

First trimester termination of pregnancy: methods in comparison between two European university hospitals

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Summary

Purpose of Investigation: To compare methods, epidemiological features, and legislations of first trimester termination of pregnancy in two European Union University Hospital: Szeged, Hungary, (UHS) and Rome, Italy (UHR). **Materials and Methods:** The study included 195 women in UHS and 197 women in UHR undergoing a termination of pregnancy. The method used in UHR was electric vacuum aspiration, while in UHS it is chosen according to the patients' features. **Results:** Mean gestational week at the time of interruption was 8.21 ± 0.12 SD for UHS and 9.00 ± 0.08 SD for UHR ($p = 0.0001$). Previous artificial termination of pregnancy was 0.40 ± 0.05 SD for UHR, and 0.77 ± 0.07 SD for UHS ($p = 0.0001$). Foreign women were 32.5% in UHR and 0.5% in UHS. Incidence of side effects was 1% for UHS and 0.5% for UHR. Parity was 2.54 ± 0.12 SD for UHR and 3.00 ± 0.14 SD for UHS ($p = 0.01$). **Conclusions:** The methods for interruption resulted safe and effective. Antibiotic prophylaxis, routinely provided in UHR, turned out to be effective to prevent post-operative infections. Cervical priming with Laminaria is safe, but patient's hospitalization is required. Different legislations may account for some epidemiological differences between the two hospitals.

Key words: First trimester termination of pregnancy; Cervical preparation; Karman method; Abortion legislation.

Introduction

An estimated 46 million pregnancies end in induced abortion each year. In almost all countries the law permits abortion to save the woman's life and in most countries abortion is allowed to preserve the physical and mental health of the woman [1].

The legislative statement on abortion of every country shows several differences, such as in Hungary and Italy, which are ruled, respectively, by Act LXXIX of 17 December 1992 on 'the Protection of the Life of the Fetus'. Latest modification: June 2000 (LXXXVII) and Law 194/78.

There are several different surgical techniques for first trimester termination of pregnancy, in particular dilatation and curettage (DC, to scrape out the contents of the uterus), vacuum aspiration (VA, sucking out the contents of the uterus with a manual or power-operated device). Literature data about DC are controversial. Preabortion medical or mechanical cervical preparation may reduce the incidence of cervical or uterine injuries [1-4].

The aim of this study was to compare first trimester termination of pregnancy between two European Union University Hospital: Albert Szent-Gyorgyi Medical Center, University of Szeged, Hungary (UHS) and Policlinico Umberto I, University "Sapienza", Rome, Italy (UHR). This comparison concerned methods used in the first

trimester of pregnancy, in order to investigate their effectiveness and complications rates, epidemiological features, and legislations.

Materials and Methods

This retrospective study was carried out in the Department of Obstetrics and Gynecology of the University of Szeged, Albert Szent-Gyorgyi Medical Center, Hungary (UHS), and in the Operative Unit-Voluntary Interruption of Pregnancy (UO-IVG), Department of Obstetrical-Gynecological and Urological Science, Policlinico Umberto I, University "Sapienza", Rome, Italy (UHR). Legislations, methods, and procedures of the two groups of study are described in the following paragraphs and summarized in Table 1.

UHS

In UHS, after a gynecological visit to attest the status of pregnancy, the woman is obliged to fill out a written application (except for medical indications) to ask the authorization to the "Service for the Protection of Families". In fact the Health Insurance Fund covers abortion if it is carried out for medical reasons and the applicant is insured; in case of "serious crisis situation" (i.e. social indication), the woman has to pay a fee. Specially trained nurses for consultation and advice run this service. There is an obligatory waiting period of three days followed by a second visit to the Service. Compulsory counseling is to be attended twice (except for abortions performed on medical grounds). If the patient is still motivated to have the abortion after the second counseling session, the date of operation is scheduled. Artificial

Table 1. — *Legislations, methods, and procedures of the two groups of study (UHS and UHR).*

<i>Legislations</i>		
Features	Italy	Hungary
Age limits	Up to 12 weeks	- Up to 12 weeks, - Up to 18 weeks, if < 18 years
Waiting period	7 days	3 days
Prices	Free of charge	- Social indication: fee due - Medical indication: free of charge
Conscientious objection	Specific rule	Absence of specific rule

