SOCIETY of FAMILY PLANNING
research, education, and leadership

Contraception xx (2013) xxx–xxx

Clinical Guidelines

Surgical abortion prior to 7 weeks of gestation

Release date March 2013
SFP Guideline #20132

Abstract

The following guidelines reflect a collation of the evaluable medical literature about surgical abortion prior to 7 weeks of gestation. Early surgical abortion carries lower risks of morbidity and mortality than procedures performed later in gestation. Surgical abortion is safe, practicable and successful as early as 3 weeks from the start of last menses (no gestational sac visible on vaginal ultrasound) provided that (a) routine sensitive pregnancy testing verifies pregnancy, (b) the tissue aspirate is immediately examined for the presence of a gestational sac plus villi and (c) a protocol to identify ectopic pregnancy expeditiously — including calculation of readily obtained serial serum quantitative human chorionic gonadotropin titers when clinically appropriate — is in place and strictly adhered to. Manual and electric vacuum aspiration methods for early abortion demonstrate comparable efficacy, safety and acceptability. Current data are inadequate to determine if any of the following techniques substantially improve procedure success or safety: use of rigid versus flexible cannulae, light metallic curettage following uterine aspiration, uterine sounding or routine use of intraoperative ultrasound.

Keywords: Early surgical abortion; Early vacuum aspiration; Early induced abortion; Electric vacuum aspiration; Manual vacuum aspiration; Early medical abortion; Failed attempted abortion; Ectopic pregnancy

Background

Early abortion can be accomplished using medical or surgical methods. Medical abortion has gained increasing favor among women since the introduction of mifepristone to the United States market more than a decade ago; nonetheless, vacuum aspiration still comprised three quarters of all US abortions obtained at 8 weeks' gestation or less in 2008 [1]. Aspiration is a safe and simple way to empty the uterus completely and quickly using modest cervical dilation and an electric vacuum pump or handheld syringe. Manual vacuum aspiration (MVA), a technology once more commonly used in low-resource settings, is now widely used and often preferred by providers in developed countries as well [2]. About 50% of US abortion providers use MVA, particularly during the earliest weeks of pregnancy [3].

Access to early abortion services has important health benefits for women. Gestational age is the most important risk factor for abortion-related mortality and morbidity. Compared to the case-fatality rate for induced abortion at 8 weeks or less (one per million), the risk of death increases by 38% for each successive week of gestation [4]. Similarly, the risk of major complications rises from about 2 per 1000 procedures for abortions performed at 7–8 weeks to 6 per 1000 at 13–14 weeks and 15 per 1000 after 20 weeks [5]. In developing countries with restrictive abortion laws, increasing use of MVA and medical abortion has reduced abortion-related mortality [6,7].

First-trimester surgical abortion techniques have evolved over time, enhancing their safety and efficacy. Early in the history of induced abortion, the most common surgical technique involved cervical dilation followed by metallic sharp curettage. This method is still practiced in many countries [8], particularly where modern instruction and vacuum devices are unavailable. No large studies have compared complication rates of vacuum abortion versus sharp curettage at gestations of 6 weeks or less, but data from abortions later in the first trimester modestly favor the suction method in terms of speed, blood loss and risk of retained tissue, endometrial abrasion and uterine trauma [9–11].

Reports of experience with electric vacuum aspiration (EVA) first appeared in a Chinese medical journal in 1958 [12,13]. Use of this method spread across Eastern and Western Europe as more countries removed restrictions to abortion, and it appeared in the pages of an American medical journal for the first time in 1967 [14,15]. The subsequent manufacture of flexible plastic cannulae with diameters considerably smaller than those of their metal

0010-7824/$ – see front matter
http://dx.doi.org/10.1016/j.contraception.2013.02.008

counterparts and the addition of local anesthesia enabled relocation of early abortion to outpatient settings, revolutionizing its availability in the United States. The report by Karman and Potts on their seminal early abortion series using a syringe and flexible cannula was published in 1972 [16], 5 years after legalization of abortion in California and 1 year prior to legalization of abortion at the federal level in the United States. In the ensuing few years, large series of vacuum-induced "menstrual regulation" procedures (so-called because they often occurred without definitive confirmation of pregnancy) confirmed the safety of early aspiration in outpatient settings [17,18].

In the 1980s, advances in ultrasound technology coupled with the introduction of highly sensitive pregnancy tests using monoclonal antibodies allowed for early confirmation of pregnancy and better detection of ectopic pregnancy, ushering in the modern era of early surgical abortion. The demand for early abortion services grew when sensitive home pregnancy tests became widely available. Whereas the proportion of US abortions occurring during the first trimester has remained stable at about 90% during the past two decades, the proportion obtained during the first 6 weeks of gestation more than doubled from 14% in 1992 to 34% in 2008 [19]. In parallel with this trend, the proportion of National Abortion Federation (NAF) member clinics offering surgical abortion before 6 weeks increased from 42% in 1997 to 65% in 2002 [3,20], and the proportion of US providers offering abortion at 4 weeks or less rose dramatically, from 7% in 1993 to 42% in 2008 [1]. These guidelines address the contemporary practice of surgical abortion before 7 weeks of gestation, focusing on issues of safety, efficacy, benefits, risks and acceptability.

