THE EVOLUTION OF INDUCED ABORTIONS OF MORE THAN 12 WEEKS IN SPAIN

FIAPAC CONGRESS SEVILLA 2010

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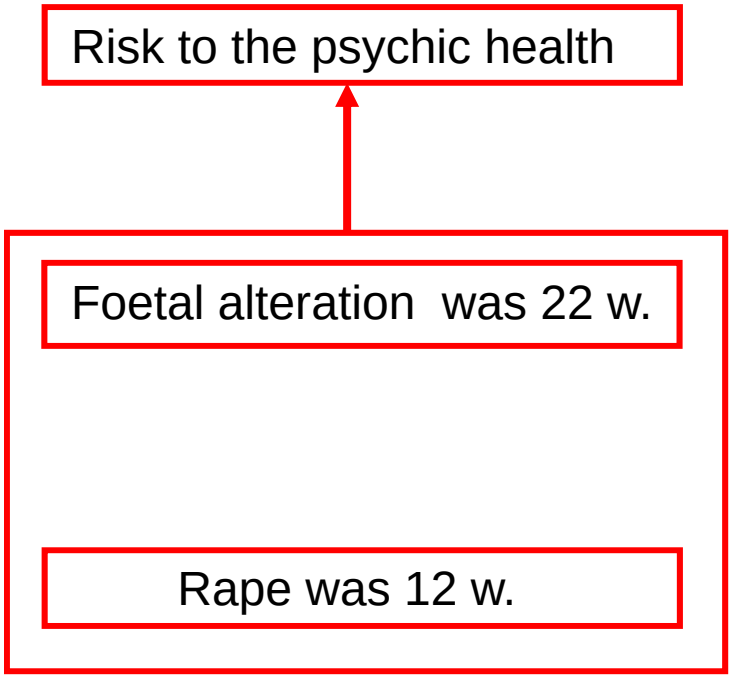
ACAI
Asociación de clínicas acreditadas para la IVE

HISTORY

PRIOR TO JULY 2010 (Law 1985)

WITHOUT TIME LIMITS



HISTORY

PROFESSIONALS
Pro choice

Create specialized clinics

88 % & 100% > 22 w.

PUBLIC HEALTH SERVICE
Law was had to be interpreted

Vital risk or foetal malformation at 22 w.

2,5 %

TABLA I
I.V.E. DISTRIBUCIÓN PORCENTUAL SEGÚN TIPO DE CENTRO, SEMANAS DE GESTACIÓN, MOTIVO DE LA INTERRUPCIÓN.
TOTAL. NACIONAL. 1999-2008

Año de intervención	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	TOTAL
TOTAL I.V.Es	58.399	63.756	69.857	77.125	79.788	84.985	91.664	101.592	112.138	115.812	855.116
Tipo de centro en %											PROMEDIOS
HOSPITALARIO	10,03	10,45	11,01	10,96	12,54	13,28	12,79	11,62	12,63	12,77	
Público	2,24	2,11	2,16	2,09	2,41	3,56	2,91	2,51	2,08	1,91	2,398
Privado	7,78	8,34	8,85	8,87	10,13	9,71	9,88	9,11	10,55	10,86	9,408
EXTRAHOSPITALARIO	89,97	89,55	88,99	89,04	87,46	86,72	87,21	88,38	87,37	87,23	
Público	0,29	0,26	0,28	0,38	0,44	0,00	0,00	0,00	0,00	0,00	0.165
Privado (especializad0)	89,68	89,29	88,72	88,66	87,01	86,72	87,21	88,38	87,36	87,23	88,026
											TOTALES
Total Promedio publico											2,563
Total Promedio privado											97,434
Nº IVES Privadas											832.883
Nº IVES Especializadas											752.673

Fuente: publicación del Ministerio de Sanidad y Política Social Interrupción Voluntaria del Embarazo datos definitivos 2008

http://www.msps.es/profesionales/saludPublica/prevPromocion/docs/publicacionIVE_2008.pdf

HISTORY

NON-RESIDENT FOREIGN PATIENTS

Non-resident foreign patients in 2008, 2,031 (1.75%)

Interrupción Voluntaria del Embarazo datos definitivos 2008 Ministerio de salud y Politica Social. España. 2010

Catalonia reported in 2008, "*1,053 (3.9%) foreign residents*".

