha = 0.74$ ) measures the intensity of pain or discomfort and the extent that it interferes with usual activities. The SF-36 was developed out of the work of the Medical Outcomes Study (1992) as a shortened measure of multiple dimensions of QOL.<sup>18</sup> The SF-36R incorporates improvements in wording, instructions, response categories, and format. The SF-36 and SF-36R demonstrate good internal consistency and discriminant validity and have been used in a wide variety of medical populations.<sup>17,18</sup> The scales are scored such that they display a mean of 50 and SD of 10 in the general well population. The subscales selected for this study were those having the greatest likelihood of being influenced by EPF and its treatment. We did not include the physical functioning scale, which assesses very basic physical capabilities, or the general health scale, which is a more global health perception measure.

We also excluded the mental health scale in favour of the more specific mental health measures described below. Self-report measures of depression and stress were employed to assess mental health status after treatment. Depression was measured with the Depression-Happiness scale  $(\alpha = 0.92)$ .<sup>17–19</sup> Measures of depression are typically designed to discriminate persons with clinical depression from the nondepressed general population. For this study, the authors believed that it was important to assess potential differences in affect even if these did not represent differences in rates of clinical depression. As no measure of affect specific for this population existed, we selected the Depression-Happiness scale because it measures the frequency of both positive and negative affect. By assessing both positive and negative emotional states, the measure is more sensitive to differences in affect apart from clinical depression, and so is especially useful in the assessment of affect in persons not seeking mental health care. The scale has excellent internal consistency and has demonstrated good convergent validity and test-retest reliability.<sup>20,21</sup> Response options were on a 1–6 scale from 'none of the time' to 'all of the time'. An overall score was generated from the mean of all 25 items, with a higher score indicating a greater degree of depression. Stress was measured with the stress sub-scale of the Depression Anxiety Stress scales ( $\alpha = 0.89$ ).<sup>22</sup> This scale, which has demonstrated good internal consistency and discriminant validity, is designed to measure a state of persistent arousal and tension that is differentiated from depression and anxiety. Response options were on a 1–6 scale from 'none of the time' to 'all of the time'. An overall score was generated from the mean of all seven items; a higher score indicates a greater degree of stress.

*Physical symptoms* were measured using a daily diary maintained by participants, who recorded the presence of 11 symptoms as well as the use of pain medication each day.

*Treatment recovery* was measured using six items assessing whether and the extent to which participants missed school or work due to treatment recovery, required the help of others in their recovery, and whether they missed work or needed to pay others to help in their recovery.

*Treatment acceptability* was measured using nine items querying perceived acceptability of the procedure, adverse effects, pain, bleeding, and duration of symptoms and treatment, as well as whether the procedure met the expectations for the experience, would be chosen again, and would be recommended to a friend.

*Demographics and reproductive history* included participant age, race, insurance status, employment status, whether or not there was a partner or children in the home, as well as history of previous pregnancy, previous miscarriage, and whether the pregnancy was planned or unplanned but wanted or unwanted.

#### Analysis

Statistical analyses were performed using SPSS statistical software (SPSS Inc., Chicago, IL, USA). Student's *t* tests were conducted to assess for differences between treatment groups in each QOL dimension. Chi-square analyses were used to test for differences in the percent of women experiencing recovery difficulties, including missing work or school, needing the assistance of others, and paying others for assistance. Student's *t* tests were conducted to determine whether the groups differed in the degree of symptoms experienced during the recovery period and to determine whether the groups reported significantly different levels of treatment acceptability.

