TESIS DOCTORAL
POR COMPENDIO DE PUBLICACIONES

UNIVERSIDAD DE LEON

REPERCUSION DE LAS CARACTERISITICAS DE LA EPISIOTOMIA EN LOS DESGARROS OBSTETRICOS DEL ESFINTER ANAL EN LOS PARTOS INSTRUMENTALES

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Agradecimientos

A mi Padre.

No te quedes inmóvil
al borde del camino
no congeles el júbilo
no quieras con desgana
no te salves ahora
ni nunca
no te salves

M. Benedetti

INDICE DEL CONTENIDO

A. TESIS COMO COMPENDIO DE TRABAJOS PREVIAMENTE PUBLICADOS

La presente tesis doctoral, de acuerdo con el informe correspondiente, autorizado por los Directores de Tesis y el Órgano Responsable del Programa de Doctorado, se presenta como un compendio de tres trabajos previamente publicados. Las referencias completas de los artículos que constituyen el cuerpo de la tesis son los siguientes:

I. González-Díaz, E., Fernández Fernández, C., Fernández Galguera, M.J., Fernández Corona A. Behavior of perineum during delivery before fetal head expulsion. Int Urogynecol J (2017) 28: 375-380. https://doi.org/10.1007/s00192-016-3166-6

II. Gonzalez-Díaz E, Fernández Fernández C, Gonzalo Orden JM, Fernández Corona A. Which characteristics of the episiotomy and perineum are associated with a lower risk of obstetric anal sphincter injury in instrumental deliveries. Eur J Obstet Gynecol Reprod Biol. 2019 Feb;233:127-133. https://doi.org/10.1016/j.ejogrb.2018.12.019

III. Gonzalez-Díaz E, Fernández Fernández C, Gonzalo Orden JM, Fernández Corona A. Incidence of obstetric anal sphincter injuries after implementing the Triepi-45 tool to improve episiotomy angle in instrumental deliveries. Int J Gynaecol Obstet. 2020 Feb;148(2):231-237. https://doi.org/10.1002/ijgo.13055

Así mismo, se considera oportuno incluir en los apéndices 1 y 2 de la Tesis los siguientes artículos que han constituido parte de la base formativa del doctorando y en los cuales participa como autor:

IV. Gonzalez-Díaz E, Moreno Cea L, Fernández Corona A. Trigonometric characteristics of episiotomy and risks for obstetric anal sphincter injuries in operative vaginal delivery. Int Urogynecol J. 2015 Feb;26(2):235-42. https://doi.org/10.1007/s00192-014-2491-x

V. Gonzalez-Díaz E, Fernández Fernández C, Fernández Corona A. Differences in characteristics of mediolateral episiotomy in proffesionals at the same hospital. J Matern Fetal Neonatal Med. 2016;29(14):2368-72. https://doi.org/10.3109/14767058.2015.1086328

B.1. RESUMEN

INTRODUCCION Y OBJETIVOS

La episiotomía es una incisión quirúrgica realizada en el periné durante el parto para facilitar el expulsivo. Su uso liberal en los partos instrumentales para prevenir los desgarros obstétricos del esfínter anal (OASIs) esta avalado por grandes estudios observacionales. Va a estar definida por tres parámetros: la distancia desde su inicio en introito hasta la horquilla vulvar, su ángulo, y su longitud, y la colocación exacta de la misma es un factor de riesgo de OASIs modificable.

Nuestros objetivos fueron establecer una correlación entre las características de la episiotomía en el momento de la incisión y tras su sutura, seleccionar el patrón de sutura asociado a un menor riesgo de OASIs en los partos instrumentales y valorar si su optimización mediante el uso de Triepi-45 puede prevenir los OASIs en este tipo de partos.

MATERIAL Y METODOS

La presente tesis doctoral se presenta como un compendio de tres trabajos previamente publicados. En primer lugar, un estudio prospectivo descriptivo con 45 primíparas, en el cual se analizaron los cambios en el periné pre-marcado mediante dos fotografías digitales, una en reposo y otra con la cabeza coronando. En segundo lugar, un estudio de casos y controles retrospectivo con 958 partos instrumentales que fueron revisados en el puerperio, incluyendo dentro de los casos aquellos partos que sufrieron un OASIs. Y por ultimo, un estudio de cohorte retrospectivo-prospectivo tras la implantación del uso de Triepi-45, un dispositivo que permite el marcado con un ángulo de 45º del periné en reposo, con 986 partos instrumentales en cada grupo.

RESULTADOS

Cuando el periné se distiende durante el expulsivo, cada línea marcada así como su punto de inicio en la horquilla vulvar se desplaza lateralmente de manera lineal, y sin cambios significativos en el ángulo y la distancia a los puntos A y B. Sin embargo, si comparamos la configuración lineal original

en reposo con unas líneas imaginarias desde la horquilla hasta los puntos A y B antes del expulsivo, el ángulo y la distancia aumentan de manera estadísticamente significativa. En el segundo estudio, encontramos que la nuliparidad, posición occipitoposterior persistente, peso al nacer> 3500 g, un ángulo de episiotomía <30º, una distancia episiotomía-horquilla <5 mm y una distancia del cuerpo perineal <30 mm son factores de riesgo independientes de OASIs. Además solo las mujeres multíparas no se benefician de ninguna característica de la episiotomía, y un ángulo mayor de 30º y una distancia episiotomía-horquilla de distancia >5 mm se asocian con una reducción del riesgo de OASI en nulíparas, cuerpos perineales menores de 30 mm y la posición occipitoanterior. En el ultimo trabajo, la cohorte intervención presento una menor incidencia de OASIs que la cohorte preintervención (7,1% Vs 9,4%), pero la diferencia no fue estadísticamente significativa, probablemente debido al bajo uso de Triepi-45 (38%). Sin embargo, la incidencia de OASIs fue significativamente menor en la cohorte Triepi-45 que en la preintervención (4,8% vs 9,4%; OR 0,47, CI:0,26-0,86).

CONCLUSIONES

La distensión causada por la cabeza fetal durante el expulsivo provoca un desplazamiento lineal del periné causando diferencias en las características de la episiotomía entre la incisión y su sutura. Con el fin de reducir el riesgo de OASIs en los partos instrumentales es necesario lograr un ángulo de sutura de la episiotomía de al menos 30º; y en aquellas mujeres nulíparas, con cuerpos perineales menores de 30 mm y con posiciones fetales en occipitoanterior también se pueden beneficiar de una lateralización de la episiotomía (aumentando la distancia a la horquilla vulvar a >5mm). El uso del dispositivo Triepi-45 ha demostrando que tiene un impacto positivo con una reducción de hasta el 50% de los OASIs en los partos instrumentales.

B.2. SUMMARY

IMPACT OF EPISIOTOMY CHARACTERISTICS IN OBSTETRIC ANAL SPHINCTER INJURY IN OPERATIVE VAGINAL DELIVERIES

INTRODUCTION AND OBJECTIVES

Episiotomy is a surgical incision made in the perineum during delivery to facilitate expulsion. Liberal use in operative vaginal deliveries to prevent obstetric anal sphincter injuries (OASIs) is supported by large observational studies. There are three parameters that defined it: the distance from its introitus start to the vulvar fourchette, the angle, and its length; and exact placement is a modifiable risk factor for OASIs.