Departament de Salut. Dades d'IVE a Catalunya del Departament de Salut (DGRS" www.gencat.cat

ETHICS

ACAI recommended to its members, from the ethical point of view, not to perform abortions of **live and healthy foetuses beyond week 26 from** the start of amenorrhea, being the borderline of foetal viability, **except in the case of foetal alterations incompatible with life or with the dignity of life and in a few cases of extremely deteriorated social conditions.**

HISTORY

EVOLUTION OF THE PRATICE AND BIRTH OF ACAI

Initiated procedures based on:

- •Knowledge acquired in the classical medical training.
- •Acquired at centres that already Practiced it in Spain or in other countries.

ASOCIACIÓN DE CLÍNICAS ACREDITADAS PARA LA INTERRUPCIÓN DEL EMBARAZO

Som s, exch al Association, created to defend the right to access quality **IA** practices, to give the practice a good image and to standardize procedures, as no scientific association was doing that at the time.

This is the manner in which ACAI was founded (1997), nearly at the same time as the FIAPAC, in which it became associated after the Maastricht Congress (1999).

HISTORY

PUBLICACIONES DEL PROGRAMA DE INVESTIGACION HISPANO-CUBANO

Misoprostol Solo

1. Carbonell JLL, et al The use of misoprostol for termination of early pregnancy. **Contraception 1997;55:165-8** .
2. Carbonell J.LL, et alThe use of misoprostol for abortion of £ 9 weeks gestation. Eur J Contrac Rep Health C 1997;2:181-5 .
3. Carbonell JLl, et al. Vaginal misoprostol for late first trimester abortion. **Contraception 1998;57:329-33** .
4. Carbonell JLl, et al. Vaginal misoprostol for early second-trimester abortion. **Eur J of Contrac Rep Health C 1998;3:93-8** .
5. Carbonell JLl, et al. Vaginal misoprostol for abortion at 10-13 weeks' gestation. **Eur J Contrac Rep Health C 1999;4:1-6** .
6. Carbonell JLl, et al. Early abortion with 800 µg of misoprostol by the vaginal route. **Contraception 1999;59:219-25** .
7. Carbonell JLL, et al. Vaginal misoprostol 600 µg for early abortion. **Eur J Contrac Rep Health C 2000;5:46-51** .
8. Carbonell JLl, et al. Dosis residuales post-aborto con misoprostol. Ensayo clínico aleatorizado. **Prog Obstet Ginecol 2000;43:297-302** .
9.Carbonell JLl, et al. Misoprostol for abortion up to 9 weeks' gestation in adolescents. **Eur J Contrac Rep Health C 2000;5:227-33** .
17. Creinin M. and Carbonell J.L.Vaginal moistened misoprostol with oral methotrexate in early abortion. **Contraception 2000.**

Methotrexate + Misoprostol

18. Carbonell JL, et al Misoprostol 3,4, or 5 days after methotrexate for early abortion. A randomized trial. **Contraception 1997;56:169-74** .
19. Carbonell JLl, et al. Oral methotrexate and vaginal misoprostol for early abortion. **Contraception 1998;57:83-8** .
20. Carbonell JLl, et al. 25 mg or 50 mg of oral methotrexate followed by vaginal misoprostol 7 days after for early abortion. **Obstet Gynecol Invest 1999;153:1410**

ACAI & SPECIALIZED SECTOR

Widespread use of Mifepristona & Misoprostol

PUBLIC & NON-SPECIALIZED PRIVATE SECTOR

Low & late use of Misoprostol

Low/no use of Mifepristona

HISTORY

Specialized Clinics

< Up to 12 w.

