A randomized controlled trial comparing surgical termination of pregnancy with and without continuous ultrasound guidance

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Received 7 February 2002; received in revised form 27 June 2003; accepted 10 September 2003

Abstract

Context: Approximately 50 million abortions are performed worldwide each year, and the majority of them are surgical terminations of pregnancy (STOP). Therefore, the safety of this procedure is a global public health concern. It is not known whether routine use of intraoperative ultrasound guidance improves the outcome of first trimester STOP. Objective: To investigate whether surgical termination of pregnancy in the first trimester with continuous ultrasound guidance is safer than the conventional procedure without ultrasound guidance. Design: A randomized controlled trial. Setting: A teaching hospital in London, UK. Participants: Women undergoing STOP in the first trimester. Intervention: Participants were randomized to have the procedure with or without continuous ultrasound guidance. Outcome measures: The primary outcome measures were intraoperative and short-term complications (anaesthetic complication, haemorrhage, ongoing pregnancy, cervical trauma, uterine perforation, need for laparoscopy and/or laparotomy, repeat evacuation, and infection). The secondary outcomes were the blood loss, procedure time, and convalescence time. Results: A total of 230 women (115 in each arm of the trial) participated in the study. Follow-up data were available for analysis in all but 15 (8 in control group and 7 in intervention group) cases. Baseline characteristics were similar in both groups. The overall complication rate was 9.8 percent. STOP under ultrasound guidance had a complication rate of 3.7% (4/108) in comparison to 15.9% (17/107) without ultrasound (RR 0.23, 95% CI 0.08–0.67). Intraoperative ultrasound guidance also had a statistically significant beneficial effect in reducing the blood loss, procedure time, and convalescence time. Conclusion: STOP in the first trimester under continuous ultrasound guidance was associated with a lower rate of complications than the conventional procedure without ultrasound.

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Keywords: Abortion; Ultrasound; Complications; Randomized controlled trial

1. Introduction

Surgical termination of pregnancy (STOP) is one of the most commonly performed gynaecological procedures. Around 180,000 pregnancy terminations are performed annually in England and Wales and approximately 12,500 in Scotland [1] and the trend is increasing. At least a third of British women will have had an abortion by the time they reach the age of 45 [2]. Although other methods of induced abortion, such as medical termination are available and may be appropriate in certain cases, first trimester STOP was the most commonly available method in a recent national audit of induced abortion in the UK [3].

Clinical research has established suction curettage (vacuum aspiration) as the safest technique for uterine evacuation for induced abortion in the first trimester [4]. However, there are inherent risks related to the invasive nature of the procedure. STOP requires dilatation of the cervix. The technique of dilating the cervix has remained largely unchanged since Alfred Hegar first demonstrated the procedure in 1874 [5]. The surgeon judges the completeness of the operation by subjective perception. The operation is generally considered safe, but a short-term complication rate of 6–10% has been reported [6–8].

To our knowledge, no randomized clinical trial comparing first trimester STOP with and without continuous ultrasound guidance has, as yet, been reported. With continuous ultrasound guidance, it should be possible to accurately identify the axis and the size of the uterus, position of the gestation sac, monitor the insertion of surgical instruments into the uterine cavity and the progress of the operation to confirm its safe completion.
The potential advantage of using ultrasonography in the management of elective STOP was described in the seventies in a series of case reports [9]. At present ultrasonography is not considered to be an essential prerequisite of abortion in all cases [2], however several reports describe its use to guide difficult therapeutic abortions [10–12], or to manage the complications [13,14]. A retrospective study has shown that the routine use of intraoperative ultrasonography reduces the incidence of uterine perforation during second trimester surgical abortion [15].

The objective of this study was to investigate in a randomized, controlled trial whether first trimester STOP under continuous ultrasound guidance is safer than the conventional procedure without ultrasound guidance.

2. Subjects and method

The research protocol was approved by the hospital’s Research and Ethics Committee (Ref. 99/97). The study population consisted of the women undergoing STOP in the first trimester at a teaching hospital in North London. The participation was voluntary and an informed written consent was obtained in each case. All women with confirmed intrauterine pregnancy with no contraindication to STOP under general anaesthesia were included in the study. Gestational age more than 13 weeks or any suspicion of an ectopic pregnancy or a missed miscarriage were the exclusion criteria.

2.1. Design

This was a randomized, controlled trial with two study arms. The participants were randomized either to have the STOP in the conventional way without the use of intraoperative ultrasound, or under continuous real-time ultrasound guidance. The randomization was carried out using sealed opaque envelopes prepared outside the study centre. The participants were considered for allocation of intervention in blocks of 10 at a time (block randomisation).