Our objectives were to establish a correlation between the characteristics of the episiotomy at the time of incision and after suturing, select the suture pattern associated with a lower risk of OASIs in operative vaginal deliveries, and assess whether optimization with the use of Triepi-45 can prevent OASIs.

MATERIAL AND METHODS

This doctoral thesis is presented as a compendium of three published reports. Firstly, a prospective descriptive study with 45 primiparas, in which changes in the pre-marked perineum were analyzed using two digital photographs, one at rest and the other with the head crowning. Secondly, a retrospective case-control study with 958 operative vaginal deliveries that was reviewed in the puerperium, including those deliveries with an OASIs in the case group. And finally, a retrospective-prospective cohort study after the implementation of the use of Triepi-45, a device that allows marking with a 45º angle of the perineum at rest, with 986 instrumental deliveries in each group.

RESULTS

When the perineum is stretched during the expulsion, each marked line as well as its starting point at the vulvar fourchette moves laterally linearly, and without significant changes in angle and distance to points A and B. However, if we compared the original linear configuration at rest with imaginary lines from the fourchette to points A and B before delivery, the angle and distance increase statistically significantly. In the second study, we found that nulliparity, persistent occipitoposterior position, birthweight >3500g, an angle of episiotomy <30º, a distance episiotomy-fourchette <5mm and a distance of perineal body <30mm are independent risk factors for OASIs. Furthermore, only multiparous women do not benefit from any characteristic of the episiotomy, and an angle greater than 30º and a distance episiotomy-fourchette >5 mm are associated with a risk reduction of OASI in nulliparous, perineal bodies <30 mm and occipitoanterior position. In the last study, the intervention cohort had a lower incidence of OASIs than the preintervention cohort (7.1% Vs 9.4%), but the difference was not significant, owing to the low use of Triepi-45 in the intervention cohort (38%). However, the OASIs incidence was significantly lower in the Triepi-45 cohort than in the pre-intervention cohort (4.8% vs. 9.4%; OR 0.47, CI: 0.26-0.86).

CONCLUSIONS

The distension caused by the fetal head during the expulsion causes a linear displacement of the perineum causing differences in the characteristics of the episiotomy between the incision and its suture. In order to reduce the risk of OASIs in instrumental deliveries, it is necessary to achieve an episiotomy suture angle of at least 30º; and in those nulliparous women, with perineal bodies less than 30 mm and with fetal positions in the occipitoanterior, they can also benefit from a lateralization of the episiotomy (increasing the distance to the vulvar fork to> 5mm). Use of Triepi-45 had a positive impact on reducing of up to 50% of OASIs in operative vaginal deliveries.

B.3. INDICE DE ABREVIATURAS:

OASIs: Lesiones obstétricas del esfínter anal

ECA: Ensayo clínico aleatorizado

OR: Odds ratio

IC: Intervalo de Confianza

OMS: Organización Mundial de la Salud

C. INTRODUCCION GENERAL

La episiotomía es una incisión quirúrgica realizada en el periné y la vagina durante la última parte del parto para facilitar el expulsivo. Esta va a estar definida por cuatro parámetros: la distancia desde su inicio en introito hasta la horquilla vulvar, su dirección, su longitud y el momento en el que se realiza. Se han identificado hasta siete tipos de episiotomía. Sin embargo, sólo tres (media, mediolateral y lateral) se usan rutinariamente. Actualmente se recomienda su uso restrictivo de manera general, o sea solo en aquellos casos en los que el profesional considere necesarios. La episiotomía está claramente indicada en los partos instrumentales, donde a pesar de no disponer de ensayos clínicos aleatorizados que avalen su uso, si disponemos de una fuerte evidencia a partir de grandes estudios observacionales basados en registros nacionales que apoyarían su uso liberal en este tipo de partos. Además la colocación exacta de la incisión de episiotomía en los partos instrumentales es importante con respecto al trauma perineal. La lateralización de las episiotomías disminuyó significativamente la incidencia de desgarros obstétricos de esfínter anal (OASIs), mientras que la episiotomía media aumenta el riesgo de los mismos, y el papel protector de la episiotomía mediolateral depende de una técnica correcta, ya que en los partos instrumentales las características de esta episiotomía tiene un fuerte efecto sobre la aparición de OASIs, y así un ángulo mayor de 20º tiene hasta un 87% menos de riesgo.

C.1. RECUERDO HISTORICO: LA EPISIOTOMIA

La primera episiotomía documentada se remonta a hace mas de 270 años (Figura 1.a) (Ould F, 1741). Durante los siglos XVIII y XIX, este procedimiento fue rara vez aplicado hasta 1921, cuando De Lee (Figura 1.b) aconsejó usar episiotomía mediolateral durante el parto con fórceps (De Lee JB, 1921). El parto era considerado como un generador de enfermedad, y por lo tanto, "un proceso decididamente