basic requirements

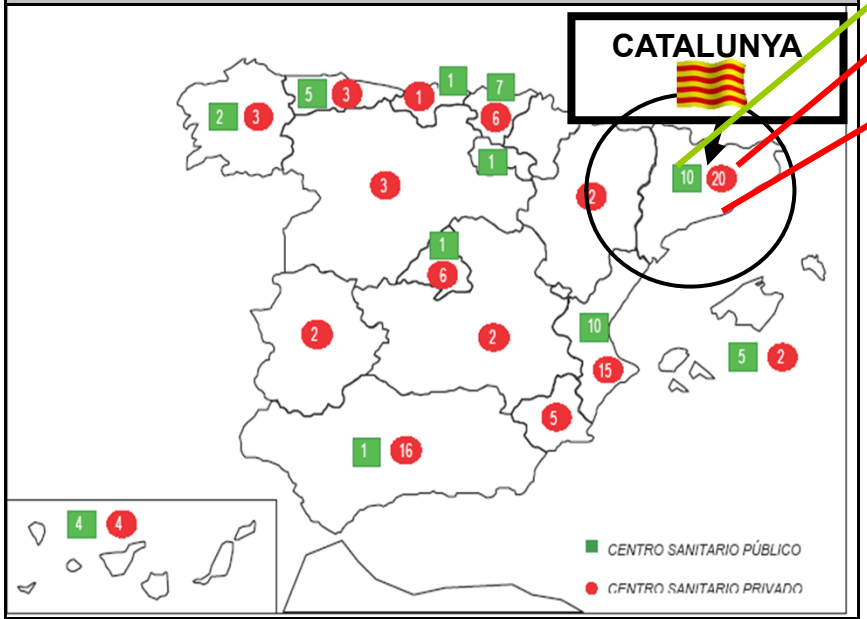
Local anesthesia or sedation

More than 12 w.

complex requirements

Freestanding wit overnight stay

Figura 1.
Distribución de centros que han notificado I.V.E.s. según Comunidad Autónoma y dependencia patrimonial. España, 2008

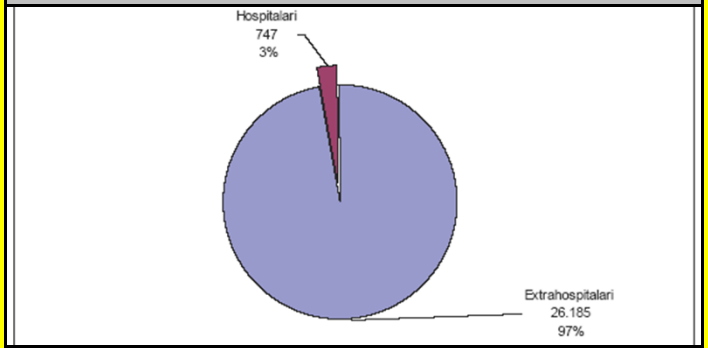


Fuente: Publicación del Ministerio de Sanidad y Política Social
Interrupción Voluntaria del Embarazo datos definitivos 2008

11 Public or private hospitals → 2.8 %

9 specialized clinics → 97,2 %

Figura 2. Avortament legal segons tipus de centre. Catalunya, 2008



Font: Generalitat de Catalunya. Avortament Legal a Catalunya, 2008
Registre d'interrupció voluntaria de l'embaràs
Actualitzada en data 20 de Novembre de 2009

http://www.gencat.cat/salut/depsalut/html/ca/dir1933/avorlegal2008.pdf

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http://www.msps.es/profesionales/saludPublica/prevPromocion/docs/publicacionIVE_2008.pdf

100.903 (11.8%) hundreds of public & private hospitals

752.673 (88%) very few specialized clinics

PROFESSIONALS HIGHLY SPECIALIZED IN CLINICAL CARE AND ASSISTANCE

HISTORY

COMPLICATIONS

Thanks to experience, in Spain the studies of complications yield very low results and the mortality levels are practically zero. This data have been compiled centre by centre, as there is not a national complications registry

Tabla IV Técnicas de 12 o mas sem. apoyado de Misoprostol y/oDilatadores osmoticos n=1396

Semanas	Misoprostol			Misoprostol+ Dilapan		
Método	Aspiración	D&E	Inducción	Aspiración	D&E	Inducción
12-15'6	192	552	0	0	16	0
16-19'6	0	533	0	0	36	0
20-26'0	0	21	38	0	8	0
Totales	192	1106	38	0	(5.4%) 60	0