<i>Medical care</i>		
Methods and procedures	UHR	UHS
Pre-abortion ultrasound	Yes	No
Cervical priming	Rare (Gemeprost 1 mg, vaginal pessaries)	Frequent (Laminaria tents)
Cerv. mechanical dilators	Porgèt urethral Dilators	Hegar dilators
Antibiotic prophylaxis	Always	Only with Laminaria
Rh-immunization	Yes	Yes
Anesthesia	Deep sedation; local if required	Deep sedation
Intraoperative ultrasound	Always	Not routinely
Postoperative ultrasound	No	Yes
Post-abortion follow-up: - BHCG Test - Transvaginal-ultrasound - Contraceptive counselling	Scheduled	Not scheduled

termination of pregnancy in the first trimester is always performed surgically and in a regimen of deep sedation. A premedication is provided, on the day of operation, early morning, with any anxiolytic or sedative medication given orally.

The preoperative preparation consists of an accurate and detailed medical history, and blood tests: Hgb, and blood type.

The surgical procedures, for the interruption up to 12 weeks, performed in this department are the following: Laminaria (or Dilapan) and curettage; DC; Laminaria (or Dilapan), electric VA and curettage; Dilatation, electric VA, and curettage.

The cervical ripening with Laminaria tents (or Dilapan sticks) is always practiced in young women (under 18 years), nulliparous, multiparous with a history of caesarean section. Up to 12 weeks, one Laminaria tent is generally used. After the cervical insertion, it is left in place overnight, nearly for 12-16 hours and the woman is admitted to the hospital for that night. The following morning the Laminaria tent is removed and the interruption is performed.

In case of multiparous with previous vaginal delivery, the cervical dilation is achieved with progressive Hegar dilators and it is followed by the curettage. This procedure is performed in a day-hospital regimen. According to the provider's choice and orientation, curettage can be preceded by electric VA. Intraoperative ultrasound (US) examination is not routinely practiced. Passive Rh-immunization of all Rh-negative women with Rh-im-

munoglobulin is routinely provided at the time of the abortion procedure. The antibiotic prophylaxis is provided only in case of use of Laminaria [5], by administration of amoxicillin and clavulanic acid. In case of hypersensitivity of the woman to penicillin or related antibiotics, a macrolid was administered.

In all the procedures, the patients are usually discharged approximately six hours after the operation. Before leaving the unit the patients undergo a US examination, in order to avoid residual tissue or incomplete abortion. After the operation, no follow-up visit or tests are scheduled. In case of side effects the women can complain in a separate "outpatient unit", where they will undergo a physical and US examination, and eventually be treated again. In any case the patients are suggested to visit her gynecologist, for a control examination and an eventual contraceptive counseling, four weeks after the surgery.

UHR

The UO-IVG is an operative unit providing women the following services: pre-abortion care, interruption of pregnancy, and post-abortion care. The whole procedure is completely covered by NHS for all women in Italy. According to the Law 194/78, to obtain an abortion, the woman must have a certificate attesting her requirement for interruption from her general practitioner, or a private physician or a public maternal-child health clinic, and must wait for seven days before the operation, in order to leave the woman time to reflect about her choice. Patient has a laboratory diagnosis of pregnancy (serum β HCG). Providers perform a transvaginal US examination in order to estimate the gestational age by the measurement of the CRL [6-8]. Pre-surgery preparation, consisting of detailed medical history, cardiological examination and electrocardiogram, blood count, hemoglobin, hematocrit, ABO and Rhesus group, prothrombine time, glycaemia, serum nitrogen, anti HCV, HBsAg, and urine test. After seven days the patient undergoes the interruption.

Termination of pregnancy is provided surgically with the procedure of the electric vacuum aspiration, applying the real "Karman's Method" [9]. The procedure is preceded by a cervical dilatation with plastic dilators of progressive size, or with Porgèt's olive-shaped point urethral catheters, and it is performed with the Karman's cannula; this is a plastic, thin, flexible, disposable, inexpensive cannula, available in different diameters, related to the gestational week. It almost eliminates perforation, dilation with rigid dilators, and anesthesia associated with conventional vacuum aspiration. In addition, because it could be used with any aspiration apparatus and then simply discarded, the Karman cannula also reduces sterilization costs and the risk of infection and cross-contamination between patients [10].