Clinical questions and recommendations

1. How does early surgical abortion compare with early medical abortion in terms of efficacy, acceptability, costs and safety?

A few studies have compared the efficacy, safety and acceptability of early surgical and early medical abortion. These studies used varying abortion protocols, and only one employed the highly effective regimen of mifepristone combined with vaginal or buccal misoprostol. Only one study compared costs associated with medical and surgical methods, and it did so in a limited fashion.

Efficacy

Comparative studies of early aspiration and early medical abortion generally support higher efficacy for surgical abortion, although results differ by the medical regimen used. In these studies, efficacy is defined as complete abortion resulting from the primary procedure without subsequent surgical intervention.

Two randomized trials have addressed the question of early abortion efficacy. In a study of 50 women at ≤ 49 days' gestation allocated to MVA with local anesthesia or to oral methotrexate 50 mg followed on day 6 or 7 by vaginal misoprostol 800 mcg, overall efficacy after 2 weeks was 96% [95% confidence interval (CI): 88%–100%] and 83% (95% CI: 68%–98%), respectively (p=.2) [21]. In a UK study that partially randomized 363 women at 63 days' gestation or less to vacuum aspiration under general anesthesia or to medical abortion using mifepristone 600 mg and gemeprost 1 mg (an E-1 prostaglandin vaginal suppository), the success rate was comparably high (98% in each group) at 49 days' gestation or less, but fell to 92% in the medical group at 50–63 days [22].

Two prospective studies have assessed efficacy in women who chose either vacuum aspiration or a medical abortion regimen consisting of mifepristone 600 mg followed 48 h later by oral misoprostol 400 mcg. Among 1373 Chinese, Cuban and Indian women at 56 days' gestation or less, the medical method yielded higher failure rates (5%–16%) than vacuum aspiration (0%–4%) [23]. Similar findings were reported in a US study involving 199 women who had electric vacuum abortions and 178 women who had medical abortions at 63 days or less [24]. Success rates up to 49 days' gestation for surgical and medical abortion were 96% and 87%, respectively [relative risk (RR) of success with surgical abortion 3.3, 95% CI: 0.9–11.5]. In these studies, the 400-mcg dose and oral route of misoprostol administration may have contributed to the disparity in success rates.

One recent retrospective review compared outcomes among women who had early surgical abortions and those who received the evidence-based mifepristone regimens currently favored by most US and many Western European providers. Conducted at a large Planned Parenthood affiliate, this study included more than 33,000 surgical abortions at 63 days of gestation or less and nearly 17,000 medical abortions using mifepristone 200 mg followed 18–48 h later by misoprostol 800 mcg administered vaginally (2004 to mid-2006) or buccally (mid-2006 to 2010). Both methods had high success rates, although medical abortion carried slightly higher risks of ongoing pregnancy (0.3% vs. 0.1%, RR 2.2, p=.0001) and curettage for incomplete abortion (1.3% vs. 0.7%, RR 1.9, p<.0001) [25].

Acceptability

Some of the aforementioned studies compared the acceptability of surgical abortion and medical abortion. Overall satisfaction is high for both methods, although the varying treatment protocols used in these studies make comparative conclusions difficult to draw. For example, in the previously cited randomized trial using methotrexate [21], acceptability of surgical abortion (92%; 95% CI: 81%–100%) greatly exceeded that of medical abortion (63%; 95% CI: 43%–82%; p<.001). The lower efficacy and longer duration of methotrexate medical abortion compared to those of contemporary mifepristone regimens may have played a role in these findings. In the prospective study comparing surgical abortion with a medical regimen of mifepristone and

oral misoprostol in China, Cuba and India [23], women who elected medical abortion were more likely than their counterparts who elected surgical abortion to express a preference for the same method in the future, despite findings of lower efficacy. Again, the protocols used may have contributed to women's responses; e.g., preference for a different method in the future was most pronounced among surgical abortion patients in China, where surgical procedures were conducted with minimal or no anesthesia.

Agency in choice of method appears to play a role in acceptability among women having early medical abortion. In the previously cited mifepristone–gemeprost trial [26], women who elected medical abortion were much more likely to report that they would opt for the same method again (96%) than were women who were randomized to it (78%), a disparity not found in the surgical abortion group. Other studies support these findings [21,27,28].

