Perineal trauma and the role of episiotomy

Jan Willem de Leeuw
Ikazia Ziekenhuis
Rotterdam, the Netherlands
Balance
Possible consequences??

[Graph showing data and bars for various countries indicating possible consequences per 100 vaginal births.]

20-6-2014
Levels of evidence

United States

Level I: Evidence obtained from at least one properly designed randomized controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
Levels of evidence

U.K

Level A: Consistent Randomised Controlled Clinical Trial, cohort study, all or none (see note below), clinical decision validated in different populations.

Level B: Consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, Case-control study; or extrapolations from level A studies.

Level C: Case-series study or extrapolations from level B studies.

Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

20-6-2014
RCT’s
Routine vs selective episiotomy: a RCT
Argentine Episiotomy Trial Collaborative Group
*Lancet* 1993; 342:1517-18

Effect of selective or routine mediolateral epi on SPT

<table>
<thead>
<tr>
<th></th>
<th>Selective</th>
<th>Routine</th>
<th>RR (95-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nulli’s</td>
<td>1.4%</td>
<td>1.8%</td>
<td>0.79 (0.36-1.72)</td>
</tr>
<tr>
<td>(n=1555)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primi’s</td>
<td>0.8%</td>
<td>0.9%</td>
<td>0.78 (0.21-2.90)</td>
</tr>
<tr>
<td>(n=1051)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1.2%</td>
<td>1.5%</td>
<td>0.78 (0.40-1.54)</td>
</tr>
</tbody>
</table>
Conclusions from this study

There is, then, no reliable evidence that routine use of episiotomy has any beneficial effect, and there is clear evidence that it may cause harm.

On the basis of the current available evidence, a policy of routine episiotomy should be abandoned and rates above the 30% found in the selective group of our study cannot be justified.
A RCT of routine versus restrictive use of episiotomy at operative vaginal delivery: a multicentre pilot study
Murphy et al, BJOG 2008;115:1695–1703

<table>
<thead>
<tr>
<th>Mode of Delivery</th>
<th>Routine (n= 99)</th>
<th>Selective (n= 101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum</td>
<td>24.2</td>
<td>22.8</td>
</tr>
<tr>
<td>Forceps (non-rotational)</td>
<td>54.6</td>
<td>61.4</td>
</tr>
<tr>
<td>Forceps (rotational)</td>
<td>7.1</td>
<td>5.0</td>
</tr>
<tr>
<td>Spont. vag. delivery</td>
<td>9.1</td>
<td>4.0</td>
</tr>
<tr>
<td>Caesarean section</td>
<td>5.1</td>
<td>6.9</td>
</tr>
<tr>
<td><strong>Episiotomy rate</strong></td>
<td><strong>???</strong></td>
<td><strong>???</strong></td>
</tr>
</tbody>
</table>
A RCT of routine versus restrictive use of episiotomy at operative vaginal delivery: a multicentre pilot study
Murphy et al, BJOG 2008;115:1695–1703

Results

<table>
<thead>
<tr>
<th></th>
<th>Routine</th>
<th>Restrictive</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphincter lesions</td>
<td>8.1%</td>
<td>10.9%</td>
<td>0.72 (0.28–1.87)</td>
</tr>
</tbody>
</table>

Power calculation:

“We estimated that there would be approximately 720 operative vaginal deliveries over a 1-year period for both hospitals, and we aimed to recruit 200 women (28%).

A previous retrospective cohort study from the Scottish unit suggested a 7.5% rate of third-degree tears with operative vaginal delivery using episiotomy and 2.5% where episiotomy was avoided.”
 Aren’t we looking for the Holy Grail?
Operative vaginal delivery and episiotomy

Which type?
With or without episiotomy?
What moment during the procedure?
In which specific patient??
### Analysis 1.8. Comparison 1 Any type of forceps versus any types of ventouse, Outcome 8 Third- or fourth-degree perineal tear (with or without episiotomy).