In particular cases, such as very young women, women in the 11th-12th gestational week, or women with uterine fibroids or stenosis, the mechanical dilatation is preceded by intravaginal administration of prostaglandins (gemeprost, one mg, at least three hours earlier) [11]. The intervention is always performed under the US guidance, in order to check for eventual retention of material (residual decidual tissue). In this case the procedure is completed by an angular cannula or, only sometimes by a gentle curettage [12]. During the procedure, under the patient's request, an intrauterine device (IUD) can be inserted [13]. The termination is provided in a regimen of deep sedation [14], hypnosis, and pain control. At the end of the procedure, five I.U. of oxytocin are injected in order to increase the cervical dilatation and uterine contractions, and an intraoperative antibiotic prophylaxis is provided (cefuroxime two g e.v.). In case of hypersensitivity, a macrolid can be given.

Table 2. — Epidemiological and obstetrical features of the two groups of study (UHS and UHR).

Characteristic	U.H.R.	U.H.S.	<i>p</i> value
Age, years	29.62 ± 0.49	29.06 ± 0.54	ns
Parity	2.54 ± 0.12	3.00 ± 0.14	0.01
Gestational week at the time of interruption	9.00 ± 0.08	8.21 ± 0.12	0.0001
Previous artificial termination of pregnancy	0.40 ± 0.05	0.77 ± 0.07	0.0001

Passive Rh-immunization of all Rh-negative women with Rh-immunoglobulin is routinely provided at the time of the abortion procedure [15]. If the patient refuse deep sedation, or if any contraindication for it exist, local anesthesia with mepivacaine 2% is provided (paracervical block) [16].

This procedure is performed in a day-hospital regimen and women are usually discharged six hours after the termination of pregnancy. After the operation, patient takes 0.2 mg of methylergonovine maleate for five days or oxytocin, if it is contraindicated (i.e. uterine fibroids, hypertension). Ten days after the operation the patient is provided a follow-up visit, with β HCG test, and a transvaginal US examination, in order to verify that the abortion was complete. During the follow-up visit the woman is furthermore provided a detailed contraception counseling [17].

Data collection and analysis

The authors collected 195 women undergoing a termination of pregnancy during the first trimester at UHS, in the period between February 2010 and October 2011, and 197 women undergoing a termination of pregnancy at UHR, in the period between October 2010 and April 2011. Data were collected from the clinical records and concerned age of the patient, nationality, obstetrical history (vaginal births, preterm births, caesarean sections, spontaneous abortions, previous artificial terminations of pregnancy, total number of pregnancy, including the index pregnancy), gestational week of the current pregnancy, method of induced abortion, and side effects. Statistical analysis was performed using SPSS 16.0 for windows computer program. Level of statistical significance was set at $p < 0.05$.

Results

The comparison between the two groups of patients shows several significant differences in epidemiological and obstetrical features (Table 2). Mean age was similar in the two groups, in particular 29.62 ± 0.49 SD years for UHR, and 29.06 ± 0.54 SD years for UHS ($p > 0.05$).

Parity (including the index pregnancy) was 2.54 ± 0.12 SD for UHR and 3.00 ± 0.14 DS for UHS, with $p = 0.01$ (Figure 1). It is worth mentioning that the maximum number of pregnancies found was nine for UHR and 15 for UHS.

Patients treated at UHS had a mean gestational week at the time of interruption slightly lower than at UHR (8.21 ± 0.12 SD vs 9.00 ± 0.08 SD, $p = 0.0001$). The different incidences of termination according to the gestational age of pregnancy are shown in Figure 2.

