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Effect of vaginal delivery on external anal sphincter muscle innervation pattern evaluated with multichannel surface EMG (Results of the multicenter study TASI-2)

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ABSTRACT

Introduction. A correlation exists between external anal sphincter (EAS) damage during birth and subsequent development of fecal incontinence. This study evaluated the effect of delivery-related trauma on the EAS innervation by means of intra anal EMG performed with a rectal probe with 16 silver electrodes equally spaced along the circumference, before and after delivery.

Methods. Pre-partum EMG measurements were performed on 511 women, by nine clinical partners from five European Countries at the 28th - 34th gestational week and 6-8 post-delivery week; 331 women returned, after delivery, for the second test. The innervation zones (IZ) of EAS single motor units were identified by means of an EMG decomposition algorithm.

Results. The subjects were divided in four groups according to the delivery mode (Caesarean, vaginal with no evident damage, spontaneous lacerations and episiotomies). The numbers of IZs were compared before and after delivery. In the 82 women who underwent right mediolateral episiotomy, a statistically significant reduction of IZs was observed, after delivery, in the right ventral quadrant of the EAS, (side of episiotomy), while women who had Caesarean section, spontaneous lacerations or no evident damage did not present any significant change in the innervation pattern.

Conclusions. Right episiotomy reduces the number of IZs on the right-ventral side of the EAS. The fast and reliable test proposed indicates the sphincter innervation pattern before delivery and helps obstetricians to evaluate the risks and to choose the preferable side if episiotomy, if deemed necessary at the time of delivery.

INTRODUCTION

Childbirth is one of the major risk factors for anal incontinence in women (Sultan et al., 1993). Anal sphincter tears and perineal trauma occur in 2–19% of vaginal deliveries (Fenner et al., 2003). According to Andrews and collaborators (2006), misclassification of perineal trauma, occurred in 87% of midwives, 28% of all junior doctors, 14% of specialists, and only 1% of those specially trained to identify sphincter injuries. Originally, medio-lateral episiotomy was thought to minimize pressure on the foetal head, and shorten the second stage of labour. Episiotomy is usually performed with scissors or scalpel on the right side of the vaginal wall since the operators are mostly right handed (Thacker et al., 1983). However, these statements have been debated and examined by Woolley (Woolley 1995) who rejected the use of episiotomy in his systematic review.

A medio-lateral episiotomy is easier to repair than spontaneous tears but implies greater bleeding and more perineal discomfort during healing (Sartore, 2004). Episiotomy is often used in association with instrumental-assisted deliveries, breech deliveries, and shoulder dystocia. When compared with a spontaneous tear, episiotomy may allow more accurate tissue apposition during primary repair with potential benefits in wound healing. Episiotomy rates in Europe range from 9% in Sweeden to 58% in Italy (Graham et al., 2005). Several previous studies have demonstrated that midline episiotomy is an independent risk factor for sphincter injuries (Andrews et al. 2006; Handa et al., 2012; Dudding et al., 2008; Edwards et al., 2001; Fitzgerald 2007; Kudish et al., 2006; McKinnie et al., 2005; Pirro et al., 2007; Pretlove et al., 2008). Nevertheless, the effect of medio-lateral episiotomy is controversial, since some studies showed it to be an independent risk factor (Sartore et al., 2004, Wheeler et al., 2007), whereas others found it to be protective for faecal incontinence in primiparous women (deLeeuw et al., 2001). A medio-lateral episiotomy should be at least 40 degrees from the midline to avoid anal sphincter injuries (Tincello et al., 2003). No midwife and only 22% of doctors perform truly medio-lateral episiotomies (Andrews et al., 2006).

No indications are provided regarding which side should be preferred, if any, for episiotomy, thus, episiotomies are usually performed on the right side.

Quantitative needle electromyography (EMG) has been used in a limited number of studies (Podnar et al., 2000, Gregory et al., 2008) because of the large variability of the results and of the pain due to this invasive procedure. A recent study showed that postpartum women affected by faecal incontinence show evidence of denervation/reinnervation of the EAS, when compared with asymptomatic women after a first vaginal delivery (Gregory et al. 2008).