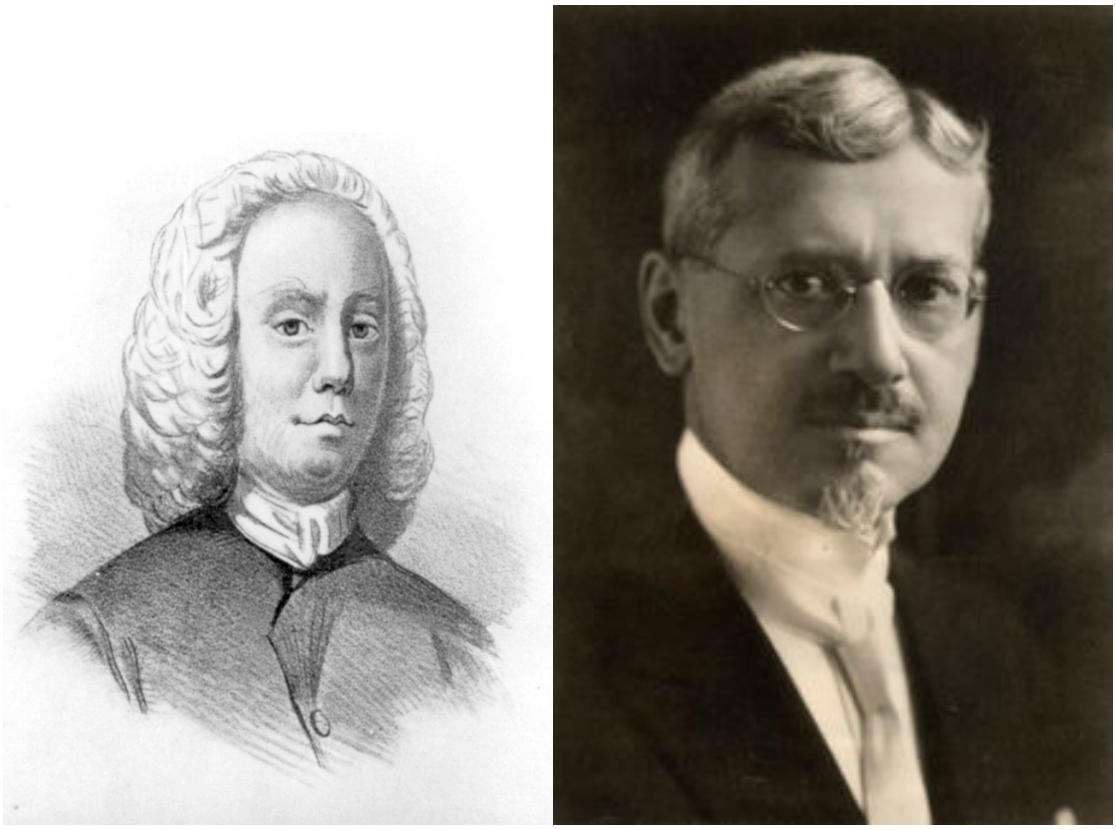

Figura 1. a) Fielding Ould, y b) Joseph DeLee

patológico". Históricamente, los médicos eran entrenados para intervenir en la enfermedad, incluyendo la protección de la madre de la morbilidad del parto. Coincidiendo temporalmente en ese momento, se estaba llevando a cabo el traslado del parto de las casas al hospital, con un aumento significativo en todas las intervenciones obstétricas. Como resultado de estos factores, se registró un aumento en el uso de la episiotomía en los siguientes años. Desde entonces, la episiotomía se convirtió en uno de los procedimientos quirúrgicos más comúnmente realizados en el mundo (Chescheir NC et al , 2008; Graham et al,1997).

Otro punto de inflexión ocurrió en 1982, cuando Banta y Thacker rechazaron la opinión establecida de que la episiotomía rutinariamente realizada reduce la morbilidad materna y neonatal (Banta D et al, 1982; Thacker SB et al 1983). Sus hallazgos tuvieron un gran impacto en la comunidad científica mundial. Esto puede verse claramente en el continuo crecimiento del número de artículos publicados anualmente desde 1983 hasta nuestros días, buscando la palabra clave "episiotomía" en la base de

datos PubMed. El resultado fue el derrocamiento de la episiotomía rutinaria y la introducción de un uso más restrictivo de la misma en la práctica obstétrica diaria. Pero no solo eso, la episiotomía se convirtió en un estigma de mala praxis a nivel social.

Las tasas de episiotomías han sido altas en algunos países, como Argentina y China, con una política de uso rutinario de episiotomía en casi todos los primeros partos (Lede R et al, 1991; Qian X et al, 2001). Otros lugares adoptaron una política de uso 'selectivo' de la episiotomía donde su uso fue restringido en lugar de realizarse universalmente: los médicos a su juicio clínico determinan la necesidad de una episiotomía en aquellos casos en los que los beneficios superen los daños causado, como en caso de riesgo de inminente desgarro perineal grave, una segunda etapa del parto prolongada, distocia de hombros, parto instrumental o una frecuencia cardíaca fetal no tranquilizadora (ACOG 2006; Melo I et al, 2014). En los EEUU, las tasas de episiotomía disminuyeron del 60,9% en 1979 al 24,5% en 2004 (Frankman EA et al, 2009). En Finlandia, la tasa de episiotomía disminuyeron entre las primiparas del 71.5% al 54.9% entre 1997-1999 y 2006-2007 , y del 21.5% al 9.2% entre las multíparas (Räisänen S et al, 2011).

C.2. DEFINICIÓN, CLASIFICACIÓN, Y TIPOS DE EPISIOTOMÍA

La episiotomía es una ampliación quirúrgica del orificio vaginal mediante una incisión en el periné durante la última parte de la segunda etapa del parto o expulsivo (Carroli G et al, 2009). Siempre debe definirse por la siguiente combinación de parámetros: la *localización del inicio* de la incisión en la horquilla vulvar, su *dirección*, su *longitud* y el *momento* exacto de la realización del procedimiento.

Un análisis exhaustivo de la literatura medica (Kalis V et al, 2012) reveló siete tipos principales de episiotomías: *media*, *media modificada*, *en forma de J*, *mediolateral*, *lateral*, *lateral radical* y *anterior* (Figura 2):

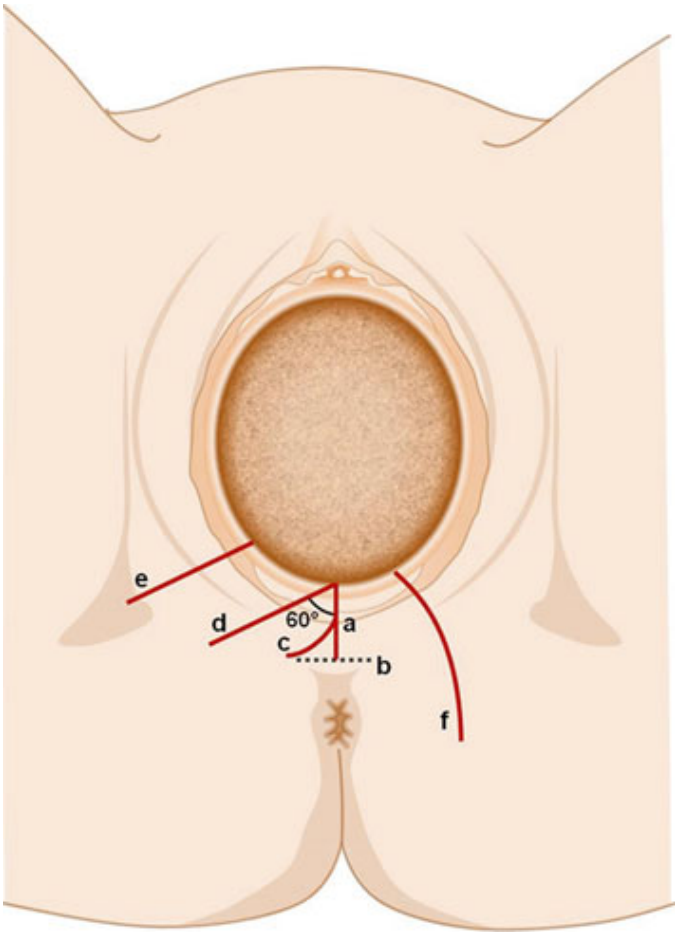

Figura 2: Tipos de episiotomía- a.) Episiotomía media, b.) Media modificada, c.) Episiotomía en forma de J, d.) Mediolateral, e.) Lateral, f.) Lateral radical (Schuchardt incisión).

a) La **episiotomía media** seria aquella que comienza en la horquilla vulvar y se extiende hasta la mitad de la longitud del cuerpo perineal (Kalis V et al, 2012; Cunningham FG et al, 2001; Cleary-Goldman J et al, 2003).

b) La **episiotomía media modificada** difiere del tipo anterior por dos cortes transversales en direcciones opuestas, ligeramente por encima a los márgenes esperados del esfínter anal externo (May JL et al, 1994). Transversamente, sólo los tejidos subcutáneos pero no la piel, debían ser cortados.

c) La **episiotomía en forma de "J"** se ejecuta inicialmente como una incisión sobre la línea media y luego a aproximadamente 2,5 cm desde el ano se curva para evitar el esfínter anal (kalis V et al, 2012;

Baker PN et al, 1995; Beischer NA et al, 1997). La última parte de la episiotomía se dirige hacia la tuberosidad isquiática (Flew JDS et al, 1944).

d) La **episiotomía mediolateral** estaría localizada entre la línea media y la episiotomía lateral, y es la episiotomía mas empleada en nuestro medio. Los resultados de investigaciones recientes demuestran claramente que la definición de la episiotomía mediolateral ha sido hasta ahora insatisfactoria (Coats PM et al, 1980; Tincello DG et al, 2003; Andrews V et al 2005; Kalis V et al, 2008; Kalis V el al, 2008; Lappen JR et al, 2010). Se ha observado una amplia variedad en la practica clínica de la episiotomía mediolateral entre países e instituciones (kalis V et al, 2008), así como entre médicos y parteras individualmente (Tincello DG, 2005; Andrews V et al, 2005; Gonzalez-Diaz et al, 2016).

