Permanent birth control: A french exception?

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Service de Gynécologie-Obstétrique,
Centre Hospitalier de Versailles
Present contraception related to age

Contraception's choice: women's opinion, satisfaction and profile. Results of a French national survey of a representative sample of 5963 women.

Gynecol Obstet Fertil. 2014 Jun;42(6):415-21
Global satisfaction of present contraceptive method

Average mark / 10

<table>
<thead>
<tr>
<th>Method</th>
<th>Average Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (4497)</td>
<td>8.4</td>
</tr>
<tr>
<td>Female sterilization féminine</td>
<td>9.7</td>
</tr>
<tr>
<td>IUD (874)</td>
<td>8.9</td>
</tr>
<tr>
<td>ST Pill (2728)</td>
<td>8.5</td>
</tr>
<tr>
<td>Implant (Implanon, Norplan)</td>
<td>8.3</td>
</tr>
<tr>
<td>Male condom (362)</td>
<td>7.3</td>
</tr>
<tr>
<td>Natural methods (88)</td>
<td>7.1</td>
</tr>
</tbody>
</table>

Base : Ens de femmes âgées de 15 à 45 ans et utilisatrices d’un moyen de contraception
Enquête TNS Sofres : P. Panel et col

*: base faible
Female sterilization: background and ethics

- Until 1999: Article 16-3 of the French Civil Code:
  “The integrity of the human body shall not be violated except if there is therapeutic necessity for the person.”

- 14 Nov 1975: Council of Europe’s resolution signed by France
  Surgical sterilization is admitted as medical service

- Article 16-3 of the French Civil Code modified by article 70 of the Law 99-641:
  “The integrity of the human body shall not be violated except if there is medical necessity for the person.”
Voluntary sterilization: Legal aspects

- Law n° 2001-588 of 4 July 2001:
  - «Art. L. 2123-1. (...) It may only be carried out if the interested adult has expressed a free, motivated and deliberate intention after considering clear and thorough information on its consequences. (...) »
  - « (...) written informed consent (...) »
  - « (...) 4-month reflection period (...) »
  - « (...) written confirmation (...) »
Informed decision

- French Law of 4 March 2002:
  - “In the light of information and advice provided by healthcare professionals and in consultation with them, patients are entitled to make the decisions concerning their health.”

- Obligation of means
  - “The healthcare professional must provide all necessary means, considering the available scientific data”

- Obligation of information
  - Article 35 (article R.4127-35 of the French Public Health Code)
    “The doctor owes the person he or she examines, treats or advises a loyal, clear and relevant information concerning the patient’s condition, the investigations and the treatments offered.”
ESSURE : “Adult women of childbearing age wishing a permanent tubal sterilization as definitive and irreversible contraceptive method.”

“ESSURE has a role in the prevention of unwanted pregnancies which is of public interest.

“For women around or over 40 years old, ESSURE can be offered as sterilization technique as first-line treatment.”
Female sterilization in France

Source: ATIH
SUCCES II

- Observational study
- Prospective
- National
- Multi-centre
  - (13 centres/14 investigators)
- Phase 4
- Beginning of study: 1st September 2008
- End of inclusions: May 2011
- Forecast end of study: 1st June 2016
- Sample: over 2,500 patients
SUCCESS II: Age

Median\textsubscript{age} = 41 years
Average\textsubscript{age} = 41.1 years
Standard deviation\textsubscript{age} = 3.6 years

n=2573

La contraception définitive en France et en Europe
SUCCESS II: Parity

Permanent contraception in France and in Europe

Average children = 2.46
Median children = 2
Standard deviation children = 1.14

n=2572
1 missing data
SUCCESS II: Previous contraception

Before

- patch: 0.42%
- autres: 1.08%
- anneau vaginal: 1.31%
- implant contraceptif: 2.82%
- stérilet hormonal: 6.36%
- macroprogesterins: 8.33%
- stérilet: 9.02%
- aucun: 11.45%
- préservatifs: 13.81%
- microprogesterins: 16.7%
- pilule: 28.69%

n=2593

After

- patch: 0.35%
- autres: 0.88%
- anneau vaginal: 1.42%
- implant contraceptif: 2.48%
- stérilet hormonal: 4.96%
- macroprogesterins: 9.32%
- stérilet: 3.95%
- aucun: 9.73%
- préservatifs: 18.94%
- microprogesterins: 14.81%
- pilule: 33.16%

n=1695
Essure procédure : anesthesia and technique

anesthesia

- Oui: 19%
- Non: 81%

Technique

<table>
<thead>
<tr>
<th>Technique</th>
<th>Count</th>
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<tbody>
<tr>
<td>Spéculum</td>
<td>638</td>
</tr>
<tr>
<td>Pozzi</td>
<td>114</td>
</tr>
<tr>
<td>Bettocchi</td>
<td>1912</td>
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</table>
SUCCESS II: 3 months control