The risk of pudendal nerve damage during physiological delivery or obstetric trauma has been largely discussed in literature but there is no general indication regarding the optimal location/orientation of episiotomy because of the large inter-individual variability of EAS innervation (Merletti et al., 2004, Enck et al., 2004).

Multichannel EMG is the summation of electrical contributions from individual motor units (MU) detected with minimally invasive electrode arrays. Recent signal processing techniques provide tools to identify the location of the innervation zone (IZ) of individual motor units (Cescon, 2006, Ullah et al. 2014). The IZ is the region where the axonal terminal branches connect to muscle fibers through the neuromuscular junctions (NMJ). The muscle fiber action potentials start at the NMJ, propagate along each fiber and extinguish at its ends,

The objective of this study was to evaluate the effect of episiotomy on the sphincter innervation, using intra-anal, minimally invasive EMG. Knowlwdge of the location of the IZs of the anal sphincter will guide episiotomy, reduce the likelihood of creating asymmetries and, possibly, lead to a reduction of the consequences of this surgery (Wietek 2007).

METHODS

Subjects

Five hundred eleven primiparous women participated in the study. Nine clinical partners from five European Countries (Germany, Italy, Latvia, Slovenia, Ukraine) were involved in the study. Each clinical partner obtained the approval from the local ethical committee. The inclusion criteria were: nulliparous woman, cephalic presentation, no episodes of anal incontinence before pregnancy, no previous pelvic operations, no presence of neuropathies affecting pelvic innervation, no planned Caesarean section, no 3rd degree haemorrhoids. Each subject was informed about the study protocol and signed an informed consent form prior to the tests.

Questionnaires describing the clinical situation before, during and after delivery were collected by questioning the subjects and analyzing medical records regarding the delivery.

Experimental design

Due to the total lack of data from the literature the sample size of the study was arbitrarily set as rather large. Five hundred eleven women were recruited from obstetrical practices but only 331 returned for the second measurement after the delivery. The study was conducted in double blind, meaning that the clinical partners did not receive any information regarding the IZs of the patients and the signal analysis was performed without having information regarding the type of delivery. Two measurement sessions were performed for each subject: the first during pregnancy at the 28th – 34th week of gestation and the second at the 6–8 weeks after the delivery (end of puerperium). The dates were chosen according to pre planned hospital visits of the subjects in order to facilitate the recruitment and reduce the patient drop-out.

EMG signal detection and acquisition system

Signals were detected using the probe shown in Figure 1a. The probe is a plastic cylinder of 14 mm diameter holding a printed circuit with 16 electrodes equally spaced along the circumference (Cescon and Merletti, 2010). The reference for electrode 1 and the depth for the anal insertion are marked on the probe. During the EMG measurements each subject was laying on her back in a gynaecologic chair with legs in stirrups while a trained doctor or midwife was holding the EMG probe in place. The probe was inserted for 15-20 mm in the anal canal in order to have the electrode array in correspondence of the anal verge. The orientation of the electrodes was always the same, with the midline between the first and the 16th electrode in ventral position (Figure 1c).

Each experimental session consisted of a series of EMG measurements performed as follows.

The tip of the probe was lubricated with a drop of glycerol and inserted in the anal canal. The use of lubricants is highly critical because oily insulating lubricants prevent electrode contact with the mucosa and soapy conductive lubricants or gels short circuit the electrodes.. After two minutes, when the electrode-mucosa contacts were stabilized, three acquisitions of 10 seconds were performed without the subject contracting the sphincter (Rest), with two minutes in between, to test possible trends of muscle activity. The subjects were then asked to perform three maximal voluntary contractions (MVC) for 10s each of the EAS with two minutes pause in between. Six recordings were performed for each experimental session (three Rest and three MVC).

The MVCs were preceded (and followed) by a progressive increase (and decrease) of force for about 5s in order to avoid movement artefacts due to sudden force changes.

The measurement protocol did not present difficulties and lasted approximately 10-12 minutes with 5-10 additional minutes for paper work, instructions and positioning of the patient in the gynaecologic chair.