# Results

The study population represented a diverse population of US women: 42% of participants were Hispanic, 30% were African American, 22% were Caucasian, and 6% were Asian.<sup>6</sup> The mean age at study entry was 30 years, and the majority of participants had at least one prior pregnancy (77%) and at least a high school diploma (77%).<sup>6</sup> Of the 652 women enrolled, 490 received misoprostol treatment and 159 underwent a VA per protocol and comprise the total sample of 649 for this study. The complete description of the study population and the results for the main outcomes of efficacy and safety have been previously published: 84% (412/488) were successfully treated with misoprostol and 97% (143/148) were successfully treated with surgical management.<sup>6</sup> The two treatment groups did not differ by demographic variables, reproductive history, or pregnancy failure diagnosis. In addition, serious adverse events were rare and did not differ by treatment group: haemorrhage requiring hospitalisation regardless of need for blood transfusion (1%), hospitalisation for endometritis (<1%), report of fever  $\geq$ 38.0°C (3%), emergency hospital visit within 24 hours of treatment (3%), and unscheduled visits (23%).<sup>6</sup>

Nearly, all of the study participants (93%) completed each of the study instruments for this analysis: 625 (96%) completed prospective symptoms diaries, 607 (94%) completed QOL and wellbeing questionnaires, and 606 (93%) completed the questionnaires regarding acceptability and recovery. Those who did not complete the QOL questionnaires were younger (mean age 27.4 years versus 30.2, P = 0.02), and a greater percentage was of lower education status (linear by linear association = 0.04). No difference was observed between those completing and not completing the QOL questionnaires by race, insurance status, employment status, presence of other children in the home, presence of a partner in the home, previous pregnancy, experience of previous miscarriage, and whether the current pregnancy was planned.

There were no differences between the medical and surgical treatment groups on 6 of 7 dimensions of QOL and wellbeing: physical role functioning, emotional role functioning, social functioning, vitality, depression, or stress (Table 1). However, those assigned to medical treatment scored significantly worse on the one dimension for bodily pain than those assigned to VA (40.04 versus 45.84, P < 0.001). Comparing scores of QOL and wellbeing between women who experienced successful medical treatment with those who experienced failed medical treatment and a subsequent VA, there were no significant differences, but two trends were noted. Two dimensions of QOL trended towards worse scores for those who subsequently required a VA (treatment failure): role emotional (P = 0.09) and depression (P = 0.09) (Table 2). Only four participants in the surgical treatment group experienced a treatment failure, thus it was not possible to compare the QOL and wellbeing by success of the method within this group.

The majority of participants in both groups reported missing some school or work and needing assistance from others during the recovery period. Despite the difference in treatment regimens and expected recovery, no difference was observed between medical and surgical treatment

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groups on any of the variables assessing recovery difficulties (Table 3). Nor was there a difference in the amount of time for recovery or assistance needed between treatment groups. The mean number of days of work or school the participant missed was 3.9 days (SD 6.1) in the medical treatment group and 4.6 days (SD 8.3) in the surgical treatment group (P = 0.28). The mean number of hours others spent assisting the participant in their recovery was 15.5 hours (SD 28.3) in the medical treatment group and 16.7 hours (SD 40.2) in the surgical treatment group (P = 0.69). Symptoms recorded prospectively by daily diary records were significantly different between the two treatment groups (Table 4). Women assigned to medical treatment reported more days with symptoms of uterine bleeding, nausea, emesis, and lightheadedness than those in the surgical treatment group. In addition, women undergoing surgical management used less pain medication and had more days without symptoms than those who received medical treatment.

Most measures of acceptability did not differ significantly between treatment groups; however, differences were observed in some of the individual dimensions comprising acceptability (Table 5). Items reflecting treatment-related symptoms—cramping acceptability, bleeding acceptability, and acceptability of symptom duration—were significantly worse for women assigned to medical treatment than those receiving surgical treatment. No differences between treatment groups was observed in ratings of the acceptability of the procedure, the adverse effects of treatment, the duration of treatment, or measures of overall acceptability (whether participants would recommend or accept this same treatment again). Among those receiving medical treatment, acceptability of the procedure was associated with treatment success. Acceptability of the procedure, duration of treatment, and whether the procedure would be recommended or chosen again were significantly worse for women who experienced a medical treatment failure (Table 6). Acceptability items related to the experience of the procedure, including adverse effects, pain, and bleeding, were similar among women who received medical treatment regardless of treatment success.