Cost

One study compared the cost of outpatient MVA under local anesthesia with the cost of medical abortion using methotrexate and misoprostol in a state that allowed only physicians to perform surgical abortion [21]. Compared to time spent with each surgical abortion patient, mean staff time per medical abortion patient was longer (58 vs. 46 min, respectively; p=.01); however, medical abortions were less likely to involve a physician. The researchers concluded that if the pay scale of a physician was twice that of a physician assistant, the staff costs associated with each abortion method would be about identical.

Complications

Niinimaki and colleagues [29] reported complication rates within 6 weeks of medical and surgical abortion by drawing on three linkable national registry databases for all abortions conducted in Finland up to 63 days' gestation for the period 2000–2006. The database included more than 20,000 abortions of each type. Medical abortion regimens, which used mifepristone alone or in combination with one of several prostaglandins in unspecified doses, had complication rates exceeding those of surgical abortion for hemorrhage (15.6% vs. 2.1%, p<.001), incomplete abortion (6.7% vs. 1.6%, p<.001), and rescue curettage/reaspiration (5.9% vs. 1.8%, p<.001). Limitations of this study include reliance on chart abstraction using International Classification of Diseases codes, nonuniform treatment regimens, the unavailability of records of primary care outside the hospital and the lack of definitions for "hemorrhage" and "incomplete" abortion, raising questions about its high complication rates [30]. In addition, instances of rescue curettage in medical abortion have been shown to decrease with greater clinician knowledge and experience.

In the aforementioned Planned Parenthood study [25], medical abortion with mifepristone combined with vaginal or buccal misoprostol carried a low risk of complications within 8 weeks of follow-up, although the rate still exceeded that for surgical abortion (1.9% vs. 1.0%, respectively). Medical abortion resulted in higher rates of incomplete abortion (1.3% vs.0.7%, RR 1.9, p<.0001), transfusion (0.02% vs. 0.003%, RR 7.84, p=.048) and hospitalization for infection (0.03% vs. 0.006%, RR 4.9, p=.048); adding routine antibiotics to the medical abortion regimen in mid-2007 reduced infection from 0.05% to 0.02% (p=.349). Good evidence supports routine use of preventative antibiotics for both surgical [31] and medical abortion [32] during the first trimester, although no studies of infection prevention have focused solely on the cohort ≤49 days.

In conclusion, direct comparison of early medical and surgical abortion outcomes is limited to a handful of studies. This research consistently shows higher efficacy rates for surgical abortion (96%–100%) than for medical abortion (83%–98%), although the difference is less for mifepristone regimens than for methotrexate regimens. Early medical abortion also carries a higher risk of complications, but the differences are small. Patient acceptability of both types of abortion is comparably high when women are allowed to choose their preferred method. One study suggests that cost comparisons largely depend on the spread in health worker pay scales, with parity in procedure expense when wages of surgeons are no more than twice as high as those of nurses and midlevel clinicians [21].

2. Is manual vacuum aspiration superior to electric vacuum aspiration for early surgical abortion?

Randomized clinical trials and observational studies have compared various aspects of EVA and MVA, although few have concentrated on gestations prior to 7 weeks. These studies support comparable efficacy, safety and acceptability of the two methods.

Two randomized trials and one cohort investigation found comparably high efficacy and safety for MVA and EVA. In a Swedish study of 200 women randomly allocated to MVA or EVA at 28–56 days of gestation, no ongoing pregnancies occurred, and only two patients in each group required resuction for retained tissue [33]. A recent prospective, double-blind, randomized controlled trial from India evaluated the effects of cervical ripening with misoprostol (400 mcg vaginally 3 h preprocedure) on complete abortion rates following MVA or EVA in 600 women, 23% of whom had pregnancies of less than 6 weeks' gestation [34]. The two abortion methods yielded identical rates of complete abortion (98%) that were not significantly affected by misoprostol administration. In a retrospective cohort study of women who had MVA (n=1002) or EVA (n=724) at a US hospital-based ambulatory clinic, the frequency of reaspiration was 2.2% and 1.7%, respectively (p=.43); however, only 37 procedures occurred at less than 6 weeks' gestation [35]. In these studies, other complications were infrequent (≤2% for presumed infection and <1% for conservatively managed uterine perforation) and did not differ by abortion method.

These findings were confirmed by a systematic analysis of ten randomized trials involving 1660 women to compare the safety, efficacy and acceptability of first-trimester MVA and EVA [36]. Half of the trials appeared in Chinese medical journals that are unavailable in English-language online databases, and the reviewers rated most of the studies as poor in quality. Nonetheless, the analysis revealed comparably high efficacy (98% complete abortion rate) and patient satisfaction for the two methods. Few complications were reported, although most studies had small sample sizes and limited duration of follow-up.