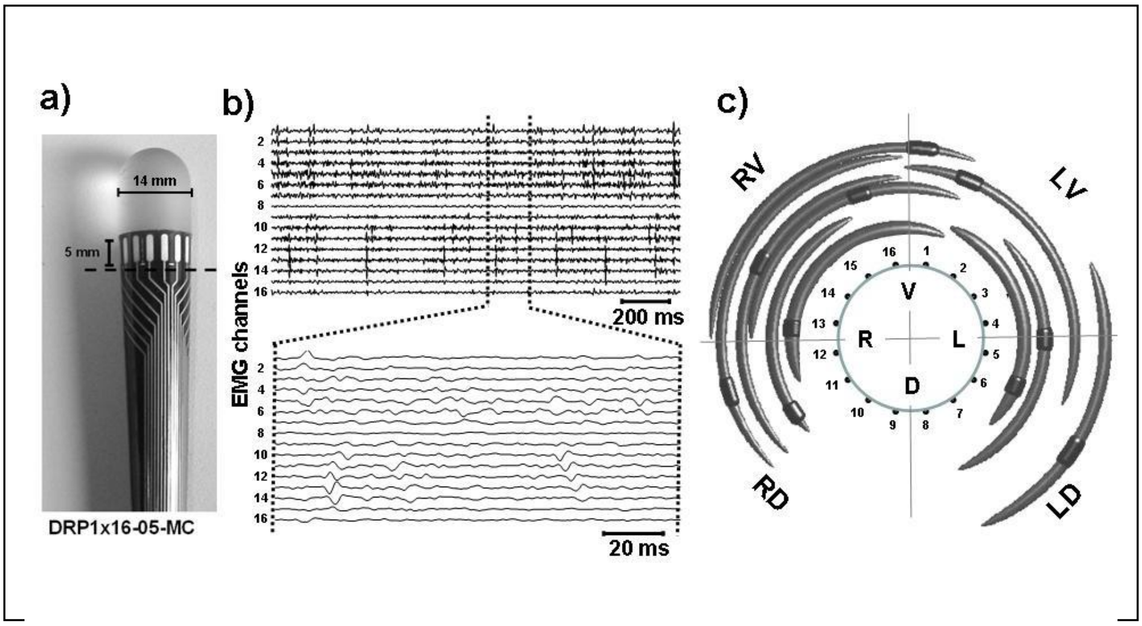

Figure 1. *a) picture of the disposable rectal probe. The probe is a plastic cylinder of 14 mm diameter holding a thin printed circuit with 16 equally spaced electrodes. b) example of sEMG signals detected from the external anal sphincter of a subject during rest. Action potentials of motor units with different innervation zones are evident. c) representation of the motor units, identified by the decomposition algorithm, and their innervation zones (dark spots) in the external anal sphincter. The distance of the motor units from the surface of the probe is different for each motor unit for graphical reasons and has no anatomical meaning.*

The 16 surface EMG signals were acquired in single differential derivation (Figure 1b) with an EMG-USB amplifier (LISiN and OT-Bioelettronica, Torino, Italy, with gain variable from 100 to 10,000 in seven steps, 10Hz to 500Hz 3dB bandwidth, roll-off of 40dB/decade, noise level lower than 1μV_{RMS}), sampled at 2048 Hz, and stored on a PC after 12bit A/D conversion. Slow signals produced by active smooth muscles (if any) were rejected because of the high pass filter at 10 Hz.

Signal Processing

Single MUAPs were identified, from the interferential surface EMG signals, by a decomposition method based on the Convolution Kernel Compensation (Holobar et al., 2007, Holobar et al. 2008). The main limitation of the decomposition algorithm and of surface EMG is that the number of active and visible MUs is a fraction of the total number of active MUs. This method has been previously applied to EMG signals from EAS muscle and was proven to be robust to noise, allowing the identification of up to 10 concurrently active MUs (Holobar et al., 2008). The IZCorr2 algorithm (Cescon, 2006; Ullah et al., 2014) was applied to the MU templates to identify the innervation zone of each MU (Figure 1c). The method cannot be expected to identify the same MUs in different tests (different MUs may be activated in different contractions), however it provides the location of the IZs of 5-15 of the currently active MUs that are most superficial and have the largest action potentials.