# Discussion

The experience of medical evacuation of the uterus compared with a surgical evacuation is different enough to generate much interest and discussion about differences in QOL and acceptability between those two treatments. Many studies in the literature regarding elective abortion compare the acceptability of medical versus surgical treatment using VA of undesired pregnancies; all confirm that both are highly acceptable.<sup>23–27</sup> The high acceptability may in part be related to the women being able to select their preferred treatment modality, whether medical or surgical.<sup>23,24</sup> In a study evaluating QOL following medical versus surgical treatment for elective abortion reported worse baseline QOL scores compared with those choosing a medical treatment, but these baseline differences resolved at the 1-month follow-up evaluation.<sup>28</sup>

There is similarly little information about QOL of the medical treatment of EPF. In a pilot study in preparation for this large randomised trial, the QOL measured after medical treatment for EPF showed worse QOL than published same-aged healthy population norms.<sup>13</sup> The pilot study confirmed that the study measures for QOL, wellbeing, and acceptability were feasible and appropriate for evaluating women undergoing treatment for EPF. However, the pilot study could not evaluate whether the method of EPF treatment affected QOL, wellbeing, and acceptability. Two other studies comparing the effect of medical versus surgical treatment of QOL over time found no differences between treatment assignment on QOL overall, but the populations studied were very different from ours. One study comparing medical versus surgical ePF treatment on QOL evaluated European women who had already failed expectant management of EPF and who were then randomised to treatment.<sup>29</sup> In another study, medical treatment was compared with surgical treatment as a primary intervention for EPF in a Chinese

population who may view EPF differently than our study population, as the majority reported a fear of 'devitalisation' due to their diagnosis and over 90% using 'tonics' for revitalisation. 30

Our study provides new information on QOL and acceptability following medical and surgical treatment for EPF with a large randomised sample recruited from four US clinical sites. Expectant management was not a treatment arm in this study and therefore we cannot compare QOL measures after treatment with expectant management. This study is limited by a single measurement period 2 weeks after treatment; data on long-term QOL outcomes for our study population are not available. The sample of women enrolled in this study may not be representative of a nonurban US population. Women were recruited from four different urban geographical regions and included large Hispanic and Black populations.<sup>6</sup> Women enrolling in the study had to be willing to be randomised to medical or surgical treatment with a threefold increased chance of receiving medical over surgical treatment and no option for expectant management. This may affect the measurement of acceptability in two ways. Women who strongly preferred surgical treatment or expectant management may have refused to participate biasing the results towards medical therapy. There is evidence that providing women with their chosen option for management of elective abortion is associated with greater satisfaction with their care.<sup>31</sup> In addition, there is evidence that willingness to undergo randomisation may be associated with worse QOL scores. One randomised trial of expectant versus surgical management also enrolled and assessed those who declined randomisation.<sup>32</sup> QOL scores were worse for women who were randomised to VA versus those randomised to expectant management.<sup>32</sup> Importantly, for women undergoing VA, women who chose their treatment (declined randomisation) were more likely to have better mental health scores than those randomised to VA.<sup>32</sup> Finally, women participating in our study were offered (and usually received) immediate enrolment and treatment, thus acceptability may have been increased for both treatment groups over that experienced with standard care where treatment may be delayed by days due to office and surgical schedules.

# Conclusion

This randomised comparison of women undergoing medical versus surgical treatment of EPF provides important information on the relative QOL, wellbeing, and acceptability for women undergoing the two different treatments. In this large randomised trial of medical versus surgical treatment of EPF, few differences between treatment groups for measures of QOL, wellbeing, and acceptability were observed. Clinicians can counsel their women experiencing EPF that both medical and surgical treatments are effective, safe, acceptable, and without differences in QOL.