- **Complicaciones mayores 0.3 %**

Barambio S. Finalización Voluntaria del Embarazo. Aspectos legales. Aborto de primer trimestre: Técnicas, resultados, complicaciones Aborto de segundo trimestre: Técnicas, resultados, complicaciones. En: Cabero L. y cols. Tratado de Ginecologia Obstetricia y Medicina de la Reproducción. Tomo1. Madrid: Ed Med Pan; 2003. P. 179-84

HISTORY

This considerable experience has made it possible to develop very effective techniques. We must keep in mind that the number of Abortions accredited centres is in fact practically unchanged, given than some of the 14 new centres that have appeared over these 10 years

Tabla II
1999-2008. TOTAL NACIONAL. I.V.E. NÚMERO DE CENTROS QUE HAN NOTIFICADO NÚMERO DE ABORTOS REALIZADOS Y TASAS POR 1.000 MUJERES ENTRE 15 Y 44 AÑOS.

Año de intervención	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Nº de Centros que han notificado IVE	123	121	121	124	128	133	134	135	137	137
Nº de Abortos realizados	58.399	63.756	69.857	77.125	79.788	84.985	91.664	101.592	112.138	115.812
Tasas por 1.000 mujeres de 15 a 44 años	6,52	7,14	7,66	8,46	8,77	8,94	9,60	10,62	11,49	11,78

Fuente: publicación del Ministerio de Sanidad y Política Social Interrupción Voluntaria del Embarazo datos definitivos 2008

http://www.msps.es/profesionales/saludPublica/prevPromocion/docs/publicacionIVE_2008.pdf

HISTORY

ACAI has facilitated the exchange of experiences and has unified knowledge levels in a nation-wide and international effort aimed at achieving the highest levels of excellence in clinical practice and in attendance

•Organizing congresses (Seville 2000)

•Participating in them: FIAPAC Maastricht (Barambio), Paris (Carbonell, Barambio), Amsterdam (Barambio), Vienna (Peña, Carbonell Rodríguez), Istanbul (Vidot), Rome (Vidot, Rodríguez, Carbonell, Barambio),

•Own publications (ACAI Bulletins, press articles)

•Publications of medical practitioners for ACAI clinics

•Cooperating with sexual and reproductive health bodies (APFCiB, FPFE, SEC etc.),

•Work involving observation and divulgation

•Political lobbying, as demonstrated by its influence upon the new Spanish Law, through the provision of its considerable experience and knowledge, as experts, to parliamentary groups, Congress and Ministries

•Divulgation of knowledge to the mass media (newspapers, radio, television).

•Divulgation to members of the profession (congresses, meetings)

•University tuition, chapter dealing with abortion in the Handbook of Obstetrics, Gynaecology and Reproduction of the Spanish Society of Gynaecology and Obstetrics (SEGO) (S. Barambio) **(5)**

•The IVE protocols of the Web page of SEGO.

PROCEDURES IN THE SECOND AND THIRD QUARTERS AT ACAI CLINICS :

- Prior evaluation of the patient:

  Medical, gynaecological, obstetric and clinical record, obstetric and foetal ultrasound, gynaecological exploration, blood analysis, performed to determine the level of risk that the centre and the medical team have to deal with, evaluating the possibility of situations that may create a risk over and above the possibilities of the institution, (Davis and A.S.A. criteria), generating the appropriate documentation.
- Evaluation of the legal situation.
- Exposure to the patient:

  Whether the centre can accept it or not and in that case explain avaiable alternatives, if any.
  Considering the technique selected and the applicable circumstances (average time, risks, possible complications, solutions, etc).
  Informed consent.
- Planning:

  In accordance with of the organization of the centre and the selected technique, efforts are made to comply with the plan at the time of the initial telephone contact or as alternatively amended, when there are new criteria that make any such change advisable.
- General aspects of the techniques:

  In the cases of Abortions of more than 12 weeks, generally the selected anaesthesia medium is conscious sedation supported by local anaesthesia at the uterine cervix and/or epidural anaesthesia at times.
  All of the instrumental procedures are performed under real time ultrasound control conditions.