Statistical analysis

A generalized mixed linear model is used to test for important effects and to obtain relevant 95% confidence intervals. The model is a generalization of standard linear models - such as ANOVA - which allows for patient random effects and non-normally distributed count responses, in our case the IZ number, which is modelled as having Poisson distribution (Zuur et al. 2009). The Poisson distribution expresses the probability of a number of events occurring in a fixed interval of time and/or space. In our case the expected number of IZs is equal in each of the four quadrants (Enk 2004).

RESULTS

Five hundred eleven women were recruited from obstetrical practices. Only 331 returned for the second measurement after the delivery. The percentage of drop-out patients was 35%.

The subjects who returned had no 4th degree lacerations and in none of them forceps or vacuum extraction had been used. The signals were visually inspected and classified in five different classes according to the overall signal quality. The quality was assessed on the basis of the absence of: a) artefacts due to contact problems and movement of the probe, b) power line interference, c) short circuits between electrodes, d) saturation of the EMG channels, and e) noise level. Contact problems and electrode short circuits where likely due to insufficient or eccessive lubricant. Signals were classified as:

Q1: Very bad quality, artefacts, interference or noise present in more than eight channels,

Q2: Bad quality, problems present in four to eight channels,

Q3: Sufficient quality, problems present in two or three channels,

Q4: Good quality, problems present in one channel,

Q5: Very good quality, no contact problems, artefact, interference or noise.

The patients with signals of quality Q1 and Q2 (bad signals) in any of the two measurement sessions were discarded from the analysis, and thus the final number of women included in the following analysis was 249 out of 331. The channels with signals of quality Q3 and Q4 were reconstructed interpolating the adjacent good channels.

Subject Grouping

The 249 women with signal quality Q3-Q4-Q5 were divided in groups according to the type of delivery (vaginal or with Caesarean section, n = 189 and 60 respectively) and in case of vaginal delivery they were divided in: intact perineum n=32, spontaneous perineal tears (lacerations n=75) and mediolateral right episiotomy (n= 82).

Table 1 shows the distribution of ages, weight of the subjects, and global parameters of the infant, according to the delivery type. No statistically significant difference was observed for the subject weight and infant weight parameters between the four groups of subjects (1-way ANOVA). A significant difference was observed in subject age (1-way ANOVA, $F = 6.09$; $p<0.01$), with older patients receiving C-section or episiotomy with respect to younger subjects with spontaneous lacerations or no damage.

Figure 2 shows an example of distribution of innervation zones for a subject who had a vaginal delivery with episiotomy of more than 4 cm on the right at approximately 30°-40°. The MU in the right side of the sphincter can no longer be detected after delivery, suggesting neural or muscular damage on the right side.

Figure 3 shows the individual counts of the number of IZs in each EAS quadrant before and after delivery. The subjects of each of the four groups (columns) are sorted according to the variation of IZ number before and after delivery and listed along the X axis. Thus, on the left side are the women with observed larger decrease of detected IZs (dark lines) while on the right side of each panel are the women with larger increase of detected IZs after delivery (light grey lines). In the middle portion of each panel are the women who did not change the number of IZs after delivery. Small variations in the number of detected IZs may be due to random factors, either physiological or technical. In the panel corresponding to the episiotomy group (RV quadrant, bottom right), the number of women who presented a decrease of the number of IZs after delivery (dark grey) is predominant compared to the other panels. The same women showed an asymmetric distribution of EMG amplitude along the circular array

Figure 4 shows the confidence intervals for the change in the number of innervation zones in the four EAS quadrants and in the two groups of patients of interest (Caesarean section as control group and Episiotomy as cases). The numerical values are reported in table 2.

Table 1. Distribution of age, weight of the mothers, and global parameters of the infant, according to the delivery type, in the 249 subjects. The data regarding Spontaneous Lacerations and Episiotomy are further divided according to the severity of the degree of laceration and of the length of episiotomy respectively. Mean and standard deviation are indicated. **CS** = Caesarean Section. **ND** = Delivery with no damage. **Lac** = Spontaneous lacerations. **Epi** = Episiotomies. **Kristel** = Kristeller manourve. **Induct** = Delivery induction. **Anesth** = local anesthesia. **Oxyt** = Stimulation with oxytocin.