Review: Choice of instruments for assisted vaginal delivery

Comparison: Any type of forceps versus any types of ventouse

Outcome: Third- or fourth-degree perineal tear (with or without episiotomy)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>forceps n/N</th>
<th>ventouse n/N</th>
<th>Risk Ratio (IVFixed 95% CI)</th>
<th>Weight</th>
<th>Risk Ratio (IVFixed 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bofill 1996a</td>
<td>90/315</td>
<td>38/322</td>
<td></td>
<td>42.0%</td>
<td>2.42 [1.71, 3.42]</td>
</tr>
<tr>
<td>Dell 1985</td>
<td>10/45</td>
<td>18/73</td>
<td></td>
<td>10.9%</td>
<td>0.90 [0.46, 1.78]</td>
</tr>
<tr>
<td>Fitzpatrick 2003</td>
<td>10/61</td>
<td>5/69</td>
<td></td>
<td>4.9%</td>
<td>2.26 [0.82, 6.25]</td>
</tr>
<tr>
<td>Johanson 1989</td>
<td>16/132</td>
<td>6/132</td>
<td></td>
<td>6.1%</td>
<td>2.67 [1.08, 6.60]</td>
</tr>
<tr>
<td>Johanson 1993</td>
<td>25/311</td>
<td>15/296</td>
<td></td>
<td>13.1%</td>
<td>1.59 [0.85, 2.95]</td>
</tr>
<tr>
<td>Maleckiene 1996</td>
<td>4/71</td>
<td>1/91</td>
<td></td>
<td>1.1%</td>
<td>5.13 [0.59, 44.87]</td>
</tr>
<tr>
<td>Mustafa 2002</td>
<td>1/20</td>
<td>0/27</td>
<td></td>
<td>0.5%</td>
<td>4.00 [0.17, 93.36]</td>
</tr>
<tr>
<td>Vacca 1983</td>
<td>24/152</td>
<td>9/152</td>
<td></td>
<td>9.4%</td>
<td>2.67 [1.28, 5.55]</td>
</tr>
<tr>
<td>Weerasereka 2002</td>
<td>4/238</td>
<td>2/204</td>
<td></td>
<td>1.8%</td>
<td>1.71 [0.32, 9.26]</td>
</tr>
<tr>
<td>Williams 1991</td>
<td>12/51</td>
<td>12/48</td>
<td></td>
<td>10.4%</td>
<td>0.94 [0.47, 1.89]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>1396</strong></td>
<td><strong>1414</strong></td>
<td></td>
<td><strong>100.0%</strong></td>
<td><strong>1.89 [1.51, 2.37]</strong></td>
</tr>
</tbody>
</table>

Total events: 1% (forceps), 106 (ventouse)

Heterogeneity: Chi² = 13.28, df = 9 (P = 0.15); I² = 32%

Test for overall effect: Z = 5.59 (P < 0.00001)
Sphincter lesions
Vacuum vs. Forceps: Observational studies

Handa et al, AJOG 2001, USA, > 2.000.000 women, 1992-1997

Figure 2. Odds ratio (and 95% confidence interval) of sphincter laceration for forceps delivery and vacuum delivery, 1992–1997.

### Sphincterlesions

**Vacuum vs. Forceps: Observational studies**


<table>
<thead>
<tr>
<th></th>
<th>Adj-OR (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nulli’s</strong></td>
<td></td>
</tr>
<tr>
<td>Vacuüm:</td>
<td>3.1 (1.9-4.3)</td>
</tr>
<tr>
<td>Forceps:</td>
<td>8.6 (6.5-10.7)</td>
</tr>
<tr>
<td><strong>Multi’s</strong></td>
<td></td>
</tr>
<tr>
<td>Vacuüm:</td>
<td>1.2 (0.1-2.3)</td>
</tr>
<tr>
<td>Forceps:</td>
<td>26.3 (18.1-34.5)</td>
</tr>
</tbody>
</table>
### Sphincter lesions

**Vacuum vs. Forceps: Observational studies**

Bagesthan et al O&G 2010, Norway, 1.673.442 women, 1967-2004

<table>
<thead>
<tr>
<th>Method</th>
<th>Spincter lesions (%)</th>
<th>Adj-OR (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forceps</td>
<td>8.1</td>
<td>3.9 (3.7 – 4.0)</td>
</tr>
<tr>
<td>Vacuum</td>
<td>6.0</td>
<td>2.0 (1.9 – 2.1)</td>
</tr>
<tr>
<td>Both</td>
<td>10.3</td>
<td>3.9 (3.5 – 4.3)</td>
</tr>
<tr>
<td>Noninstrumental</td>
<td>1.4</td>
<td>reference group</td>
</tr>
</tbody>
</table>
Sphincter lesions
Vacuum vs. Forceps: Observational studies


<table>
<thead>
<tr>
<th>Spincter lesions (%)</th>
<th>Adj-OR (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forceps</td>
<td>4.7</td>
</tr>
<tr>
<td>Vacuum</td>
<td>3.0</td>
</tr>
<tr>
<td>Both</td>
<td>7.8</td>
</tr>
</tbody>
</table>

Women with SVD 1.7 reference group
In Summary

Eason et al, Obstet and Gynecol 2000 (Sys review):
......”One anal sphincter tear would be avoided for every 18 women whose delivery was assisted by vacuum rather forceps”...