All participants had a clinical history taken and general physical examination performed in the clinic. Endocervical and high vaginal swabs were taken to screen for genital tract infection. An ultrasound examination was performed to confirm intrauterine pregnancy, to determine the gestational age, and number of gestational sacs and fetuses. Any incidental findings, such as presence of a uterine fibroid or ovarian cyst were recorded. The operation was scheduled within 5 days of consultation.

The operations were performed as a day case under general anaesthesia. Gemeprost 1 mg was inserted vaginally 2 h before the operation to prime the cervix in all cases >11 weeks gestation. All operations were performed by one senior gynaecologist with experience of performing an average of 15 such procedures per week for more than 10 years. The participants randomized to have the procedure under ultrasound guidance had their entire operation monitored with real-time ultrasound. A 3.5 MHz mechanical sector abdominal transducer (Ultramark 4, Advanced Technology Laboratory, USA) was used for this purpose. The principal investigator performed all intraoperative scans.

2.2. Operative procedure

The women were allowed to empty their urinary bladder before induction of anaesthesia, but catheterisation was not performed. After positioning the patient appropriately on the operating table, bimanual pelvic examination was performed under anaesthesia to assess the axis and the size of the uterus. A Sim’s speculum was inserted into the vagina, the cervix was visualised and grasped using Vulsellum forceps. The cervical canal was dilated gradually with Hegar dilators up to the size corresponding to the weeks of gestation. The uterine cavity was evacuated using a plastic cannula attached to an electric suction apparatus. Negative pressure of 75 mm Hg was used. The aspirate was examined to confirm the presence of products of conception. The completeness of the evacuation was checked by gentle sharp curettage and final suctioning at the end of procedure. All patients received 5 IU of syntocinon intravenously during the procedure.

The women in the intervention group had a preliminary scan to assess the size and axis of the uterus, and position and size of the pregnancy while the surgeon cleaned and draped the operation site. The transducer was held on the abdomen to obtain a longitudinal image of the uterus and cervix and provide the surgeon with a visual reference of the gestational sac, cervical canal and any instruments passed into the uterus.

The progress of the operation was continuously monitored as the uterine contents were evacuated under visual control. It was possible to keep the dilators and the suction cannula under constant view (Fig. 1) by slightly tilting the transducer.

Fig. 1. A longitudinal view of the uterus showing a suction cannula within the uterine cavity.
as required. Advancement of any instrument was allowed only under direct ultrasound control. The completeness of the evacuation was confirmed by the scan in these cases (Fig. 2).

Patients were allowed home about 4–6 h after the operation. Analgesics were routinely prescribed. Antibiotics were prescribed only for those who had a positive screening result for genital tract infection. Routine hospital follow up was not arranged after discharge.

2.3. Data collection

Baseline information including age, number of previous pregnancies and their outcome, gestational age, number of fetuses, and any incidental findings, such as fibroids or ovarian cysts were recorded for each participant.

The primary outcomes were intraoperative and short-term complications. These included anaesthetic complication, failed procedure (ongoing pregnancy), haemorrhage (measured blood loss including products of conception >500 ml), cervical trauma (cervical laceration requiring suture or false passage), uterine perforation, need for laparoscopy and/or laparotomy, retained products of conception (RPOC) requiring repeat evacuation, and infection. The infection was defined as a clinical need for antibiotic (excluding prophylactic use due to positive screening for genital tract infection), or a temperature of ≥38 °C on at least two occasions, or endometritis (abnormal vaginal discharge and pelvic tenderness). The women developing more than one complication were counted only once for the purpose of data analysis.

The secondary outcomes were intraoperative blood loss, procedure time (the time required to complete the procedure from the start of cervical dilatation to the removal of the Vulsellum from the cervix) and convalescence time. Whether intraoperative scanning was considered satisfactory for visualisation by the surgeon was also recorded.

Information on the events and any complications that occurred after discharge from the hospital were assessed by means of a questionnaire. The participants and their physicians were not informed whether the procedure was carried out with or without ultrasound guidance. The participants were provided with a questionnaire on discharge from the hospital, which they were requested to complete and return in a prepaid self-addressed envelope 2 weeks after the operation. They were asked to state the number of days of bleeding requiring sanitary protection, pain requiring painkillers, “off sick” or disrupted daily routine (convalescence time), number of visits made to the family doctor or the hospital, antibiotic prescriptions, hospital admissions or any other problem. The participants not returning the questionnaire by 4 weeks were interviewed by telephone.