	N	**% of total**	**Age (years)**	**Weight before (kg)**	**Weight after (kg)**	**Infant weight (kg)**	**Week of pregn.**	**Head circumf. (cm)**	**Infant Length (cm)**	**Kristel. (%)**	**Induct. (%)**	**Anesth. (%)**	**Oxyt. (%)**
CS	**60**	**24**	**33±7**	**71±6**	**65±6**	**3.4±0.6**	**31±1**	**34±1**	**49±2**	**-**	**6%**	**-**	**6%**
ND	**32**	**13**	**29±5**	**69±7**	**62±8**	**3.3±0.4**	**32±2**	**33±2**	**49±2**	**8%**	**34%**	**24%**	**45%**
LacI	49	20	29±5	64±7	62±6	3.3±0.5	32±2	31±2	49±2	8%	32%	22%	44%
LacII	22	9	31±5	73±2	66±4	3.4±0.8	31±1	33±1	49±1	7%	34%	24%	45%
LacIII	4	2	22±3	65±4	61±2	3.4±0.4	33±1	33±2	50±1	75%	50%	75%	75%
Lac	**75**	**30**	**30±10**	**71±8**	**63±6**	**3.4±0.3**	**32±2**	**33±2**	**50±2**	**15%**	**22%**	**30%**	**52%**
Epi 2cm	21	8	32±3	65±4	61±2	3.4±0.4	33±1	34±2	50±1	35%	23%	31%	4%
Epi 3cm	43	17	35±3	74±4	64±2	3.2±0.4	32±1	32±2	49±1	72%	21%	31%	16%
Epi 4cm	16	6	29±5	74±7	64±6	3.3±0.5	32±2	34±2	49±2	8%	32%	42%	14%
Epi >4cm	3	1	29±5	69±2	61±4	3.2±0.8	34±1	33±1	49±1	7%	34%	24%	0%
Epi	**83**	**33**	**32±8**	**70±4**	**64±6**	**3.4±0.5**	**33±1**	**34±2**	**50±1**	**42%**	**29%**	**34%**	**14%**

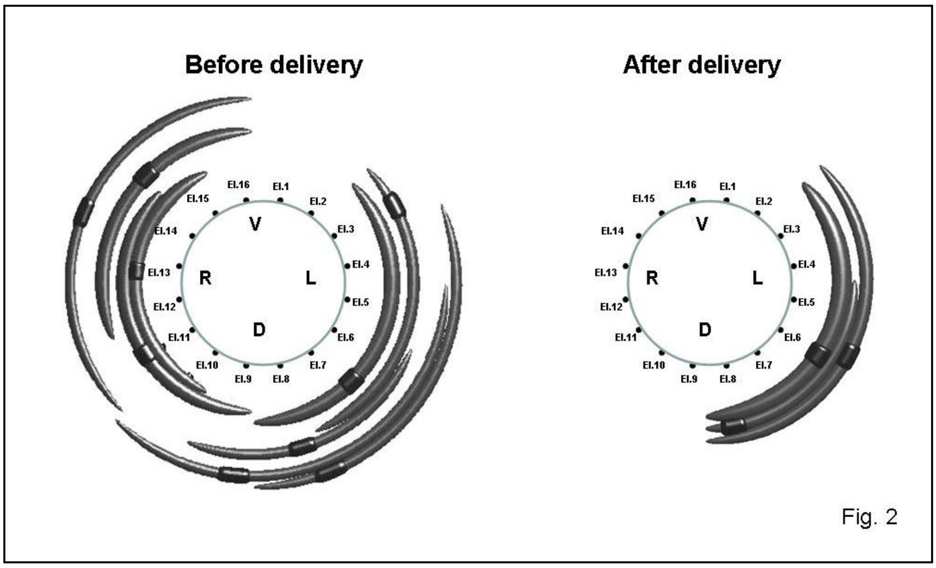

Figure 2. *Example of motor units and their innervation zones for a subject who had vaginal delivery with episiotomy of more than 4 cm on the right side at approximately 30°-40°.*