Basado en los estudio de Tincello et al. (Tincello DG et al 2003), Eogan et al. (Eogan M et al, 2006), y Kalis et al. (Kalis V et al 2008; Kalis V et al, 2011) que evaluaron la colocación de la episiotomía, se ha propuesto un ángulo de episiotomía de 60° en el momento de la incisión como parte de la definición (Kalis V el al, 2012). Por lo tanto, la episiotomía mediolateral se definiría como una incisión que comienza en la horquilla vulvar a nivel de línea media y se dirige en un ángulo de al menos 60° hacia la tuberosidad isquiática con la cabeza coronando (Kalis V et al, 2012; Kalis V et al, 2011).

e) La **episiotomía lateral** comenzaría en el introito vaginal 1-2 cm lateralmente desde la línea media y se dirigiría hacia la tuberosidad isquiática (Flew JDS et al, 1944; Dudenhausen JW et al, 2001; Cech E et al 2006; Soiva K et al, 1973; Martius H et al, 1967). La episiotomía lateral a menudo no es mencionada en la literatura obstétrica, un estudio que analizo los trabajos de investigación sobre episiotomías revelo que normalmente solo se describen dos tipos, la media y la mediolateral, (Kalis V et al, 2012) siendo el término “episiotomía lateral” reutilizado sólo recientemente (Räisänen SH et al, 2009; Räisänen SH et al, 2011; Räisänen SH et al, 2012; Räisänen SH et al, 2012; Fodstad K et al, 2013; Karbanoba J et al, 2014), existiendo únicamente un ensayo clínico (ECA) en el que ha sido usada (Karbanova J et al, 2014). Además, una revisión que analizo los siete libros de texto generales mas comúnmente vendidos (Stepp KJ et al, 2006) encontró que "ambos métodos de realizar

episiotomía (media/mediolateral)" son recogidos en los textos, pero no se menciona otros tipos de episiotomía. Sin embargo, se ha encontrado que la episiotomía lateral se ha utilizado de facto, aunque involuntariamente por la comunidad médica de manera amplia en Europa (Andrews V et al, 2005; Kalis V et al 2008). Y en países como Finlandia o Grecia este tipo de episiotomía se utiliza rutinariamente.

f) La **lateral radical** (incisión de Schuchardt) es una episiotomía originalmente no obstétrica realizada al comienzo de la histerectomía vaginal radical o la traquelectomía, comienza como una episiotomía lateral pero pasando alrededor del recto en una curva lateral hacia abajo. Rara vez se recomienda su uso como ayuda al parto salvo durante partos complicados.

g) La **episiotomía anterior** (o desinfibulación) es la apertura de la cicatriz asociada con la mutilación genital femenina. Se trata de una potencial elección en caso de parto e incluso antenatalmente (Cleary-Goldman J et al; 2003). El tejido cicatricial anterior se corta en la línea media hasta la uretra (Shaw E et al, 1985). Además puede ser necesario emplear otros tipos alternativos de episiotomía en el expulsivo.

C.3. LOS DESGARROS OBSTETRICOS DEL ESFINTER ANAL Y LA EPISIOTOMIA

Dentro de los múltiples supuestos beneficios atribuidos a la episiotomía clásicamente, los había tanto para la salud del neonato como en la reducción de la morbilidad materna, y dentro de estos uno de los fundamentales era la reducción de las lesiones obstétricas del esfínter anal (OASIs). Estas suponen la principal causa de incontinencia anal en mujeres jóvenes (Kapoor DS et al, 2015). El 30% de las mujeres que sufren un OASI serán sintomáticas al 1 año (OberWalder M et al, 2003), y en el seguimiento a mas largo plazo entre el 40-53% de mujeres con un antecedente de OASIs reveló incontinencia anal persistente (Mous M et al, 2008; Evers EC et al, 2012), y con urgencia fecal en el 80% de ellas (Soerensen MM et al, 2013).

Dentro de los factores de riesgo modificables para los OASIs, la duración de la segunda etapa, la posición occipitoposterior (Sultan AH et al, 1994; Fitzpatrick M et al, 2011; de Leeuw JW et al, 2001; Wu JM et al, 2005), el uso de oxitocina y la analgesia epidural, no tienen alternativas creíbles. La elección del tipo de instrumental para partos vaginales quirúrgicos seria un factor modificable en cierta medida y pueden ser factores críticos en la causalidad de los OASIs. La protección perineal manual también ha sido objeto de considerable interés en la prevención de las OASIs (Aasheim V et al, 2011; Laine K et al, 2012; Fretheim A et al, 2013; Fodstad K et al, 2013). Hay dos componentes en esta protección perineal manual. El primero es la salida lenta y controlada de la cabeza con el fin de evitar un desgarro precipitado "explosivo" del periné cuando la "tensión" en los tejidos excede su "rigidez". Asi un estiramiento lento del periné ha sido defendido como un factor protector (Green JR et al, 1989). El segundo componente es la aplicación de los dedos en el periné posterior durante la coronación de la cabeza fetal de manera que se disipe o alivie la presión en su parte central, donde el estrés es máximo, y que si este se desgarrara, muy probablemente resultaría en una ruptura directa del esfínter anal. Sin embargo, hay variaciones interindividuales a esta técnica, y la verdadera contribución de ella a la prevención de los OASIs es difícil de cuantificar (Zemcik R et al, 2012; Jansova M et al, 2014).

Pero existe un factor protector, que descrito y defendido desde principios del siglo XX (Martin DL, 1921; De Lee JB , 1921), y que a pesar de las controversias que ha suscitado a lo largo del tiempo sigue teniendo vigencia en la actualidad, y es el uso de la episiotomía.

Tal como ya dijo Martin DL en 1921: "*La protección del periné por la episiotomía en el parto a término parece una paradoja. ¿Cómo es posible incidir en el periné para protegerlo de una lesión? ... La incisión del periné o la salida de la vulva en el parto es nuestra única medida profiláctica de la lesión irreparable del suelo pélvico*" (Martin DL, 1921). La declaración anterior refleja la naturaleza histórica del debate sobre los méritos de realizar una episiotomía. Ampliar el canal del parto frente a un periné rígido e inflexible es la indicación más obvia para una episiotomía (Kapoor DS et al, 2015). También se han sugerido su capacidad para aliviar la presión perineal y así prevenir la relajación del

suelo pélvico asociada con desgarros perineales espontáneos, que ocurren con frecuencia en los primeros partos vaginales (Martin DL et al, 1921). La episiotomía mediolateral está diseñada para evitar lesionar el cuerpo perineal (nivel III de DeLancey), el soporte de las vísceras pélvicas (DeLancey JO et al, 1992), el rafe de inserción de las fibras del periné transverso, el bulbocavernoso y el complejo del esfínter anal. También tendría como objetivo evitar el daño del músculo elevador del ano, aunque este hecho no ha sido probado (Cassadó J et al, 2014).