A recent randomized trial dispelled a common assumption that MVA is superior to EVA in facilitating accurate identification of early products of conception in the fresh tissue aspirate. Of 498 women allocated to MVA or EVA for abortion at less than 6 weeks of gestation, 82% of those in the MVA group had products identified on postoperative tissue examination and had subsequently confirmed completed abortions, compared with 76% in the EVA group (p=.13, RR .83, 95% CI: 0.64–1.07) [37].

Most researchers have reported comparable procedure times for MVA and EVA [2,34,35]. In one small randomized trial, however, MVA took slightly longer than EVA (mean procedure time 6.9 vs. 5.7 min, respectively; p=.05), and procedures performed by attending physicians were significantly faster than those provided by residents, regardless of method [38].

A few randomized trials have evaluated patients' perceptions of noise during manual or electric aspiration and its effect on pain scores or acceptability. One trial allocated 114 women at 11 weeks' gestation or less to MVA or EVA using paracervical anesthesia with preoperative oral diazepam. Although women who had EVA were significantly more likely to report that the noise of the procedure increased their pain, their objective mean ratings of procedural pain did not differ significantly from those in the MVA group [38]. Similar results emerged from a randomized trial of 84 women who had abortions at less than 10 weeks using moderate sedation. Reported procedural pain and measures of acceptability were comparable between groups, even though significantly more women in the EVA group found the noise "a little" or "somewhat" bothersome (19% vs. 2.4%, p=.03) [2]. Similarly, an acceptability study of 127 women randomly allocated to MVA or EVA found comparably high satisfaction in the groups, even though women's perceptions of the method differed in several aspects, including the perception of noise [39].

One randomized trial of MVA and EVA assessed physicians' acceptability of the methods as a secondary outcome [2]. Of the 84 abortions in this study, about one third were provided by 13 attending gynecologists, and the rest were performed by eight residents. Overall, physicians rated the procedures as "easy" in 70% of cases, "average" in 19% and "difficult" in 11%, with no significant differences emerging between manual and electric suction. Compared to attending physicians, residents reported more prior experience with MVA and a stronger preference for it.

No studies have compared costs associated with first-trimester MVA and EVA for induced abortion, but two have done so for their use in managing abnormal pregnancies in hospital settings. In a recent study from India that randomized 127 women to MVA or EVA in the operating room, MVA resulted in significantly shorter hospital stays and lower hospital costs [40]. Notably, general anesthesia was employed for 96% of EVA procedures, but only 60% of MVA procedures. A small study conducted at a US medical center from 1990 to 1992 analyzed charges associated with treatment of spontaneous abortion before and after introduction of MVA [41]. Compared to the traditional approach of EVA in the operating room using moderate or deep sedation, use of outpatient MVA decreased mean hospital stays by more than 70% and average total hospital charges by 41%.

In summary, strong and consistent evidence supports high efficacy, safety and patient acceptability for both MVA and EVA, although studies have included limited numbers of women with pregnancies of less than 7 weeks. Women's objective pain ratings do not differ significantly for the two methods, even though women may find the noise of electric suction bothersome or subjectively associate it with increased pain. Few data address physician acceptability, but one study suggests that physicians' preferences may depend on their level of training and their degree of experience with each method [2]. For hospital-based treatment of incomplete abortion, use of MVA in an ambulatory setting incurs less expense than the traditional approach of EVA in the operating room; however, no study has compared costs of the two methods in the freestanding clinical settings where most US abortions occur.

3. What special risks are involved in offering surgical abortion at less than 7 weeks' gestation?

Women requesting early abortion may lack definitive evidence of an intrauterine pregnancy on ultrasound, and products of conception may be difficult to identify in the aspirate. Therefore, providers must remain vigilant for failed attempted abortion and ectopic pregnancy.

Failed attempted abortion

Large retrospective studies from the 1970s consistently found a three- to fourfold increased risk of failed attempted abortion for aspirations performed at less than 7 weeks' gestation compared with those provided later in the first trimester [42–44]. Notwithstanding their historic interest, these early studies have limited implications for contemporary abortion practice given the technological advances that have occurred since their publication.

More recent large case series from Planned Parenthood affiliates have examined the risk of failed attempted abortion in women having early surgical procedures. A study by Edwards [45,46] included 2399 women who had suction

abortions at less than 6 weeks' gestation from 1994 to mid-1996. Edwards performed all of the abortions using a uniform protocol that included pre-and postprocedure vaginal sonography, MVA using a 7-mm rigid plastic cannula, and inspection of the fresh tissue aspirate using flotation with backlighting and magnification (manual or colposcopic) when needed. Only three continuing pregnancies (failed abortion rate 1.3 per 1000) were identified, although the proportion of women returning for follow-up was not reported.