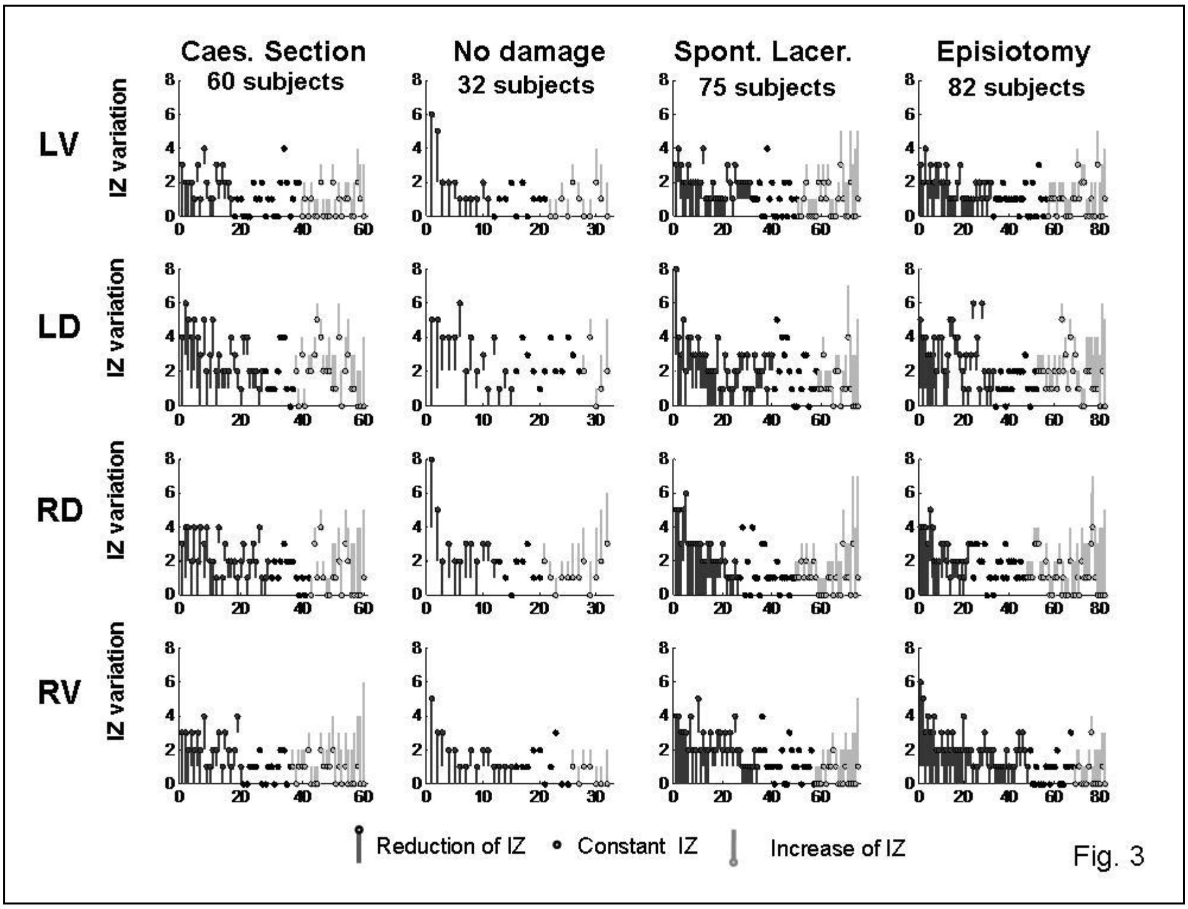

Figure 3. Individual counts of number of innervation zones before and after delivery: light grey lines indicate that the number of IZs increased after delivery, dark grey lines indicate a decrease of the number of IZs. The black dot represents the number of IZs detected before delivery while the

other extremity of each line represents the number of IZs detected after delivery. If the number of IZ did not change only a dot is represented.