2.4. Statistical methods

The data were analysed using the Statistical Package for Social Sciences for Windows Version 9.0 (SPSS Inc., Chicago, IL, USA). Analyses were performed using the intention-to-treat principle. The comparison between two groups was made using χ²-test for categorical, Mann–Whitney U-test for nonparametric and independent sample t-test for parametric data and calculating the relative risk (RR) with 95% confidence intervals (CI). All tests were performed two-sided and the differences were considered statistically significant if the P-value was <0.05.

3. Results

A total of 248 women attending clinics in between March 2000 to February 2001, with a request for STOP on psychosocial grounds (clause C of the Abortion Act 1967 as amended by the Human Fertilisation and Embryology Act 1990, UK) were invited to participate in the trial. Among them eight did not meet the inclusion criteria (four were more than 13 weeks gestation, two had ectopic pregnancy, two had missed miscarriage) and 10 others refused to participate. Two hundred thirty women were randomized and there were no dropouts after randomization. The flow of participants is summarised in Fig. 3.

The demographic and baseline clinical data are summarised in Table 1. There were no statistically significant differences between the study groups. The ultrasound images were found to be satisfactory by the surgeon for the visualisation of the uterus and its contents, guiding the instruments, monitoring the progress of the operation, and confirming the completeness of the uterine evacuation in all but one case.

Overall significant complications occurred in 21 out of 215 cases (9.8%) with complete follow up information. Among women having the procedure under ultrasound guidance only 4 out of 108 (3.7%) had complications compared to 17 out of 107 (15.9%) among the control group (RR 0.23; 95% CI 0.08–0.67). Eight patients needed to have the procedure under ultrasound guidance (number needed to treat) to prevent one additional complication (95% CI 5–23).
Evacuation of retained products of conception.

STOP: surgical termination of pregnancy, US: ultrasound guidance, ERPC:
Repeat ERPC 0 5 (4.7%) 0.023
Infection 2 (1.9%) 8 (7.5%) 0.005


Failed procedure 0 1 (0.9%) 1
Haemorrhage
Cervical trauma 0 1 (0.9%) 1
Anaesthetic complication 1 (0.9%) 1 (0.9%) 1

There were no uterine perforations or visceral damages and statistically significant for the intraoperative complications but significant for the short-term postoperative complications. There were no uterine perforations or visceral damages and

The intraoperative and short-term complications observed are summarised in Table 2. The differences were not statistically significant for the intraoperative complications but significant for the short-term postoperative complications. There were no uterine perforations or visceral damages and

<table>
<thead>
<tr>
<th>Variable</th>
<th>STOP with US (n = 115)</th>
<th>STOP without US (n = 115)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>25.60 ± 6.38</td>
<td>26.48 ± 6.10</td>
<td>0.28</td>
</tr>
<tr>
<td>Gestation (days)</td>
<td>62.74 ± 11.79</td>
<td>61.33 ± 10.82</td>
<td>0.35</td>
</tr>
<tr>
<td>Twin pregnancy</td>
<td>1 (0.9%)</td>
<td>1 (0.9%)</td>
<td>1</td>
</tr>
<tr>
<td>Nullipara</td>
<td>77 (67.0%)</td>
<td>75 (65.2%)</td>
<td>0.78</td>
</tr>
<tr>
<td>Miscarriages</td>
<td>0 (0–3)</td>
<td>0 (0–2)</td>
<td>0.80</td>
</tr>
<tr>
<td>Abortion</td>
<td>0 (0–4)</td>
<td>0 (0–4)</td>
<td>0.60</td>
</tr>
<tr>
<td>Fibroids</td>
<td>6 (5.2%)</td>
<td>7 (6.1%)</td>
<td>0.78</td>
</tr>
<tr>
<td>Corpus luteal cyst</td>
<td>8 (7.0%)</td>
<td>7 (6.1%)</td>
<td>0.79</td>
</tr>
<tr>
<td>Chlamydia positive</td>
<td>6 (5.2%)</td>
<td>4 (3.5%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Cervical priming</td>
<td>11 (9.6%)</td>
<td>7 (6.1%)</td>
<td>0.33</td>
</tr>
</tbody>
</table>

Data are presented as mean ± S.D., median (range) or n (%) as appropriate. STOP: surgical termination of pregnancy, US: ultrasound guidance.