An early abortion series conducted from 1998 to mid-2000 by Paul and coworkers found a higher rate of failed attempted abortion [47]. In this study of 1132 women with ultrasound-confirmed early pregnancies, several experienced physicians performed the abortions using 6-mm or 7-mm rigid plastic cannulae, manual or electric suction, and postprocedure ultrasound per provider preference. After the physicians inspected the tissue on site using flotation with backlighting and handheld magnification as indicated, they sent the specimens for pathology examination in accordance with state regulations. Rigorous efforts achieved 66% follow-up. Seventeen women had continuing pregnancies, representing a failed abortion rate of 15 per 1000 (95% CI: 9–24) for the total study population and 23 per 1000 (95% CI: 14–37) for women with follow-up. Likewise, a recent randomized trial conducted in a similar setting identified 7 failed attempted abortions among 498 women (14 per 1000) allocated to MVA or EVA for abortion at less than 6 weeks of gestation [37]. The higher failure rates in these studies compared to that of Edwards may reflect the use of multiple practitioners, diverse surgical protocols or better follow-up.

In summary, limited evidence suggests that, when performed by a single practitioner, a uniform surgical protocol combining routine pre- and postoperative transvaginal ultrasound, an adequate-sized cannula and meticulous tissue inspection (with manual or colposcopic magnification as needed) results in impressively low rates of failed attempted abortion (about 1 per 1000). Failure rates may be somewhat higher (14–23 per 1000) in community-based practices employing multiple providers with varying preferred surgical practices. Specific protocol elements that contribute most to the difference in rates remain unclear. Moreover, the modest reduction in failed abortion must be weighed against restricted access that could result from expecting all early abortion providers to have routine ultrasound capability or colposcopic magnification on site.

Ectopic pregnancy

According to estimates by the Centers for Disease Control and Prevention (CDC), ectopic pregnancy occurred in approximately 19.7 per 1000 pregnancies in the United States in 1992 [48]. The reported incidence in women seeking early induced abortion is much lower, ranging from 1.4 to 6.0 per 1000 in series reporting more than 500 abortions [45–47,49–52]. To date, no satisfactory explanation has emerged for this enduring phenomenon.

Diagnosis of ectopic pregnancy preoperatively poses considerable challenges. Although patients with ectopic pregnancy may present with a history of abnormal bleeding or abdominal pain, up to half are asymptomatic [53]. Because bleeding and pain can also occur with normal intrauterine pregnancy or early pregnancy loss, clinical symptoms and signs alone do not usually distinguish ectopic pregnancy from these other conditions. Ultrasound is often nondiagnostic as well, although ectopic pregnancy should be suspected in any patient with a positive pregnancy test and a sonogram showing an empty uterus and a noncystic adnexal mass. Sonographic findings of an extrauterine gestational sac or fetal pole (with or without cardiac activity) occur in only 20% and 13% of ectopic pregnancies, respectively; free fluid is present in the cul-de-sac in about 30% of cases [54], but is not pathognomonic. Some intrauterine fluid collections can mimic a gestational sac (pseudosac), but they lack a yolk sac and reside centrally in the uterine cavity (unlike the typical eccentric implantation of true gestational sacs).

In clinically stable pregnant women with nondiagnostic ultrasounds, serial monitoring of serum human chorionic gonadotropin (hCG) levels helps to decipher the diagnosis. A single initial preoperative hCG value above the discriminatory level (the concentration of hCG at which the gestational sac invariably should be seen) does not establish a diagnosis of ectopic pregnancy because about two thirds of women in these circumstances will have failing intrauterine pregnancies [55,56]. Prospective studies indicate that hCG levels rise exponentially in normal early pregnancy, with a minimum expected increase of 53% over 48 h [57,58], and they decline by 21%–35% over 48 h with failing intrauterine pregnancies [58,59]. The hCG pattern of most ectopic pregnancies either rises or falls more slowly than these parameters, although exceptions can occur [58,60].

In lieu of preoperative hCG testing, immediate uterine evacuation may establish the diagnosis more efficiently when the ultrasound is nondiagnostic [45,46]. Absence of products of conception in the fresh tissue aspirate warrants prompt hCG testing. In this situation, ectopic pregnancy is likely if the initial hCG value is above the discriminatory level or concentrations fail to drop by at least 50% within 24–48 h after surgery [56,61]. By using this approach in his early surgical abortion series, Edwards [46] identified 14 women with ectopic pregnancy, half of whom received the diagnosis on the day of their abortion visit.

In summary, heightened vigilance for ectopic pregnancy is a critical component of early abortion care. When a pregnant woman has no gestational sac on ultrasound, her differential diagnosis includes very early normal intrauterine pregnancy, spontaneous abortion or ectopic pregnancy. Although serial serum quantitative hCG monitoring alone usually can establish the diagnosis of ectopic pregnancy over time, immediate aspiration may do so more quickly, allowing for earlier and less invasive treatment options.