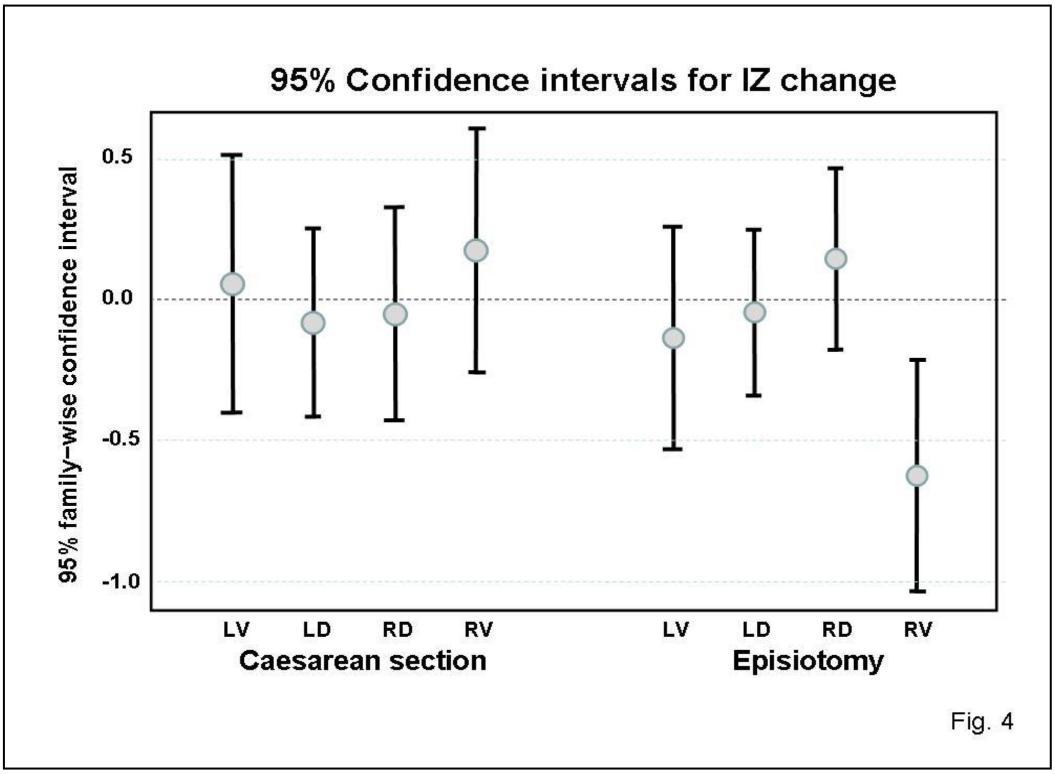

Figure 4: *95% confidence intervals of the change of innervation zones of the subjects grouped according to the factors: type of delivery (Caesarean section: CS, Episiotomy: Epi) and quadrant (LV, LD, RD, RV). The only confidence interval which does not include the zero is relative to the right ventral quadrant of women who had episiotomy.*

Table 2. Estimates of the difference (pre-post) in the number of innervation zones in the four quadrants for two groups of subjects (Caesarean section, Episiotomy). Estimates and their 95% confidence intervals, in brackets, are reported. The only significant difference is for the ventral right side of the women who had episiotomy.

quadrant / **delivery type**	**Left Ventral LV**	**Left Dorsal LD**	**Right Dorsal RD**	**Right Ventral RV**
Caesar. Section Mean [95%CI]	0.05 [-0.40 0.51]	-0.08 [-0.41 0.25]	-0.04 [-0.42 0.32]	0.17 [-0.25 0.60]
Episiotomy Mean [95%CI]	-0.13 [-0.53 0.26]	-0.04 [-0.34 0.24]	0.14 [-0.17 0.46]	-0.62 [-1.03 -0.21]

DISCUSSION

Limitations and weaknesses of the study.

The first limitation in the analysis of the database is the very high drop-off for the second measurement (post partum). This phenomenon might be attributed to many reasons, including the limited availability of the subjects due to maternal duties. However, we were able to collect delivery data of 73 of the 180 women who did not return for the second measurements. The distribution of delivery types for those women was 39% Caesarean section, 25% episiotomies, 21% spontaneous lacerations and 13% with no evident damage, indicating that there was a higher proportion of Caesarean section and a lower proportion of lacerations and episiotomies in the non-returning population. Despite the difference with the percentages of Table 1, it is reasonable to assume that the lack of data due to the non-returning women did not affect the results.

A second limitation of the study is the relatively high number of low quality signals which is likely due to lack of experience of the operators in using the lubricant, as well as to the limited time devoted to performing the tests.