PROCEDURES IN THE SECOND AND THIRD QUARTERS AT ACAI CLINICS

According to the results of the preliminary evaluation, the female patient is programmed for:

A) Ambulatory Surgery Mode (AS) (discharged in 1-2-3 hours)
Techniques:
01) Aspiration without cervical preparation.
02) Aspiration with prior cervical preparation using PGE1* (nº) h**.
03) Aspiration with prior cervical preparation using PGE1 (nº) h., Dilapan®*** (nº) h.
04) (D&E) without cervical preparation.
05) (D&E) with prior cervical preparation using PGE1 (nº) h.
06) (D&E) with prior cervical preparation using Dilapan® (nº) h.
07) (D&E) with prior cervical preparation using PGE1 (nº) h. and Dilapan® (nº) h.
B) AS mode with extended recovery (Discharged after 8 hours or the following day).
Techniques:
01) D&E with prior cervical preparation using PGE1 (nº) h.
02) D&E with prior cervical preparation using Dilapan® (nº) h.
03) D&E with prior cervical preparation using PGE1 (nº) hours and Dilapan® (nº) h.
04) Induction using PGE1 until the usage of Oxytocin, following PGE1 or not.
05) Equal to 04 using Dilapan® (nº) h. On starting PGE1
C) Mode of hospitalization surgery (more than one night)
Techniques:
01) D&E, with some preparations mode.
02) Induction.
03) Micro-Caesarean section (hysterectomy) either as a recourse or as a programmed procedure.

* PGE1:Misoprostol in variable doses, in accordance with the case.
** h. nº.:Means the number of hours applied to the quoted element, may vary depending on cases and centres.
*** Osmotic dilator, Dilapan® is the most frequently used, introducing all the possible ones in the cervical canal.

It is possible to perform a prior treatment 24 - 48 hours before using Mifepristone hours (no.) in either a systematic or selective manner, depending upon the obstetric characteristics of the patient.
In inductions it is possible to perform an Instrumental Finalization (IF), in order to shorten the expulsive, whenever foetal necropsy is not advised.