Pero la episiotomía en sí misma es un trauma para el periné que necesita reparación quirúrgica con posibles consecuencias a largo plazo. Sin embargo, no tener episiotomía no equivale a no existir traumatismo perineal ni necesidad de sutura perineal. De hecho, en un estudio de cohortes británico, la reducción de las tasas de episiotomía del 19% al 15% supuso en un aumento de desgarros de segundo grado en un 23% (Gurol-Urganci I et al, 2013). Y además las consecuencias a largo plazo de los OASIs, como la incontinencia anal, son mucho más graves y mucho mas difíciles de manejar, por ello es obligatorio un entrenamiento adecuado en el reconocimiento del grado de trauma perineal así como lograr la mejor reparación quirúrgica posible de los mismos. Pero mas importante aun, es poner en marcha todos aquellos mecanismos con el fin de prevenir su aparición.

La revisión Cochrane que evalúa el efecto de la episiotomía sobre el riesgo de OASIs utiliza únicamente los resultados de ECAs. La revisión más reciente del 2017, recomienda su uso selectivo frente al rutinario porque causa menos trauma perineal y vaginal severo (puede haber hasta un 30% menos de traumatismo perineal severo en aquellas mujeres en que se aplico un manejo selectivo de la episiotomía en comparación con las se aplicó una política rutinaria) (Jiang H et al, 2017). Las tasas de episiotomía en los grupo selectivos fueron de media del 32% (8-59%) frente al 83% (51%-100%) de los de uso rutinario. En el corto plazo esta revisión no encuentra diferencias en las perdidas sanguíneas, ni en el Apgar a los 5 minutos, ni en el riesgo de infección perineal. Y en el largo plazo tampoco encuentran diferencias en la dispareunia (a 6 meses o mas), ni en la incontinencia urinaria (a 6 meses

o mas), ni en el prolapso de órganos pélvicos (a 3 años) entre ambas usos de la episiotomía (Jiang H et al, 2017).

Lo sorprendente de estos resultados es como el uso selectivo de la episiotomía, o sea la disminución en la frecuencia en su utilización, disminuye la probabilidad de OASIs frente a un uso mas frecuente. Y por tanto cabe la pregunta, si esta reducción no seria máxima con la eliminación radical de todas las episiotomías, pero ningún país del mundo tiene una tasa cero. Por lo cual los resultados parecen incongruentes, seria mas lógico tal vez la ausencia de diferencias entre ambos grupos y de esa manera seria justificable el uso selectivo.

Recientemente, la Organización Mundial de la Salud (OMS) publicó su directriz "*Atención intraparto para una experiencia de parto positiva*" (Intrapartum care for a positive childbirth experience, 2019). Este extenso artículo contiene recomendaciones para todas las etapas del parto basadas en la evidencia. En la guía, no se recomienda el uso rutinario de la episiotomía debido a la falta de evidencia con respecto al efecto protector en general, pero el uso selectivo tampoco fue respaldado.

C.4. EL PARTO INSTRUMENTAL Y LA EPISIOTOMIA

El parto instrumental constituye uno de los factores de riesgo mas importantes para el desarrollo de los OASIs (Gurol-Urganci I et al, 2013), tanto la ventosa (Räisänen S et al, 2012) como el parto con fórceps (con un riesgo mayor que la ventosa)(Halle TK et al, 2016).

Respecto a este parto instrumental, la revisión Cochrane no encontró ningún ECA que comparara el efecto de la episiotomía frente a no usarla en la tasa de OASIs (Jiang H et al, 2017). Pero si incluyó un ECA que comparó el uso rutinario versus el uso restrictivo de la episiotomía (Murphy DJ et al, 2008), y no encontró diferencias con respecto a la incidencia de OASIs entre las dos políticas, pero reconocieron que el ensayo con 175 mujeres tenía escaso poder estadístico. Los autores de la revisión mostraron sus dudas respecto al uso rutinario de la episiotomía en los parto instrumentales, pero

advierten de la necesidad de mas investigaciones para ayudar a aclarar su utilidad en este grupo en particular (Jiang H et al, 2017).

En una publicación posterior, a partir de los datos de este ECA (Murphy DJ et al. 2008), Macleod et al encuentran que el uso *restrictivo* de la episiotomía en los partos instrumentales podría incrementar la tasa en la morbilidad urinaria, en particular en la incontinencia de esfuerzo, y el dolor perineal en el periodo del postparto inmediato (Macleod M et al, 2013). Sin embargo no encontraron estas diferencias a largo plazo.

La directriz de OMS sobre la atención al parto (Intrapartum care for a positive childbirth experience, 2019), como ya hemos visto, no respalda ni el uso selectivo de la episiotomía debido a la falta de evidencia sobre su efecto protector, ni siquiera en los partos instrumentales donde prácticamente no aborda el tema.

Un grupo de experto, en el año 2019, reviso la evidencia disponible acerca del uso de la episiotomía en el parto instrumental, criticando las escasas recomendaciones surgidas del documento de la OMS. Y concluye que la evidencia proveniente de los estudios observacionales proporciona una base suficiente para recomendar el *uso liberal* de la episiotomía mediolateral o lateral con una incisión a 60º de la línea media cuando se precisa de un parto vaginal quirúrgico (Sultan AH et al, 2019).

Si bien, estos autores reconocen que es cierto que un ECA es el mejor tipo de estudio para evaluar la efectividad de una intervención terapéutica, sin embargo la episiotomía no es un tratamiento para los OASIs, sino que es un factor de modificación del riesgo (Sultan AH et al, 2019). Este tipo de relación se aborda mejor en estudios observacionales bien diseñados similares a los que actualmente se utilizan para evaluar el impacto de ciertos factores ambientales, nutricionales o sociales en el riesgo de la población de desarrollar cáncer o enfermedades cardíacas. Además, el reclutamiento de mujeres para un ECA que evalué el efecto de la episiotomía en los partos instrumentales donde la intervención se dicotomiza como rutina (100%) versus ninguna episiotomía (0%) podría ser un verdadero desafío.