4. Is there a gestational age that is too early to abort safely by surgical means?

In the most recent Guttmacher Institute survey of all known US abortion providers, 42% of respondents reported that they offered abortions at 4 weeks' gestation or less in 2008 [1]. This section examines the available evidence pertaining to uterine aspiration at very early gestational ages, including when a definitive gestational sac is not evident on preprocedure ultrasound.

In the aforementioned series by Edwards [45,46], women were eligible for abortion as long as they had a positive sensitive pregnancy test (sensitivity 25 mIU). All test-positive women underwent transvaginal ultrasound dating and were classified according to the criteria of Warren [62] as 5 weeks (yolk sac, no fetal pole, $n=1504$), 4 weeks (gestational sac only, $n=651$) or 3 weeks (decidua and no sac, $n=242$). As previously described, Edwards performed all procedures using a protocol that included pre- and postoperative ultrasound, MVA, a 7-mm rigid plastic cannula with additional sharp curettage for patients who lacked a sac on ultrasound, and tissue inspection using flotation with backlighting and magnification with a 3× manual lens or colposcope as needed. Absence of the gestational sac in the aspirate prompted calculation of serial serum hCG titers. Patients whose initial hCG value exceeded the discriminatory level of 1700 mIU/mL were referred promptly to rule out ectopic pregnancy. Titers that did not fall by 50% in asymptomatic patients triggered repeat transvaginal screening or referral to a private gynecologist or emergency room.

Overall, 99% of patients in this study had a complete abortion, with most women (93%) receiving this reassuring diagnosis before leaving the clinic. Products of conception were identified in the fresh tissue aspirate of nearly all (99%) women at 4–5 weeks' gestation and in about half of women who had no sac on preoperative ultrasound. Six reaspirations, three for failed attempted abortion and three for hematometra, constituted the totality of recognized complications in this study, all of which occurred in patients at 4–5 weeks. Unsurprisingly, of the 14 (0.6%) ectopic pregnancies diagnosed in this cohort, 13 occurred in women who lacked sonographic confirmation of a gestational sac. Seven of these women were treated on the day of their abortion visit when their initial hCG exceeded the discriminatory level. Ten of the 14 ectopic pregnancies resolved with methotrexate therapy alone, and only 4 women required surgery.

The series by Paul [47] included women who had a gestational sac without a yolk sac, but not those who completely lacked a gestational sac on ultrasound. Rates of failed attempted abortion at 4 weeks and 5 weeks of gestation were nearly identical (about 25 per 1000 in women with follow up), and the frequency of other complications was low. This study emphasized that confirmation of complete abortion at early gestational ages may require considerable resources. Of the 727 women with known complete abortion, 22% required special monitoring to confirm the final diagnosis, in large part because the physician or pathologist was unable to identify products of conception in the aspirate. Another study found that 17% of women who had vacuum abortions at less than 6 weeks of gestation required hCG monitoring to confirm completed abortion after products of conception were not identified or were incomplete (villi without sac) on gross inspection by the physician [37].

In summary, surgical abortion may be carried out before a definitive gestational sac appears on ultrasound if evidence-based protocols [63] are in place to rule out ectopic pregnancy. Facilities that provide aspiration during the earliest weeks of gestation must dedicate the resources needed to track patients and provide timely follow-up with serial hCG monitoring and ultrasound when indicated. Additionally, providers must inform patients of the possible need for additional follow-up to assure satisfactory resolution of the pregnancy.

5. Is surgical abortion before 7 weeks' gestation more or less painful than procedures later in the first trimester?

Current data are inadequate to evaluate how abortion pain may differ by gestational age. Descriptive studies suggest that women having first-trimester aspiration abortions using local cervical anesthesia experience at least moderate pain [64–66]. Numerous factors have been found to correlate with abortion pain [67–69], but few studies have assessed early gestational age as an independent risk factor. One study [65] reported no overall association between gestational age and self-reported procedural or recovery pain in 1055 women who had abortions using local cervical anesthesia at 5–14 weeks. Nulliparous patients at less than 7 weeks' gestation, but not those with prior vaginal delivery, reported higher pain scores than did women at 7–12 weeks. A small but well-designed study used pain scales and the McGill Pain Questionnaire to evaluate procedural pain in 109 women having first-trimester aspiration abortions with local anesthesia [64]. In multiple regression analysis, early gestational age (5–7 weeks) accounted for only a small portion of the variance in pain scores. Overall, data are insufficient to determine if surgical abortions prior to 7 weeks are more or less painful than those occurring later in pregnancy.

6. What are the key prerequisites for a safe and effective early surgical abortion service?

A number of prerequisites for safe and effective early surgical abortion emerge from a review of the literature. The first is that longstanding medical consensus has established that induced abortion in modern settings should occur only after confirmation of pregnancy, either by a sensitive positive pregnancy test or by ultrasound [70–75].

