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

FIAPAC CONGRESS SEVILLA 2010

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Toco ginecólogo Presidente de ACAI
Eduardo Perez Lujan Clínica Poliplanning
Toco ginecólogo
PRIOR TO JULY 2010 (Law 1985)

WITHOUT TIME LIMITS

Risk to the psychic health

Foetal alteration was 22 w.

Rape was 12 w.
**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%

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

<table>
<thead>
<tr>
<th>Año de intervención</th>
<th>1999</th>
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<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL I.V.Es</td>
<td>58.399</td>
<td>63.756</td>
<td>69.857</td>
<td>77.125</td>
<td>79.788</td>
<td>84.985</td>
<td>91.664</td>
<td>101.592</td>
<td>112.138</td>
<td>115.812</td>
<td>855.116</td>
</tr>
<tr>
<td>Tipo de centro en %</td>
<td></td>
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<td></td>
<td></td>
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<td>PROMEDIOS</td>
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<tr>
<td>HOSPITALARIO</td>
<td>10,03</td>
<td>10,45</td>
<td>11,01</td>
<td>10,96</td>
<td>12,54</td>
<td>13,28</td>
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<td>11,62</td>
<td>12,63</td>
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<tr>
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<td>8,34</td>
<td>8,85</td>
<td>8,87</td>
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<td>9,71</td>
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<tr>
<td>EXTRAHOSPITALARIO</td>
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<td>87,46</td>
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<td>87,21</td>
<td>88,38</td>
<td>87,37</td>
<td>87,23</td>
<td>88,026</td>
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<tr>
<td>Público (especializad0)</td>
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<td>0,26</td>
<td>0,28</td>
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<td>87,36</td>
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**TOTALES**
- Total Promedio público: 2,563
- Total Promedio privado: 97,434
- Nº IVES Privadas: 832,883
- Nº IVES Especializadas: 752,673


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

*Interrupción Voluntaria del Embarazo datos definitivos 2008 Ministerio de salud y Política 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.**
Initiated procedures based on:

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

Some SCs got in touch with other practitioners in Spain and in other countries, exchanging experiences and knowledge, which generated the need to create a National 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).
PUBLICACIONES DEL PROGRAMA DE INVESTIGACION HISPANO-CUBANO

**Misoprostol Solo**

**Methotrexate + Misoprostol**

### HISTORY

**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.
- Local anesthesia or sedation

- More than 12 w.
- Freestanding with overnight stay

9 specialized clinics → 97.2%

11 Public or private hospitals → 2.8%

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**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

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**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

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| Total Promedio publico |       |
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| Nº IVES Privadas |   |
|                 | 832,883|
| Nº IVES Especializadas |  |
|                 | 752,673|


100.903 (11.8%) hundreds of public & private hospitals

752.673 (88%) very few specialized clinics

PROFESSIONALS HIGHLY SPECIALIZED IN CLINICAL CARE AND ASSISTANCE
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.

<table>
<thead>
<tr>
<th>Semanas</th>
<th>Misoprostol</th>
<th>Misoprostol+ Dilapan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Aspiración</td>
<td>D&amp;E</td>
</tr>
<tr>
<td>12-15'6</td>
<td>192</td>
<td>552</td>
</tr>
<tr>
<td>16-19'6</td>
<td>0</td>
<td>533</td>
</tr>
<tr>
<td>20-26'0</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Totales</td>
<td>192</td>
<td>1106</td>
</tr>
</tbody>
</table>

Complicaciones mayores 0.3 %

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.
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.
• 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 available 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.
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. n°.: 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.
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.
<table>
<thead>
<tr>
<th>FARMACOLÓGICAS</th>
<th>QUIRÚRGICAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostaglandinas solas (oral/vaginal) (P)</td>
<td>Dilatación y Legrado (DyC)</td>
</tr>
<tr>
<td>Mifepristone (oral) + Prostaglandinas (oral/vaginal) (MyP)</td>
<td>Dilatación y Aspiración (DyA)</td>
</tr>
<tr>
<td>Mifepristone (RU 486) (oral) Prostaglandinas E1(oral/vag) + Oxitóicos (M,PyO)</td>
<td>Dilatación y Evacuación (DyE)</td>
</tr>
<tr>
<td>Prostaglandinas E1(oral/vag) + Oxitóicos (Endovenosos) (EyO)</td>
<td>Histerotomía o Microcesárea</td>
</tr>
<tr>
<td>Intraovulare (Suero salino/urea/Prostaglandinas) (IO)</td>
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Tabla III
Técnicas de Aborto Provocado
Utilización en relación a semanas de amenorrea

<table>
<thead>
<tr>
<th>Semanas de amenorrea</th>
<th>Métodos más recomendados</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23</td>
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<table>
<thead>
<tr>
<th>Méthodos menos utilizados</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23</td>
</tr>
</tbody>
</table>

Muy utilizado: 
Debe dominarse la técnica: 
En investigación:
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.
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.
Indicaciones: hasta la 22 W, de Embarazo.

Riesgo que la gestación implique el riesgo para la salud del paciente. Incluye la salud psíquica, certificada por un especialista en medicina.

Alteración fetal certificada por dos especialistas en medicina, en ambos casos limitada.

Períodos de tiempo: hasta la 14 W.

La paciente decide por sí misma, sin entrada de terceras partes, con un periodo de reflexión de tres días, después de recibir información sobre la asistencia materna y sobre cualquier otra ayuda proporcionada por las autoridades de los Estados Autónomos, lo que varía entre las comunidades.

Sin límites de tiempo:

En casos de alteraciones fetales incurables o muy serias, la interrupción del embarazo está permitida, aunque requiera la validación diagnóstica de un comité específico, designado por las autoridades sanitarias relevantes.

ACAI defiende que en efecto son tres semanas más, ya que la WHO en: Definiciones y Indicadores en Planificación Familiar, Salud Materno-Infantil y Salud Reproductiva Usada por el Oficina Regional de la OMS Para Europa (http://test.cp.euro.who.int/document/e68459.pdf), explica que la concepción es en el momento cuando la nidación termina, lo que extendría la accesibilidad en relación con la asimilación que el embarazo es el equivalente de la amenorrea. En cualquier caso, y según este documento, la OMS considera que la edad de la gestación expresada en semanas de amenorrea, debe considerarse como desde la primera semana (de la primera semana del ciclo menstrual o del primer día, y que hasta el sexto día de amenorrea) hasta la semana 0, de modo que al menos las 22 semanas de amenorrea convencional son en realidad 21 semanas de edad gestacional de la OMS.
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.
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.