The innervation of the sphincter is only a proxy for anal incontinence (the final clinical endpoint) which has not been assessed in this study. The proxy is valid if there is a causal connection between innervation and incontinence. This connection is suggested in the literature (Wietek et al., 2007; Oberwalder et al., 2004).

Strengths of the study.

This is the first study investigating innervation of the EAS pre- and post-partum. Although the focus was on episiotomy, a number of additional findings are now available. Some of these findings whwew prwdictable but have never been documented by an electrophysiological analysis of the EAS.

Caesarean section did not modify the number of innervation zones in any quadrant in a statistically significant way. The same results can be observed for the vaginal delivery with no evident perineal damage and for the spontaneous laceration group.

Although the obvious conclusion would be that episiotomy should be avoided in order to preserve EAS innervations, clinicians have to take into account the other risk factors related to Caesarean section and the benefits of episiotomy during vaginal delivery.

A Cochrane review to determine the possible benefits and risks of the use of restrictive episiotomy versus routine episiotomy during delivery (Carroli et al., 1999) found that the restrictive use of episiotomy shows a lower risk of clinically relevant morbidities including severe perineal trauma.

In addition, the guidelines from the Royal College of Obstetricians and Gynaecologists (RCOG) and from the British National Institute for Health and Clinical Excellence (NICE) indicate that routine episiotomy should not be carried out during spontaneous vaginal birth, and that it should be performed only if there is a clinical need such as instrumental birth or suspected fetal compromise.

In our studies all the episiotomies were performed because of suspect fetal compromise or threat of severe perineal tears, and no routine episiotomy was performed. In this case we cannot predict the degree of spontaneous lacerations that would have occurred if episiotomy had not been performed, but according to the literature (Carroli et al., 1999) the lacerations would have likely been of III or IV degree.

In our group of subjects the spontaneous lacerations are mostly of I or II degree and none is of IV degree. These lacerations do not significantly affect the innervation of the EAS muscle. In addition occult laceration or sphincter injuries could have occurred also in the group of vaginal delivery without evident damage. For this reason the cases considered in the final analysis were only episiotomies (as cases) and Caesaren sections (as controls).

This study does not provide guidelines about the type of delivery that should be preferred. This has to be decided by the gynecologists giving consideration to many factors. The conclusion of this work is that episiotomy causes a loss of innervation on the side where it is performed. The operator should then choose the side which is less innervated in order to reduce possible damage due to the loss of innervation.

Unanswered questions and future research.

Follow-up studies are necessary to evaluate the possible reinnervation of the EAS and to observe if anal incontinence will occur more likely in patient who had severe loss of innervation of this muscle. Episotomy is usually performed at the right side because the operators are right handed. The finding that a left mediolateral episiotomy is preferable when the dominant innervation is in the right side implies the development or adaptation of surgical instrumentation to perform left episiotomy with the right hand.

Possible mechanisms and implications for clinicians or policymakers.

Reducing the consequences of episiotomy by minimizing EAS innervation damage would have an obvious impact on the quality of life of middle aged and elderly women as well as on the cost of health care. This would be important in the countries where episiotomy is a relatively common practice. The technique is easy to learn and simple to apply. The development of a friendly user-interface will facilitate its use and clinical acceptability.

CONCLUSION

A rigorous statistical analysis (Generalized mixed linear model) was applied to evaluate interaction between factors such as EAS quadrant, type of delivery and time (before and after delivery) for the count variable “IZ number”. The results of the analysis showed that there is a statistically significant decrease of the number of innervation zones (mean=0.62, 95%CI [-1.03:-0.21]) in the right ventral quadrant of the EAS in women who had mediolateral right episiotomy. Statistically significant changes of the number of innervation zones were not observed in the cases of Caesarean sections or vaginal delivery with spontaneous lacerations.

Knowledge of the pre-partum distribution of IZs allows gynaecologists and obstetricians to evaluate the risk of episiotomy and to choose the side where to perform it in case it would be deemed necessary at the time of delivery. This knowledge, which can be obtained with a disposable probe and a minimally invasive surface EMG pre-partum test, is expected to reduce the consequences of episiotomy.

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