PROCEDURES IN THE SECOND AND THIRD QUARTERS AT ACAI CLINICS

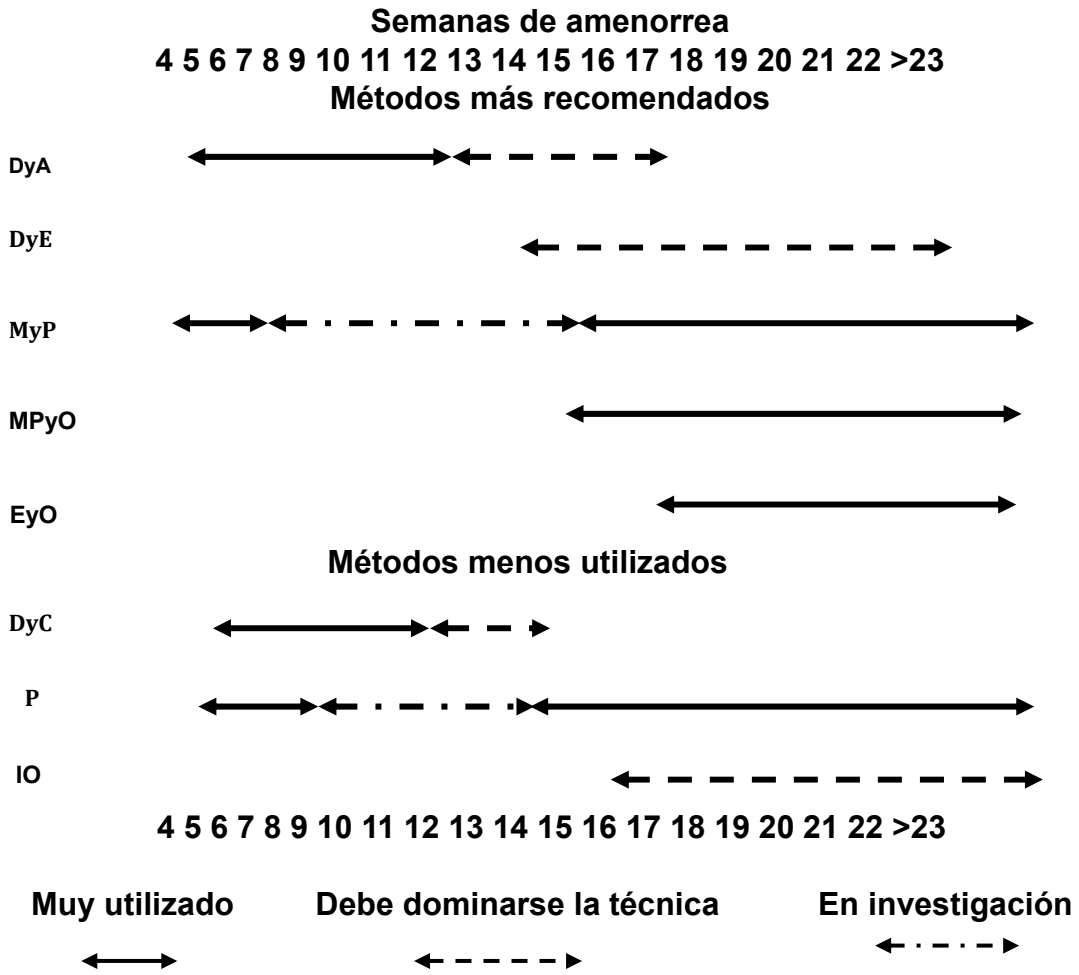
POST-SURGICAL ADVICE

- **Antibiotic prophylaxis:**
  - **With Doxycycline or Metronidazol or if it is immediate, then 5 days after the procedure, except when contraindicated.**
  - **If the case requires it, then wide-spectrum intraoperative cephalosporins or antibiotics are used, specially covering Gram negative germs.**
  - **The prophylaxis of the β haemolytic streptococcus, with penicillin derivatives.**
- **Social-sanitary instructions and an indication of the precise required medication.**
- **Manner in which advice is given personally at the centre or by a 24 h telephone hot line service at the patients' home.**

PROCEDURES IN THE SECOND AND THIRD QUARTERS AT ACAI CLINICS

Tabla III
Técnicas de Aborto Provocado
Utilización en relación a semanas de amenorrea

FARMACOLÓGICAS	QUIRÚRGICAS
Prostaglandinas solas (oral/vaginal) **(P)**	Dilatación y Legrado **(DyC)**
Mifepristone (oral) + Prostaglandinas (oral/vaginal) **(MyP)**	Dilatación y Aspiration **(DyA)**
Mifepristone (RU 486) (oral) Prostaglandinas E1(oral/vag) + Oxitócicos **(M,PyO)**	Dilatación y Evacuación**(DyE)**
Prostaglandinas E1(oral/vag) + Oxitócicos (Endovenosos) **(EyO)**	Histerotomía o Microcesárea
Intraovulares (Suero salino/urea/Prostaglandinas) **(IO)**	Histerectomía



PROCEDURES IN THE SECOND AND THIRD QUARTERS AT ACAI CLINICS

At the ACAI clinics, in contrast with the public hospital sector, with the improvement of the experience of the **professionals has increased the rate of application of the D&E over the induction**, due to the added advantages of safety, comfort and speed.

Recognized in a 2008 Cochrane review (6) by Lohr PA, Hayes JL, Gemzell-Danielsson K., when they say: “The number of women experiencing adverse events was also lower with D&E than with mifepristone and misoprostol (OR 0.06, 95% CI 0.01-0.76). Although women treated with mifepristone and misoprostol reported significantly more pain than those undergoing D&E, efficacy and acceptability were the same in both groups. In both trials, fewer subjects randomised to D&E required overnight hospitalisation”.

The great experience in D&E has caused us to use more and more the Instrumental Finalization technique, which we also empirically know improves the results and the level of comfort.

ACTIVITIES AND GENERAL CONDITIONS OF THE SPECIALIZED CLINICS SCs

The 2nd and 3rd quarter ACAI clinics have:

1. A pre-operation area for valuation and advice
2. A surgical block with complete operating rooms (anaesthesia, monitors, gases, clean-dirty sterilization circuit without crossings, etc)
3. Post anaesthesia recovery area,
4. Environment adaptation area
5. Post-surgical information area.

All of them are used to look after women patients that come from far away towns or from foreign countries.

There are architectural design variations in conformance with the health criteria of the various autonomous communities.