Differences noted in this trial related to QOL and acceptability were specifically related to differences in the experience of each treatment. Women receiving medical treatment of EPF reported greater bodily pain and lower symptom-related acceptability than those undergoing surgical treatment of EPF. Despite these differences, all other dimensions of QOL and overall treatment acceptability were unaffected. Interestingly, despite greater report of symptoms, women receiving medical treatment did not report greater recovery difficulties. A second difference between the two treatments was the higher failure rate of medical treatment. Those for whom medical treatment failed reported similar QOL, wellbeing, and symptom-related acceptability as those for whom the treatment was successful, but lower overall acceptability of the procedure. These results can inform the focus of counselling for women choosing a treatment option. Women should understand the differences in experience, expected adverse effects, and efficacy between the two methods as well as the similarities in recovery and QOL measures.

As the number of options for the treatment of EPF increases, counselling regarding the safety, efficacy, and expected experience of each treatment option increases in importance for clinical care. Future research will undoubtedly aim to improve the safety, efficacy, and recovery of the medical methods of uterine evacuation. But as we strive to improve the medical regimen for EPF, we will also need to better understand the factors that influence QOL, recovery, and satisfaction with care. If, as suggested by the results of this study, the treatment regimen does not influence QOL, then it is important to better understand which aspects of EPF care do influence QOL—whether it is the efficacy of the treatment, associated symptoms, aspects of treatment recovery, or characteristics of the women themselves.

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# Mean (SD) QOL\*, Depression-Happiness\*\*, and Stress\*\*\* scores 2 weeks after medical versus surgical treatment of EPF

QOL domain	Medical ( <i>n</i> = 457)	<b>Surgical</b> ( <i>n</i> = 150)	t test statistic	P value
Bodily pain	40.04 (10.31)	45.84 (10.95)	-5.88	< 0.001
Role emotional	42.27 (12.52)	42.91 (13.57)	20.53	0.60
Role physical	44.43 (10.40)	45.57 (11.01)	-1.15	0.25
Social functioning	44.53 (10.72)	45.12 (11.51)	-0.57	0.57
Vitality	47.99 (11.16)	47.15 (11.16)	0.80	0.43
Depression	2.85 (0.89)	2.80 (0.88)	0.63	0.53
Stress	2.45 (1.15)	2.33 (1.04)	1.13	0.26

\* The five domains of QOL: bodily pain, role emotional, role physical, social functioning, and vitality are scored from 1 (total impairment) to 100 (no impairment) with an overall mean of 50 and SD of 10 in the general well population. Higher scores indicate greater QOL.

\*\* The Depression–Happiness scale is scored as the mean of 25 items each ranging from 1 (none) to 6 (all of the time). Higher scores indicate greater depression.

\*\*\* The Stress scale is scored as the mean of seven items each ranging from 1 (none) to 6 (all of the time). Higher scores indicate greater stress.

Mean (SD) QOL<sup>\*</sup>, Depression–Happiness<sup>\*\*</sup>, and Stress<sup>\*\*\*</sup> scores 2 weeks after medical treatment comparing successful versus failed medical treatment

QOL domain	Success $(n = 385)$	<b>Failed</b> ( <i>n</i> = 72)	t test statistic	P value
Bodily pain	40.00 (10.09)	40.27 (11.46)	0.21	0.84
Role emotional	42.70 (12.38)	39.94 (13.10)	-1.70	0.09
Role physical	44.67 (10.47)	43.13 (10.01)	-1.15	0.25
Social functioning	44.84 (10.72)	42.91 (10.70)	-1.40	0.16
Vitality	48.17 (11.00)	46.98 (12.02)	-0.82	0.41
Depression	2.82 (0.90)	3.02 (0.82)	1.72	0.09
Stress	2.44 (1.12)	2.47 (1.28)	0.22	0.81

<sup>\*</sup>The five domains of QOL: bodily pain, role emotional, role physical, social functioning, and vitality are scored from 1 (total impairment) to 100 (no impairment) with an overall mean of 50 and SD of 10 in the general well population. Higher scores indicate greater QOL.