	Gurol-Urganci	Räisänen	Van Bavel	Jangö	Friedman
Año	2013	2012	2017	2015	2015
País	UK	Finlandia	Holanda	Dinamarca	EEUU
Nº partos	1.035.253	189.834	1.534.850	214.256	7.100.000
Tipo Epi	ML	LT	ML	ML	M
Fórceps % Epi	85		93,4		
Fórceps + Epi **Fórceps - Epi**	6,1 22,7		3,4 26,7		28,3 25,7
aOR	1,89 (1,74-2,05)		0,09 (0,07-0,11)		
Ventosa % Epi	73	84,9	87,3	28,7	
Ventosa + Epi **Ventosa - Epi**	2,3 6,4	3,2 4,3	2,5 14	10,6 14,9	18,6 10,4
aOR	6,53 (5,57-7,64)	0,54 (0,42-0,70)	0,14 (0,13-0,15)	0,6 (0,56-0,65)	

Figura 3. Estudios Observacionales basados en registro poblacionales sobre el riesgo de OASIs y el uso de la Episiotomía en los partos instrumentales. *Epi*: Episiotomía; ML: Mediolateral; LT: Lateral; M: media; *aOR*: Odds ratio ajustada (IC95%) (encuadrado la prevalencia de OASIs)

Por tanto, a pesar de la falta de ECA, disponemos de una solida evidencia a partir de grandes estudios observacionales (Figura 3). El primer gran estudio de cohortes a partir de un registro nacional se publicó en 2008 (de Leeuw J et al, 2008). En esta cohorte, la tasa de OASIs durante los partos con ventosa fue del 9,4% sin episiotomía y del 1,4% con episiotomía (OR 0,11; IC del 95%: 0,09-0,13). En los partos con fórceps, estas tasas fueron de 22,7% y 2,6%, respectivamente (OR 0,08; IC del 95%: 0,07-0,11).

Después de la publicación del estudio holandés, se han publicado otros cuatro estudios que utilizan registros nacionales y que abordan este tema en fundamentalmente en mujeres nulíparas. El estudio de Gurol-Urganci et al del 2013, que incluyó a 1,2 millones de mujeres nulíparas, mostró una menor incidencia de OASIs con el uso de episiotomía mediolateral durante los partos instrumentales tanto con ventosa y como con fórceps (Gurol-Urganci I et al, 2013). La incidencia de OASIS durante los partos ventosa fue casi tres veces menor cuando se realizó una episiotomía mediolateral (2,3% versus 6,4%). En los fórceps, esta diferencia fue aún más pronunciada (6,1% versus 22,7%).

Estos resultados de la episiotomía mediolateral en los partos instrumentales se confirmaron también en el estudio de cohorte holandés (van Bavel J et al, 2018), donde la incidencia de OASIs en partos ventosas fue de 14,0% entre las mujeres sin episiotomía, y del 2,5% con episiotomía, y en los partos

con fórceps esta incidencia fue del 26,7% sin episiotomía versus el 3,4% con episiotomía. Además, las mujeres multíparas con parto vaginal quirúrgico con episiotomía también tuvieron una menor incidencia de OASIs en comparación con las mujeres sin episiotomía, 2,1% y 7,5% en ventosas y 2,6% y 14,2% en partos con fórceps.

Este efecto preventivo de la episiotomía mediolateral durante los partos ventosa se confirmó en el estudio de cohorte de Dinamarca (Jango H et al, 2014), aunque la incidencia real de OASIs fue mucho mayor en esta cohorte en comparación con los otros estudios. Una diferencia importante con ellos fue la tasa de episiotomía mediolateral, así en la cohorte danesa fue solo del 28,7% en comparación con más del 70% en los estudios del Reino Unido y del 90% en los Países Bajos (Gurol-Urgaci I et al, 2013; van Bavel J et al, 2018).

En Finlandia, donde la episiotomía lateral es la usada tradicionalmente, un estudio de Räisänen et al. basado en datos del registro medico de nacimientos finlandés, evaluaron 16.802 partos ventosas (Räisänen S et al, 2014), encontrando una disminución significativa en la incidencia de OASIs con el uso de episiotomía tanto en nulíparas como en multíparas.

En contraste con la situación europea, la episiotomía media ha sido el tipo preferido en los Estados Unidos. En 2015, Friedman et al analizaron 7,1 millones de nacimientos en los Estados Unidos durante un período de 10 años (Friedman AM et al, 2015). Aunque no se describió el tipo de episiotomía, se puede suponer que la episiotomía media fue la más frecuente en este conjunto de datos. En los fórceps, la incidencia de OASIs fue del 18,3% con y 19,3% sin episiotomía. En las ventosas, la incidencia fue del 18,6% y 10,4%, respectivamente. Por lo tanto, en esta cohorte, la episiotomía media no tuvo efecto en la prevalencia de OASIs en los partos con fórceps y se asoció con una mayor prevalencia en los partos con ventosa. Este resultado confirmó otros estudios anteriores en EEUU en los que la episiotomía media durante el parto vaginal quirúrgico se asoció con tasas de OASIs significativamente más altas.

Otras evidencias acerca del uso de la episiotomía en los partos instrumentales provendrían de las revisiones sistemáticas, como la realizada por la Agencia Sueca de Evaluación de las Tecnología de la Salud que publico una revisión sistemática en el año 2016 sobre las lesiones del esfínter anal (www.sbu.se/249E). La revisión concluyó que existe una fuerte evidencia científica a favor del uso de la episiotomía en los partos instrumentales (particularmente en las ventosas).

En una revisión sistemática y metaanálisis de 15 estudios que compararon no usar episiotomía con el uso de la episiotomía mediolateral o lateral entre mujeres nulíparas con parto por ventosa, la episiotomía redujo significativamente el riesgo de OASIS en un 50% (OR 0,53; IC del 95%:0,37-0,77) (Lund NS et al, 2016). Cuando los estudios incluidos en esta revisión fueron subanalizados por la tasa de episiotomía, parecía que el efecto protector de la episiotomía parecía más pronunciado cuando se realizaba en más del 75% de los partos ventosa (OR 0,37; IC del 95%: 0,15– 0,92).

C.5. EL TIPO DE EPISIOTOMIA Y EL RIESGO DE OASIS EN LOS PARTOS INSTRUMENTALES

Por tanto, en vista a los estudios disponibles y a la espera de ECAs que puedan aportar la evidencia definitiva (aunque es improbable su realización), parece que el uso de la episiotomía de manera liberal podría ser útil en la prevención de los OASIs en aquellos partos que precisen ser instrumentados para su finalización. Pero ¿que tipo de episiotomía seria el mas adecuado?, ¿sirven de la misma manera todos los tipos?.

Los datos publicados son limitados y contradictorios con respecto a la evaluación del uso de episiotomía en relación con el parto vaginal instrumental, como ya hemos visto, y al evaluar el tipo de episiotomía en cada estudio, las episiotomías medias siempre se comportan como un factor de riesgo (Robinson JN et al,1999; Kudish B et al, 2006), las episiotomías laterales se asocian como un factor

protector (Räisänen S et l, 2012) y los resultados de las episiotomías mediolaterales son contradictorios (de Vogel J et al, 2012; Combs CA et al, 1990; de Leeuw JW et al, 2008, Hudelist G et al, 2005)).