There are **Spanish SCs authorized** to carry out IAs that perform **up to 17-18 weeks.**, others that take **up to 22-24 weeks** and there are some that **do not have any time limits**, there are some that **work in conjunction with public health** services sharing the workload, so that **the clinic performs the abortion (feticide) procedure and the public or private hospital performs the expulsive procedure** and alternatively there are cases in which the clinic performs **the interruption procedure and the hospital later takes in the patient,**

Each Autonomous Community organizes health services with the framework of the applicable Spanish regulations.

FUTURO DEL ABORTO PROVOCADO EN ESPAÑA:

Law March 2010

Indications: up to the 22 W, of Pregnancy.

Risk that the pregnancy may involve to the health of the patient. Includes psychical health, certified by a specialist medical practitioner.

Foetal alteration certified by two specialist medical practitioners, in both cases limited.

Time periods: up until the 14 W.

The patient decides by herself, without any input from third parties, with a three day reflection period, after receiving information about maternity assistance and about any other aid rendered by the Autonomous Community authorities, which varies between communities.

Without any time limits: In cases of incurable or very serious foetal alterations, interruption of the pregnancy is permitted, although requiring the diagnostic validation of a specific committee, appointed by the relevant health authorities.

ACAI defends that it is in fact three weeks more, based on the fact that the WHO in: Definitions And Indicators In Family Planning Maternal & Child Health And Reproductive Health Used In The Who Regional Office For Europe (http:/test.cp.euro.who.int/document/e68459.pdf), explains that **the conception is at the time when nidation ends**, which would extend accessibility regarding the assimilation that pregnancy is the equivalent of amenorrhea. In any case, and according to this document, the WHO considers that pregnancy age expressed in weeks of amenorrhea, must be considered as from the first week (of the first day of menstruation or day 0 and up to day six of amenorrhea) to be week 0, so that at the very least **what are considered to be 22 weeks of conventional amenorrhea are in fact 21 weeks of WHO gestational age**.

SITUATION OF FOREIGN PATIENTS THAT ARE NOT SPANISH RESIDENTS

Continues allowing non-resident foreign patients to abort in Spain

Limited up to the 22 w. (23- 25 w. of amenorrhea depending on interpretation)

We understand that the public health system will not foot the bill in the case of foreign patients, given that the procedure has not been carried out in their own countries

But we do not know whether services may be invoiced out to third parties whenever they may need to be looked after at public facilities due to complications or to any other need that may be beyond the limited possibilities of the attendant specialized clinic, that is to say in case of emergency, which is a possibility that may apply to a small but not non-existent percentage of women patients

It would be advisable for patients that come to Spain to have an abortion to bring documentation evidencing the reciprocity of health services, for the applicable countries.


ACAI
Asociación
de clínicas
acreditadas
para la IVE

The new Law continues allowing non-resident foreign patients to abort in Spain, as the law is applicable to any woman which at the time of abortion is within the Spanish borders.

It is still possible to abort for social reasons, with a live and healthy foetus, using the risk for psychical health indication, except that it is now limited to the first 22 weeks of pregnancy (23, 24 or 25 weeks of amenorrhea depending on interpretation), and the same provisions apply to foetal alteration, although it is not yet clear whether foreign patients will be subject to the report issued by the specific committee appointed by the autonomous government where the abortion is to take place or not, in any case, if possible it will necessarily involve a waiting period.

The new Act says that if the patient so wishes, this service will be paid by the public health service for beneficiaries of the Spanish Social Security system (health card), a matter which for the time being is being sorted out in different ways by the relevant authorities of each autonomous community. We understand that the public health system will not foot the bill in the case of foreign patients, given that the procedure has not been carried out in their own countries, but we do not know whether services may be invoiced out to third parties whenever they may need to be looked after at public facilities due to complications or to any other need that may be beyond the limited possibilities of the attendant specialized clinic, that is to say in case of emergency, which is a possibility that may apply to a small but not non-existent percentage of women patients. According to the data collected from an ACAI clinic (Tutor Medica) there was a 0.3% rate of major complications that required hospitalization (Table **IV**), although there are authors that quote a 0.7 % of major complications when the D&E procedure is employed and even greater in the case of inductions and hysterectomies (6) (7), notwithstanding this, **it would be advisable for patients that come to Spain to have an abortion to bring documentation evidencing the reciprocity of health services, for the applicable countries.**