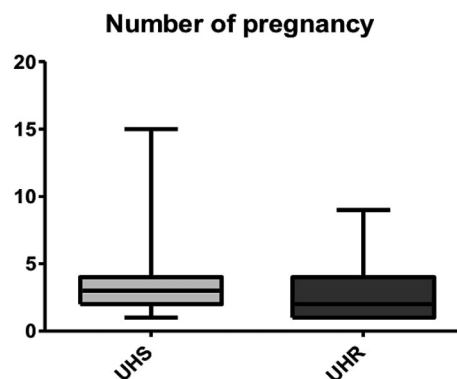


Figure 1. — Parity in the two groups of study (UHS and UHR).

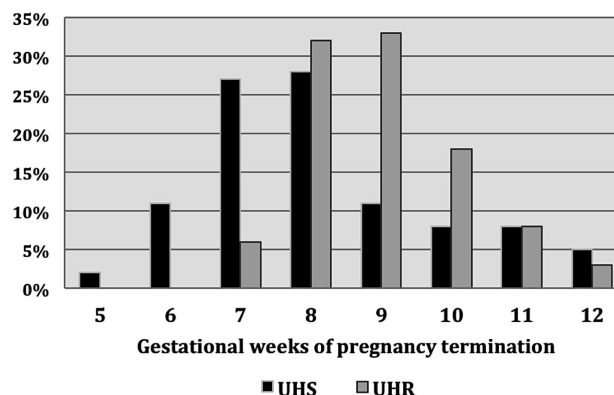


Figure 2. — Gestational week of pregnancy termination in the two group of study (UHS and UHR).

Previous artificial terminations of pregnancy in UHS (0.77 ± 0.07 SD) resulted to be more than in UHR (0.40 ± 0.05 SD), with $p = 0.0001$. In particular, 73% of patients treated at UHR and 50% at UHS did not have previous interruptions, while 18% at UHR and 34% at UHS had one previous interruption. Finally, the maximum number of previous interruption was five for UHR and seven for UHS.

In UHS, 8.2% of women had a medical indication for the interruption, while 91.8% a social one. This data is not available for UHR, since in Italy patients should not provide any information about indication for termination.

Interestingly, in UHS almost all patients have local nationality (99.5%), while in UHR 67.5% of women were Italian, and the remaining 32.5% were foreigners.

The overall rate of side effects in the first trimester termination was 1% for UHS and 0.5% for UHR. One case of bleeding, that required a revision of the uterine cavity for residual decidual material, occurred in each group, in particular a nulliparous 25-year-old woman in UHS and a nulliparous 16-year-old woman in UHR. In UHS this was a

complication of Laminaria and curettage and in UHR of dilatation and electric VA. Finally, in UHS one case of moderate to severe pain, with signs of pelvic inflammation, that required an antibiotic treatment, occurred in a multiparous woman after DC.

The different methods used for the interruption were in UHS Laminaria + electric VA + curettage (27.69%), dilatation + electric VA + curettage (25.64%), Laminaria + curettage (24.62%), and dilatation + curettage (22.05%). In UHR all cases were performed by dilatation + electric VA and in a limited proportion of women a curettage was also performed (3.55%).

Discussion

This study revealed significant differences concerning women obstetrical history. Indeed, parity resulted higher in UHS, the mean number of previous termination of pregnancy resulted higher in UHS, and the mean gestational week at the time of the abortion was higher in UHR.

Some of these differences may be partly related to the legislative statements on abortion of the two countries. According to the laws, the shorter waiting period in Hungary can shorten the time from application to intervention.

Another important issue regards the conscientious objection. In fact, the Italian law states that healthcare provider and operator of the ancillary activities are not required to take part in the procedures and in actions for termination of pregnancy if they have previously declared their conscientious objection, which must be communicated to the provincial doctor. In Hungary a healthcare provider may refuse to perform an abortion on ethical/moral grounds, but no official declaration or time limits are required.

The Hungarian law states that women have to pay for getting the pregnancy interruption, except for medical indications. Consequently, the indication for the interruption has to be reported in the patient charge. In Italy, the interruption is free of charge and the information about indications is not required.

The UHR data about patient nationality reflects the high number of immigrant women who access the healthcare system in Italy.