Searching the literature:

Forceps less risk than vacuum: 1 study
Equal risk of forceps and vacuum: 5 studies
Forceps larger risk than vacuum: 35 studies
The Northern-American continent
Episiotomy in instrumental delivery: Forceps

Type of episiotomy: probably midline
Rate: 94.2%

Sfinccter lesions

Epi +: 20.6 %
Epi -: 12.7 %

Adj.-OR: ???
Episiotomy in instrumental delivery: Vacuum

Type of episiotomy: probably midline
Rate: 84.7%

Sfincter lesions
Epi +: 17.0 %
Epi -: 5.9 %
Adj.-OR: ???
Episiotomy in instrumental delivery: Vacuum and Forceps

Type of episiotomy: probably midline

Nulliparous
OR: 4.5 (95%-CI: 3.7 – 5.4)

Multiparous
OR: 14.6 (95%-CI: 10.4)

20-6-2014
Europe (?)
Episiotomy in instrumental delivery: Forceps

Type of episiotomy: probably mediolateral
Rate: 95.7%

Sfincter lesions

Epi +: 9.1 %
Epi -: 4.7 %

Adj.-OR: 1.88 (0.58 – 6.11)
Episiotomy in instrumental delivery: Vacuum

Type of episiotomy: propably mediolateral
Rate: 71.3%

Sfincter lesions

Epi +: 2.3 %
Epi -: 1.7 %

Adj.-OR: 1.93 (0.50 – 7.42)
Episiotomy in instrumental delivery:

Bagesthan et al O&G 2010, Norway, 1.673.442 women, 1967-2004

Nulli’s:
Episiotomy protected for OASIS: OR: 0,8 (95% CI: 0,76 – 0,9)

Multi’s:
No protection for OASIS in multi’s with episiotomy:
OR: 0,8 (95% CI: 0,6 – 1,1)
Episiotomy in instrumental delivery: Vacuum

De Leeuw et al, BJOG 2008, Holland, 21.254 vacuum deliveries
7.478 forceps deliveries

78,9% mediolateral episiotomies

<table>
<thead>
<tr>
<th>Sphincter lesions</th>
<th>Adj.-OR (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epi +: 1,36%</td>
<td>0,11 (0,09 – 0,13)</td>
</tr>
<tr>
<td>Epi -: 9,40%</td>
<td></td>
</tr>
</tbody>
</table>

NNT: 12 mediolateral episiotomies to prevent 1 sphincter lesion
Episiotomy in instrumental delivery: Forceps

De Leeuw et al, BJOG 2008, Holland, 21,254 vacuum deliveries 7,478 forceps deliveries

89,0% mediolateral episiotomies

<table>
<thead>
<tr>
<th></th>
<th>Sphincter lesions</th>
<th>Adj.-OR (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epi +:</td>
<td>2,60%</td>
<td>0,08 (0,07 – 0,13)</td>
</tr>
<tr>
<td>Epi - :</td>
<td>22,73%</td>
<td></td>
</tr>
</tbody>
</table>

NNT: 5 mediolateral episiotomies to prevent 1 sphincter lesion
Episiotomy in instrumental delivery

When during the procedure?

Before or after applying forceps blades or vacuum-cup?

Nobody knows the definitive answer

But everyone is an expert!
Possibilities for the future?

Online database: estimates of risks

Nulliparous woman, occipitoposterior presentation, Estimated fetal weight $\geq 4000$ grams $\rightarrow$ Vacuum?

Sphincter lesion

Epi - 21.4%
Epi + 2.6%
Possibilities for the future?

Online database: estimates of risks

Multiparous woman, occipito-anterior presentation, Estimated fetal weight $\geq$ 3500 grams $\rightarrow$ Vacuum?

- Sphincter lesion
  - Epi - 6,5%
  - Epi + 1,2%
Conclusions

Large differences between continents and countries
Be careful with extrapolation of the results of RCT’s on episiotomies
Forceps or vacuum? → Vacuum!
Midline episiotomy in instrumental delivery: No!
Mediolateral episiotomy in instrumental delivery:

Think twice if you think that your patient is better of without it!