- Included patients = 2575
  - procedure withdrawal after unilateral failure = 166
  - bilateral failures = 40

2369 patients scheduled for 3 months control

- Controls done = 90.7 % (2149/2369)

- Lost of follow-up despite multiple reminders 9.3% (220/2369)
SUCCESS II: Subjective effective sterilization

- Positive control tests = **97.7%** (2099/2149)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Simple procedures</th>
<th>Difficult procedures</th>
<th>OR</th>
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</thead>
<tbody>
<tr>
<td>Bilateral procedure</td>
<td>98.7% (1764/1787)</td>
<td>93.5% (259/277)</td>
<td>OR=0.27; IC=0.14-0.48; p&lt;0.0001</td>
</tr>
<tr>
<td>Unilateral procedure</td>
<td>93.5% (43/46)</td>
<td>83% (5/6)</td>
<td>OR=0.24; IC=0.07-0.82; p=0.02</td>
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</tbody>
</table>
5 years follow-up

- 1 patiente a eu un ménopause
- 5 patientes ont eu une hystérectomie

*Sessesses: 2 patientes ont déclaré une grossesse lors du suivi à un an, 1 à 2 ans

**Aucune infection de dispositif
Essure® permanent birth control effectiveness: a seven-year survey

- Questionnaire sent to the 1268 surgeon using ESSURE
- Interventions between January 2003 and December 2009
- Pregnancies between January 2003 and September 2010
- Answers by e-mail, or mail.
- 53,003 interventions between 2003 and 2010
- 287 answers from 206 institutions, representing 63.4% of the surgeons
- Results combined with the pregnancies reported to the laboratory

Results: 58 pregnancies

- One EUP
- 2 pregnancies happened before the 3-month control (non luteal pregnancies): interval pregnancies
  - of which, one with HSG bilateral tubal obstruction
  - one with an intra-abdominal device
- 36 pregnancies reported / 33,611 procedures
  - $1,07/1000$
- 58 pregnancies / nb of sold kits
  - $1,09/1000$
Tubal sterilization: pregnancy rates after hysteroscopic versus laparoscopic sterilization in France, 2006-2010

- Assessment of the efficiency of sterilization techniques based on PMSI data from 2006 to 2010
  - Efficiency assessed on the classic surgical technique by laparoscopy and by Essure® tubal sterilization
  - Efficiency criterion: **number of natural pregnancies post sterilization**

- Characterization of regret ratios after tubal sterilization based on PMSI data from 2006 to 2010
  - Number of pregnancies carried through to full term
  - Number of medically assisted reproductions (MAR)
  - Number of repermeabilizations
  - Number of pregnancies post repermeabilizations
  - Number of successful pregnancies after MAR

*Eur J Gynecol Reprod Biol. 2014 Sep;180:133-7*
Synthesis of regrets (MAR+RPT)

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<th>2008</th>
<th>2009</th>
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<td><strong>ESSURE</strong></td>
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<tr>
<td>&lt;1 an</td>
<td>1</td>
<td>2</td>
<td>0</td>
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<tr>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3</td>
<td>5</td>
<td>4</td>
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<td><strong>Ligature tubaire</strong></td>
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<tr>
<td>&gt;1 an</td>
<td>71</td>
<td>38</td>
<td>30</td>
<td>5</td>
<td>144</td>
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<tr>
<td>TOTAL</td>
<td>88</td>
<td>53</td>
<td>42</td>
<td>21</td>
<td>204</td>
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Ratio or MAR ESSURE : 0,8 ‰ versus 2,7‰ during the 4 years of observation.

Ratio of MAR in 2009 : 0,11% versus 0,23%, whereas ESSURE technique represents 49% of ligations.