The number of participants lost to follow up was not different between the groups and complete follow up information was obtained from over 90% of the participants. Therefore the results are valid for the study population. Although it was not possible to blind the surgeon to the intervention, the other registrants of the outcome, i.e. the patients and their physicians were not informed whether the procedure was performed under ultrasound guidance, and the outcomes which are significantly different were registered by those least likely to know about the intervention allocation. However as the personnel in the operating room could see how the procedure was carried out, a small possibility that the patients could obtain this information existed. The skill and experience of the surgeon are important determinants of the safety of STOP [2,16]. A single experienced gynaecologist performed all the operations in this study minimising possible operator related bias.

Regarding external validity of the results, our study population was representative of a large inner city population.

Table 3
Secondary outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TOP with US</th>
<th>TOP without US</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative bleeding (ml)</td>
<td>103 ± 57.2</td>
<td>139 ± 69.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure time (s)</td>
<td>19 ± 46a</td>
<td>26 ± 52b</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Analgesic requirement (days)</td>
<td>1.5 ± 1.6</td>
<td>2.8 ± 2.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postoperative bleeding (days)</td>
<td>6.3 ± 4.0</td>
<td>11.9 ± 5.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Convalescence time (days)</td>
<td>1.7 ± 2.3</td>
<td>5.1 ± 3.6</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data are presented as mean ± S.D. STOP: surgical termination of pregnancy. US: ultrasound guidance.

- a 2 min.
- b 3 min.

none of the patients required blood transfusion or additional surgery, such as laparoscopy and/or laparotomy.

The secondary outcomes and other information obtained following discharge from the hospital are summarised in Table 3. There was also a positive correlation between the procedure time and the blood loss at the operation (Pearson r = 0.53, P < 0.001). Eighty-two women (76.6%) who had their operation without ultrasound guidance reported prolonged vaginal bleeding (more than a week) postoperatively in comparison to 27 (25%) in the intervention group (P < 0.001). Only 7 (6.5%) women required to see a doctor after STOP with ultrasound guidance in comparison to 27 (25.2%) women in the control group (P < 0.001).

4. Discussion

This study demonstrates that intraoperative ultrasound guidance has a significant beneficial effect in reducing the recognised complications of first trimester STOP (relative risk 0.23; 95% CI 0.08–0.67). The differences were especially obvious for short-term complications, such as RPOC and infection.

The number of participants lost to follow up was not different between the groups and complete follow up information was obtained from over 90% of the participants. Therefore the results are valid for the study population. Although it was not possible to blind the surgeon to the intervention, the other registrants of the outcome, i.e. the patients and their physicians were not informed whether the procedure was performed under ultrasound guidance, and the outcomes which are significantly different were registered by those least likely to know about the intervention allocation. However as the personnel in the operating room could see how the procedure was carried out, a small possibility that the patients could obtain this information existed. The skill and experience of the surgeon are important determinants of the safety of STOP [2,16]. A single experienced gynaecologist performed all the operations in this study minimising possible operator related bias.

Regarding external validity of the results, our study population was representative of a large inner city population.
according to baseline characteristics and the overall complication rate (9.8%) in this study is comparable to previous reports [6,7]. However, the complication rate in the control group was found to be relatively high (15.9%) in this study. This was partly due to a higher rate of infection and may be related to the practice of selective rather than routine universal antibiotic prophylaxis used in our institution. A rather low threshold for prescribing antibiotic for patients reporting prolonged vaginal bleeding after the procedure may be another explanation.

With the use of ultrasound guidance it may be possible to virtually eliminate the complications related to the blind nature of the conventional procedure, i.e. ongoing pregnancy, false passage caused by the dilators, uterine perforation, and RPOC. There were no such complications in this study when ultrasound guidance was used. Whereas five women in the control group required repeat evacuation for RPOC and one had a failed procedure. The gestational age in the woman who had continuing pregnancy was 7 weeks and 5 days and she had a fibroid uterus. Ongoing pregnancy was diagnosed 3 weeks later. A repeat procedure was performed under ultrasound guidance, which was uneventful. It can be argued that if the tissue obtained during STOP is routinely sent for histopathological examination, the diagnosis of ongoing pregnancy can be made earlier. However, routine histological examination of the tissue does not seem to be beneficial [17] and it is not a routine to send the aspirate for histology in many institutions including ours.

Routine use of intraoperative ultrasonography during second trimester abortion has been shown to reduce the rate of uterine perforation [15]. Uterine perforation during suction curettage is a potentially dangerous complication but can go unrecognized on many occasions [18]. Intraoperative ultrasonography not only provides visual guidance to the surgeon to direct the instruments and minimize the risk of perforation but also provides confirmation of suspected perforation [19] and may enable completion of the evacuation [13].