Second, current recommendations of authoritative medical organizations include the requirement for immediate on-site evaluation of the fresh tissue aspirate following surgical abortion to ensure removal of intrauterine gestations; at gestations prior to 7 weeks, definitive visual identification must include both the gestational sac or membranes and placental elements. The Royal College of Obstetricians and Gynecologists includes the following instruction: "To increase confidence that the gestational sac has been removed, protocols include safeguards such as magnification of aspirate and follow-up serum beta-hCG estimation" [76]. The NAF Clinical Policy Guidelines set the following standard: "Completion of abortion must be confirmed prior to the woman leaving the facility." They recommend that "[i]n first trimester terminations, flotation of tissue with backlighting should be used to identify products of conception, including gestational sac" [70]. A recent randomized trial confirms that MVA for early abortion confers no benefit over EVA in detecting early products of conception in the aspirate [37]. No studies have assessed other measures to improve tissue examination, such as floating the specimen in saline instead of water or the use of backlighting or the addition of a small amount of colored liquid (e.g., iodine–povidone solution) to enhance visual clarity in questionable cases. One study found no clinical benefit to routine pathology review of the tissue; experienced abortion providers' tissue examinations were as good at predicting abnormal outcomes as were those of pathologists [77].

Third, providers of early abortion services must have mechanisms in place to rule out ectopic pregnancy, usually through a combination of ultrasound and hCG monitoring as delineated in these guidelines. Of note, a finite number of women with nondiagnostic preoperative ultrasounds will receive unnecessary aspirations if the clinical goal is the rapid diagnosis of ectopic gestation. Most women with unnecessary aspirations will be found to have had completed, or nearly completed, early pregnancy failures, although a few may have slowly regressing serial hCG titers suggesting spontaneously resolving ectopic gestations [51].

Fourth, consistent but methodologically limited evidence primarily from the 1970s suggests that clinician experience is associated with lower complication rates in first-trimester surgical abortion. One large multihospital retrospective analysis involving 33,000 abortions at 12 weeks or less found a 2.2-fold (95% CI: 1.3–3.8) increased risk of failed attempted abortion for procedures performed by resident physicians compared to staff physicians [44]. A more recent single-institution series of 828 first-trimester vacuum abortions also found a positive association between efficacy and the seniority of the surgeon [78]. Other large series have reported associations between surgeon experience and decreased rates of uterine trauma, including cervical laceration [79] and uterine perforation [80–82].

Fifth, several US prospective cohort studies and an international randomized trial suggest that well-trained advanced practice clinicians (APCs) can provide early abortion services where state and national laws allow it. A study of 2458 first-trimester vacuum abortions (8% at less than 7 weeks of gestation) performed in 1981–1982 in Vermont by experienced physicians or physician assistants (PAs) found comparably low rates of immediate, delayed and total complications [83]. Likewise, a prospective comparison of contemporaneous outcomes of mostly first-trimester vacuum abortions performed by experienced PAs at one clinic (546 cases) and experienced physicians at a nearby allied clinic (817 cases) in 1996–1997 yielded nearly identical complication rates (2.2% for PAs and 2.3% for MDs); 16 of 19 complications in physician-performed abortions were infections, whereas 7 of 12 complications in PA performed abortions entailed incomplete or failed procedures and included the only perforation [84]. The safety of early abortion provision by APCs was confirmed in a recent large multisite cohort study from California that included more than 16,000 first-trimester aspiration abortions performed in nearly equal numbers by physicians and trained nurse practitioners, nurse midwives or physician assistants (NP/NM/PAs). The group-specific abortion-related complication rate was 1.5% for NPs/NMs/PAs and 1.0% for physicians. This variation in complication rates between the two groups is within an acceptable clinical margin of difference, with 98% of the complications defined as minor (e.g., not requiring hospital transfer, transfusion or abortion-related surgery) [85]. An international randomized equivalence trial conducted in 2003–2004 also supports these findings [86]. This investigation compared outcomes of first-trimester MVA abortions at up to 12 weeks' gestation performed by physicians or "mid-level providers" (MLPs; consisting of nurses, midwives and doctor-assistants) at eight Marie Stopes International nonprofit outpatient clinics located in Vietnam or South Africa. In Vietnam, where both physicians and MLPs had about a decade of surgical abortion experience, total complications occurred in 1.2% of procedures performed by each group. In South Africa, where MLPs had considerably less experience than physicians (4 years vs. 10 years), no physician experienced a known complication, and MLPs had a complication rate of 1.4% (1.2% retained products and 0.2% pelvic infections).