\*\* The Depression–Happiness scale is scored as the mean of 25 items each ranging from 1 (none) to 6 (all of the time). Higher scores indicate greater depression.

The Stress scale is scored as the mean of seven items each ranging from 1 (none) to 6 (all of the time). Higher scores indicate greater stress.

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# Percent of respondents reporting recovery difficulty by treatment group

Recovery difficulty	Percent ans	wering yes	Chi-square statistic	P value
	Medical (n = Surgical (n = 456) 150)			
Did you miss any days of school or work due to your miscarriage?	62.5	63.8	0.076	0.78
Has your illness required any members of your family or friends to help you out?	57.9	58.7	0.028	0.87
Were they (friends or family) required to take off time from work to assist you?	28.8	31.5	0.379	0.53
Did you pay for someone to take care of you, your household or your children?	9.1	9.0	0.001	0.98

# Mean percent of days symptoms reported after medical versus surgical treatment of EPF\*

Symptoms reported	Mean percen	t test statistic	P value	
	<b>Medical</b> ( <i>n</i> = 477)	<b>Surgical</b> ( <i>n</i> = 148)		
NSAID taken	37.15	30.25	3.24	0.001
Narcotic taken	18.06	4.36	10.70	< 0.001
Uterine bleeding	84.33	68.58	6.93	< 0.001
Heavy uterine bleeding	11.94	2.31	13.03	< 0.001
Nausea	13.27	8.71	2.92	0.004
Vomiting	2.94	1.16	4.04	< 0.001
Diarrhoea	7.33	6.33	0.75	0.46
Chills	11.20	10.17	0.58	0.57
Fever	5.26	4.28	0.81	0.42
Headache	30.65	27.94	1.08	0.28
Tiredness	35.79	33.00	1.00	0.32
Lightheadedness	15.79	10.71	2.76	0.006
Faintness	1.13	0.74	1.01	0.32

Percent of days symptoms were noted in 2 weeks after treatment in diary.

## Reported acceptability (mean scores) of treatment comparing medical versus surgical treatment of EPF

Acceptability item <sup>*</sup>	<b>Medical</b> (n = 456)	Surgical $(n = 150)$	t test statistic	P value
Cramping pain	3.02	3.33	-2.28	0.02
Bleeding	3.25	3.79	-4.75	< 0.001
Duration of symptoms	3.53	3.79	-2.21	0.03
Procedure	4.23	4.06	1.53	0.13
Adverse effects	3.68	3.84	-1.33	0.18
Duration of treatment	3.99	4.04	-0.47	0.64
Expectations	3.72	3.88	-1.72	0.09
Recommend	4.29	4.27	0.12	0.91
Choose again	4.16	4.00	1.35	0.18

Each item is scored on a 1–5 scale from totally unacceptable (1) to totally acceptable (5).

## Reported acceptability (mean scores) of medical treatment comparing women who experienced successful or failed treatment

Acceptability item <sup>*</sup>	Success (n = 385)	Failed $(n = 71)$	t test statistic	P value
Cramping pain	3.03	2.96	-0.42	0.67
Bleeding	3.28	3.09	-1.16	0.25
Duration of symptoms	3.60	3.14	-2.88	0.004
Procedure	4.33	3.69	-3.77	< 0.001
Adverse effects	3.78	3.14	-3.23	0.002
Duration of treatment	4.12	3.31	-4.64	< 0.001
Expectation of experience	3.76	3.51	-1.66	0.10
Recommend	4.39	3.69	-4.11	< 0.001
Choose again	4.30	3.38	-5.01	< 0.001

Each item is scored on a 1–5 scale from totally unacceptable (1) to totally acceptable (5).