The rate of significant haemorrhage (blood loss ≥ 500 ml) was equal in both groups and no patient required blood transfusion. However, measured intraoperative blood loss was significantly less in the intervention group. The amount of blood loss at STOP is related to the gestational age and the operative time. As the mean gestation was similar in the both study groups it is possible that the reduction in blood loss was mainly due to the reduction in the procedure time.

There were two anaesthetic complications, one in each group. Although the appropriateness of using anaesthetic complication as a primary outcome measure in this study can be argued, it is an important complication that is consistently reported in most of the published literature on complications of abortion. Furthermore, the STOP is performed under general anaesthesia in the vast majority of cases in the UK due to concerns about the acceptability of local anaesthesia. There is also a theoretical possibility that the steady pressure constantly applied on woman’s abdomen by the ultrasound transducer during the procedure may affect the course of anesthesia.

The time required to evacuate the uterine contents was significantly shorter when ultrasound guidance was used. This may be mainly due to reduction in time required to determine the completeness of abortion by repeated check curettage and suctioning. Sharp curettage, has been associated with increased risk of uterine perforation during suction termination. In a large observational study in Sweden (n = 84,850) involving 145 recognized perforations in the first trimester, 31% occurred during the “security check” [20]. There are no data to suggest that check curettage reduces the risk of retained products or failed abortion. However many clinicians check the completeness of the procedure by gentle sharp curettage followed by final suctioning. This has also been the practice in our institution. With the use of ultrasonography it should be possible to confirm the completeness of evacuation without resorting to check curettage and avoid associated risk of uterine perforation or excessive curettage leading to Asherman syndrome.

A significant number of patients in the control group had vaginal bleeding requiring sanitary protection for more than a week and required analgesics for a longer time compared to those having STOP under ultrasound guidance. Although only five women required repeat evacuation, it is possible that many of them had a small amount of RPOC. A small amount of RPOC after surgical TOP is not uncommon. Up to 32% of reaspirates obtained 30 s after a clinically complete surgical abortions performed by an experienced operator contain microscopically identifiable chorionic villi [21]. However, small amounts of RPOC may pass spontaneously, avoiding the need for further intervention. The risk of severe haemorrhage or infection is low in this situation.

A total of 10 (4.6%) women in this study required antibiotic treatment after discharge from the hospital and eight of them had their operation without ultrasound guidance. Longer procedure time and possibly a small amount of RPOC in these cases may have increased the risk of infection. The total incidence of infection in this study is high but comparable to the reported incidence of 3.6% in a previous study from the UK [7]. A relatively high rate of infection among the control group may be explained by the definition of infection (i.e., need for an antibiotic prescription) used in this study. Prolonged bleeding is likely to be interpreted by the patients’ physicians as endometritis and the threshold for prescribing antibiotic may be low.

The convalescence time was longer in women who had their operation without ultrasound guidance and they were more likely to see a doctor following the operation. This may again be related to longer postoperative pain and bleeding in this group of patients.

Medical termination of pregnancy is becoming increasingly popular and could have been a suitable option for many women in this study. However, STOP remains the most popular method of first trimester abortion in the UK as it has the advantage of being a simple, quick, relatively pain free.
one-off procedure. A recent national audit of induced abortion in UK and Wales [3] reported that of the 194 units with facilities for abortion before 13 weeks, both medical and surgical abortion was provided by 64 (33%) units. Among 130 units where only one method was available, STOP was the only option in 112 (86%) units.

The cost of intraoperative ultrasound scanning was not assessed in this study. It is recognised that an extra person is required to perform the procedure under continuous ultrasound guidance. Capsi et al. [22] used real-time ultrasound guidance in 20 cases and ultrasound examination before and after the procedure in 80 cases of early pregnancy termination (menstrual regulation) and found this to be safer than the conventional procedure. Whether an approach of performing a scan preoperatively followed by another scan at the end of the procedure will have a similar effect in terms of outcomes needs to be investigated.

5. Conclusion

The use of intraoperative continuous real-time ultrasound guidance is associated with a significant reduction in the complications of STOP in the first trimester and appears to be safer than the conventional procedure without ultrasound.

Acknowledgements

We are indebted to Dr. Gro R. Berntsen, Ph.D., Institute of Community Medicine, University of Tromsø for her thoughtful comments.

References