Sixth and finally, ample evidence supports the safety of abortion provision in both hospital and outpatient settings, although no comparative study has focused specifically on early surgical abortions. In 1973, 50% of US abortions were performed in hospitals, whereas by 2008, only 4% took place there [1]. In an early study using data from the CDC and Guttmacher Institute for 1974–1975, Grimes et al. [87] calculated an identical death-to-case rate of 1 per 100,000 for abortions performed in hospitals or outpatient facilities after adjustment for preexisting conditions and concurrent sterilization. Reported series of early surgical abortion during the 1970s and early 1980s were as likely to originate in hospital settings (usually in faculty offices within hospitals) [44,74,75] as in outpatient clinics. Success and complication rates have been similar. Since the mid-

1980s, the preponderance of reported US series have taken place with proven safety in physicians' offices and clinics [45,88–90].

Conclusions and recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Early surgical abortion carries lower morbidity and mortality than procedures performed later in gestation. In addition, early aspiration may expedite the diagnosis of ectopic pregnancy, resulting in less invasive treatment.
- Manual vacuum aspiration and electric vacuum aspiration for first-trimester abortion have comparably high efficacy, safety and patient acceptability.
- Immediate gross examination of the aspirate is important in discovering failed attempted abortion, retained tissue and ectopic pregnancy. Compared to EVA, use of MVA does not improve the ability of the clinician to accurately detect products of conception in the aspirate following surgical abortion at less than 6 weeks of gestation.
- Clinical outcomes are indistinguishable in comparable, suitably equipped inpatient and outpatient abortion settings staffed with well-trained personnel.
- Licensed or accredited midlevel providers with the requisite training are able to perform first-trimester surgical abortion procedures with outcomes comparable to those of their physician counterparts.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Surgical abortion can be performed successfully and safely as early as 3 weeks from the onset of last menses if a protocol exists that includes sensitive pregnancy testing, immediate and meticulous examination of the aspirate, and assiduous follow-up of questionable specimens to rule out ectopic pregnancy or continuing gestation.
- In contrast to the vacuum method for early induced abortion, use of sharp or blunt curettage (dilation and curettage) for pregnancy termination is associated with a modest increase in blood loss, uterine or cervical injury (including endometrial abrasion), and retained tissue. No studies are available to assess whether sharp curettage abortion increases long-term risk of developing intracavitary adhesions, cervical stenosis or subfertility.
- In abortion settings where gross or microscopic examination of pregnancy tissue is routinely carried out by well-trained and experienced staff members and where local or regional laws mandating outside pathologic examination do not supervene, routine outside pathologic referral of tissue aspirates adds little diagnostic value.
- Complication rates are higher for clinicians with less experience in surgical abortion provision.

The following recommendations are based primarily on consensus or expert opinion (Level C):

- Confirmation of pregnancy prior to uterine aspiration is standard practice in modern medical settings. Occasionally, even in expert hands, false-positive results can occur.
- Cost depends largely on the prevailing wage differential between advanced practice clinicians who often staff medical abortion programs and the providers who perform surgical abortions.

Important questions to be answered

Given the challenges inherent in providing abortion during the earliest weeks of pregnancy, particularly before a gestational sac is visible on ultrasound, additional research aimed at improving providers' ability to verify successful abortion in the immediate postoperative period would be beneficial. In addition, more policy research is needed to understand and address the barriers that prevent women who desire pregnancy termination from accessing services early in pregnancy. Because economic issues can affect access to care, more rigorous comparison of the costs associated with early medical abortion and early surgical abortion is an important corollary to these efforts.

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Sources

The authors used MEDLINE and PUBMED databases, the Cochrane Database of Systematic Reviews and personal files to identify information relevant for review in the English language literature. The authors also culled abstracts in all languages (e.g., Chinese). Search terms included, but were not limited to, early surgical abortion; early vacuum aspiration; early induced abortion; electric vacuum aspiration; manual vacuum aspiration; early medical abortion; failed attempted abortion; ectopic pregnancy and menstrual regulation. The bibliographies of identified articles, and citations within those bibliographies, supplied additional sources for review.

Authorship

These guidelines were prepared by E. Steve Lichtenberg, MD, MPH, and Maureen Paul, MD, MPH, with administrative assistance from Laura Dodge, MPH; and reviewed and approved by the Board of Directors of the Society of Family Planning.

Conflict of interest

E. Steve Lichtenberg, MD, MPH, and Maureen Paul, MD, MPH, report no significant relationships with industries relative to these guidelines. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries.

Intended audience

This guideline is for Society of Family Planning fellows and any other health care professionals involved in the provision of abortion care. This guideline may be of interest to other professional groups that set practice standards for family planning services. The purpose of this document is to review the medical literature on surgical abortion prior to 7 weeks gestation. This evidence-based review should guide clinicians, although it is not intended to dictate clinical care.