Como ya hemos visto previamente en los grandes estudios observacionales sobre la incidencia de OASIs en los partos instrumentales, existen grandes diferencias en función del tipo de episiotomía utilizada (Gurol-Urganci I et al, 2013; Jangö H et al, 2014; van Bavel J et al, 2018; Räisänen S et al, 2014; Friedman AM et al, 2015). Así en el estudio de Friedman (Friedman AM et al, 2015) realizado en EEUU, donde utilizan preferentemente episiotomías medias, no encuentra un efecto protector de la episiotomía media en los partos fórceps e incluso en los partos ventosas se asocia a una mayor prevalencia de OASIs. Y en comparación con los estudios del continente europeo, donde se utilizan predominantemente episiotomías mediolaterales, la incidencia de OASIS en los fórceps con episiotomía media fue de cuatro a ocho veces mayor, y en las ventosas con episiotomía media fue 8 veces mayor en comparación con los estudios del Reino Unido (Gurol-Urganci I et al, 2013) y los Países Bajos (van Bavel J et al, 2018) y casi el doble de la informada en la cohorte danesa (Jangö H et al, 2014).

C.6. VARIACIONES DE LA EPISIOTOMIA MEDIOLATERAL

La episiotomía mediolateral, que es la mas frecuentemente utilizada en nuestro medio; estaría situada entre una episiotomía media y una episiotomía lateral, o sea que la variabilidad de la técnica de esta episiotomía mediolateral puede dar lugar a patrones mas similares a uno de los otros dos tipos. Históricamente, las episiotomías se han clasificado como media o mediolateral por su intención declarada, y tal vez esta sea la causa de los datos contradictorios respecto al efecto protector de la episiotomía mediolateral, ya que el ángulo de las mismas en los estudios no estaban controlados, y muchas de ellas no eran realmente mediolaterales o "no medianas" (Andrews V et al, 2005), siendo en muchos casos prácticamente imposible diferenciarlas de episiotomías medias (Fenner DE et al, 2003).

Andrews et al (Andrews V et al, 2005) encontraron que ninguna matrona y solo el 22% de los médicos realizaban episiotomías mediolaterales con un ángulo de sutura entre 40-60°. El ángulo medio alcanzado por las parteras fue de 20° y el de los médicos fue de 27°, con solo un tercio de las episiotomías con un ángulo ≥40°. En otro estudio de 300 episiotomías teóricamente mediolaterales, Fodstad et al. encontró una variación considerable en el ángulo y la distancia desde la línea media, (Fodstad K et al, 2013), así tras analizarlas: el 7% eran medias (con ángulos de sutura <25°), el 13% eran mediolaterales (25-60° y la distancia desde la horquilla posterior ≤3 mm), el 36% se describieron como "no clasificables" y el 44% laterales (25–60° y con >10 mm de distancia desde la horquilla vulvar). Sin embargo, esto puede ser un reflejo de la dificultad para percibir el tamaño y el ángulo al realizar una episiotomía. Pero parece también haber dificultades para estimar los ángulos visualmente incluso en entornos ex vivo. Tincello et al (Tincello DG et al, 2003) encontraron que solo un tercio de los médicos pudieron dibujar una episiotomía de ≥40° en papel. Un estudio que utilizó un modelo de simulación encontró que solo el 13% de las matronas y el 7% de los médicos pudieron realizar una episiotomía mediolateral correcta (Silf K et al, 2015).

Además, las características de la episiotomía varían entre los distintos periodos del parto. Kalis et al fueron los primeros en informar sobre las diferencia entre el ángulo de la incisión de la episiotomía y el ángulo de sutura de la misma (kalis V et al, 2008; Kalis V et al, 2011). Así observaron que una episiotomía premarcada con un ángulo de 40° daba como resultado un ángulo de sutura tras el parto de 22°, mientras que una premarcación de 60° daba un ángulo de sutura de 45º. También se han observado grados similares de distensión perineal en el lado opuesto de la episiotomía (el lado intacto del periné), descartando un efecto de la episiotomía por si misma. Este grado de distensión perineal se ha observado también cuando se realizan episiotomías a 60° con la tijera Episcissors-60™ (Medinvent Ltd., Romsey, Reino Unido) en partos instrumentales (dando ángulos de sutura de 43°) (Freeman RM et al, 2014) y espontáneos (dando ángulos de sutura de 50°) (Patel R et al, 2014). Ginath et al (Ginath

S et al, 2017) sugirió una distensión perineal en términos angulares de 30° desde la primera etapa del parto hasta la coronación de la cabeza fetal.

La explicación de estas diferencias son debidas a que al coronar la cabeza fetal en el expulsivo, el cuerpo perineal está particularmente expuesto a un alto grado de deformación, y además después del parto, la tensión en los tejidos perineales y el edema retrocede, y posteriormente la deformación desaparece. Su biomecánica durante el parto se ha estudiado mediante observación clínica (kalis V et al, 2008; Kalis V et al, 2011), estudios de resonancia magnética (Lien KC et al, 2004) y estereofotogrametría (Zemcik R et al 2012). Lien y col. (Lien KC et al, 2004) encontraron un aumento de 2.5 a 3 veces en las dimensiones del músculo elevador durante el parto, siendo el estiramiento de hasta el 300% en la parte más medial del pubococcígeo debido a la ubicación de sus orígenes cerca de la línea media. No esta claro si este estiramiento se transmitiría al cuerpo perineal, que suele ser una estructura pasiva. La estereofotogrametría del periné ha mostrado un estiramiento máximo del 177% en el diámetro transversal y del 43% en el diámetro anteroposterior (Zemcik R et al 2012). La consecuencia final de todas estas alteraciones en la geometría de la región perineal resultan en una diferencia entre las localizaciones observadas de episiotomía: en el momento de la incisión, después de la reparación, y después del posparto. Basados en estos estudios antropométricos del periné se han introducido tres nuevos términos: ángulo de incisión, ángulo de sutura y ángulo de cicatriz de la episiotomía (kalis V et al, 2008).

Si ha esta variabilidad del ángulo en el expulsivo, le sumamos la inexactitud de los obstetras a la hora de determinarlo de manera correcta, hará que la imprecisión de la episiotomía sea aun mayor. Así cuando se les pide cortar una episiotomía a 60° con unas tijeras de Mayo rectas sobre un periné dibujado en papel, solo el 36% de los médicos pudieron cortar un ángulo en el rango de 55-65°(Naidu M et al, 2015), el 44% subestimó el ángulo (<55°) y el 18% sobreestimó el ángulo (> 65°).

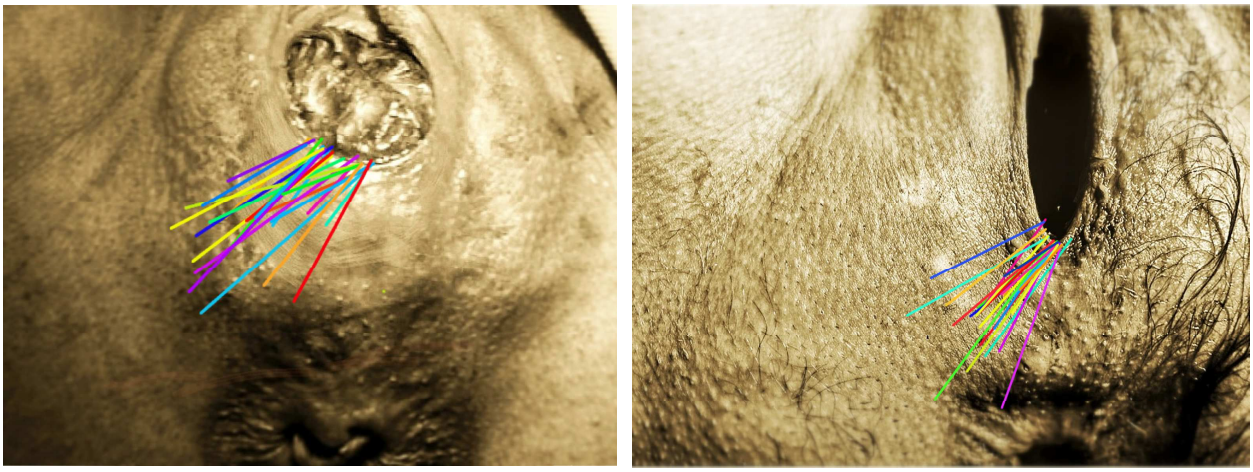

Figura 4: Representación grafica de la episiotomías mediolaterales de los profesionales de paritorio del Complejo Asistencial Universitario de León: A) Con el periné con la cabeza coronando, y B) Después del parto en reposo (Gonzalez-Diaz E et al, 2016)