There is lack of conformity about DC in the literature, as this method seems to be less safe than VA [18], and it is considerably more painful for women because it requires greater dilation [19]. Moreover, the rate of major complications of DC is two to three times higher than VA [20]. Finally, a randomized controlled trial comparing DC with VA found that, up to ten weeks since last menstrual period, VA is quicker and associated with less blood loss than DC [21].

According to these data, WHO [1] and International Planned Parenthood Federation (IPPF) [3] recommended that where DC is currently practiced, all possible efforts should be made to replace it with VA, in order to improve the safety and quality of care. Where no abortion-related

services are currently offered, VA should be introduced rather than DC.

A Cochrane review comparing VA and DC found that there were no statistically significant differences for excessive blood loss, blood transfusion, febrile morbidity, incomplete or repeat uterine evacuation procedure, re-hospitalization, postoperative abdominal pain or therapeutic antibiotic use [4]. Duration of operation was statistically significantly shorter with VA compared to DC. The review concluded that both DC and VA are safe and effective methods for first trimester termination of pregnancy and complications are rare.

The choice of the method depends on the setting and the availability of the equipment. Although the duration of procedure is shorter with VA compared to DC, DC may play a role when using local anesthetics or for busy clinics [4]. The present study confirms that both DC and VA are effective and safe methods of abortion.

All the procedures performed in the two University Hospitals showed a very low rate of complications (1% in UHS and 0.5% in UHR). The use of US (intraoperatively in UHR and six hours after operation in UHS) may help to reduce complications. Additionally, intraoperative US may confirm the success of the intervention, thus reducing the duration of hospitalization.

The routine use of perioperative antibiotics is debated in the literature. Indeed, WHO [1] and IPPF guidelines [22] state that antibiotic prophylaxis reduces the post-procedural risk of infection, while, according to a Cochrane review [23], there seems to be not enough evidence on routine antibiotics to prevent infection for women seeking care after incomplete abortion.

In the present study, only a case of pelvic inflammation, that required an antibiotic treatment, occurred in UHS. Thus, the choice to administer an antibiotic prophylaxis remains recommendable, though not fairly supported by data [5, 24].

A previous Hungarian study reported that premature labour was a serious problem in Hungary where it often results from a cervix injury by a previous first or second trimester induced abortion. The dilatory effect of Laminaria was a fair aid in the termination of both first and second trimester pregnancies [25]. An international review supported that the ability to easily achieve the desired dilation with rigid dilators is comparable with all the other methods of cervical ripening [26].

A Cochrane review asserted that modern methods of cervical ripening are generally safe, though with variable efficacy and side effects [27]. Adverse events, such as cervical laceration or uterine perforation, are uncommonly reported and there is no study investigating the impact of the type of cervical preparation on complications. The present study did not report any case of cervical laceration or uterine perforation, in spite of the use of different methods for cervical ripening.

According to the literature and to the results of this retrospective study, it seems reliable to assert that cervical dilatation can be safely achieved by means of plastic or semirigid dilators. However, the UHS protocol with Laminaria requires the hospitalization of the patient, and consequently increased costs for the procedure. The UHR procedure, however, with mechanical dilators [28-30], requires a shorter operative time, as the procedure is practiced in a day-hospital regimen. Nonetheless, a case-by-case assessment should guide the provider in choosing the most appropriate cervical preparation.

The post-abortion care is different in the two countries. In UHS a follow-up visit is not planned, but in case of side effects women may refer to a different outpatient unit. However, the patient is suggested to visit her gynecologist (outside the hospital setting), for contraceptive counseling and control examination, four weeks after surgery. In UHR a follow-up visit including a transvaginal US examination and, according to the law 194/78, a detailed and free of charge contraception counseling are provided to all women.

In conclusion, the UHR healthcare system provides a more complete service to the women, although both the University Hospitals, by means of different strategies, warrants the care of the patients.

Conclusions

According to the laws, the termination of pregnancy seems to be more easily and readily available in Hungary due to a shorter compulsory waiting period and the lack of stated rules for conscientious objection. However, this procedure is free of charge in Hungary only for medical indications. All methods used for first trimester termination of pregnancy in this study result safe and effective. The choice of the method depends on the setting and the availability of the equipment. The use of intraoperative US may play a role in the reduction of complications rate.

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