En un estudio realizado en nuestro propio entorno, entre el personal del paritorio del Complejo Asistencial Universitario de León (Gonzalez-Diaz E et al, 2016), usamos un modelo digital sobre el que se realizo el marcado de la episiotomía tanto con el periné con la cabeza fetal coronando como posteriormente en reposo. Los resultados muestran, además de la enorme variabilidad en las episiotomías mediolaterales entre los profesionales de un mismo centro (Figura 4), que el 28% realizaban episiotomías con ángulos más agudos con la cabeza coronando que en reposo.

B.7. CARACTERISTICAS DE LA EPISIOTOMIA MEDIOLATERAL Y RIESGO DE OASIS

Cada vez hay más pruebas de que la colocación exacta de las episiotomías juegan un papel importante en el grado de trauma perineal. Tincello et al (Tincello DG et al, 2003) fueron los primeros en cuestionar la técnica de la episiotomía mediolateral y plantear la cuestión del grado de alivio de la fuerza sobre el periné en relación con el ángulo de la episiotomía. Más tarde, Andrews et al (Andrews V et al, 2005) con un estudio observacional, y Eogan et al (Eogan M et al, 2006) y Stedenfeldt et al (Stedenfeldt M et al, 2012) con estudios de casos y controles mostraron diferencias en las

características de las episiotomías entre las mujeres con y sin lesión del esfínter anal. Eogan et al (Eogan M et al, 2006) solo estudió el ángulo de la episiotomía, y su análisis mostró una reducción relativa del 50% en el riesgo de OASIs por cada 6,3° que la cicatriz de la episiotomía se alejaba de la línea media perineal. Andrews et al (Andrews V et al, 2005) también estudiaron la longitud de la episiotomía y la profundidad que alcanza, pero solo encontró diferencias significativas en el ángulo. Stedenfeldt et al (Stedenfeldt M et al, 2012) agregaron la distancia hasta horquilla vulvar y encontraron una asociación con esa distancia, la profundidad y la longitud de la episiotomía, pero no en el ángulo o el tamaño del cuerpo perineal. La episiotomía per se aliviará la presión sobre el periné posterior central siempre que no sea demasiado lateral y tenga un ángulo de sutura postparto de >60° (Stedenfeldt M et al, 2012).

Un estudio aleatorio reciente en nulíparas encontró una incidencia del 2.4% de OASIs cuando el ángulo de episiotomía se realizó a 60º versus 5.5% si era 40º, aunque la diferencia no fue estadísticamente significativa debido al escaso tamaño muestral (El-Din AS et al, 2014).

Específicamente en partos instrumentales, disponemos de un estudio prospectivo de casos y controles realizado en nuestro centro donde también encontramos que cuando se realiza una episiotomía mediolateral en un parto instrumental, la técnica tiene un fuerte efecto sobre la aparición de OASIs, y así un ángulo mayor de 20º tiene un 87% menos de riesgo (Gonzalez-Diaz E et al, 2015), pero no encontramos asociación con otras características de la episiotomía.

D. COPIA DE LOS TRABAJOS PUBLICADOS

D.1. Behavior of perineum during delivery before fetal head expulsion.

D.2. Which characteristics of the episiotomy and perineum are associated with a lower risk of obstetric anal sphincter injury in instrumental deliveries.

D.3. Incidence of obstetric anal sphincter injuries after implementing the Triepi-45 tool to improve episiotomy angle in instrumental deliveries.

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ORIGINAL ARTICLE

Behavior of perineum during delivery before fetal head expulsion

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Abstract
Introduction and hypothesis The aim of this study was to describe perineum deformation during the final part of delivery and suggest a modification of the episiotomy cut to increase accuracy for obtaining a suitable angle (45°) for surgical wound suture.
Methods This prospective study enrolled 45 primiparous women. The perineum at rest was marked with five lines (0°, 30°, 45°, 60°, 90°), and each line was marked with two dots (point A–B: to 2–3 cm from initial point in fourchette, respectively). Two digital pictures were taken: one with the women at rest and the second during fetal head crowning; displacements were calculated for each point and angle.
Results When the perineum is distending, the initial point of every line in the posterior fourchette moves laterally in introitus (only the 0° line remains at midline). The angle and the distance to points A and B of each line drawn do not change significantly from at rest to crowning. However, comparing original line configuration with an imaginary line from the fourchette to points A and B before expulsion, the angle and the distance is increased statistically significantly.
Conclusions Perineal distension at the moment of fetal head crowning causes a linear displacement of the perineum, which causes the difference in angle between the incision and episiotomy suture. Therefore, to obtain an episiotomy suture from fourchette with an angle of 45°, theoretically, we would have several angle incision options (between 45° and 60°), with a less acute angle when the introitus cut is closer to the fourchette (45° to 6 mm and ~60° in the fourchette) and a sharper angle with a longer episiotomy.

Keywords Mediolateral episiotomy · Episiotomy technique · Obstetric anal sphincter injuries

Introduction

Obstetric anal sphincter injuries (OASIS) are the most established and potentially most modifiable risk factor for developing fecal incontinence after vaginal delivery. The most important treatment is prevention [1], but there are a few interventions shown to reduce the risk. Recent researchers have established that the angle of episiotomy is an important determinant of OASIS risk [2–5]. Also, there are differences between the angle at which the incision is made during head crowning (when the perineum is stretched) and that of the surgical wound once the infant has been delivered [6, 7]. Furthermore, individual interpretation of mediolateral episiotomy differed widely among professionals [8], and 28.1 % of accoucheurs indicated an acuter episiotomy angle of 45° with a crowning head [9]. This evidence suggests that correct execution of the episiotomy incision might have significant implications on the degree of perineal trauma.

The aim of the study was to describe and quantify perineum deformation during the final part of delivery and suggest modification of the episiotomy cut that might increase accuracy for a suitable angle (45°) for surgical wound suture.

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Methods

This prospective study, conducted at Complejo Asistencial Universitario de León, Leon, Spain, enrolled primiparous women at term undergoing noninstrumental vaginal delivery assisted by the same obstetricians between 1 September 2009 and 1 September 2010. Of the 1919 vaginal deliveries during this period, 1497 (78 %) were noninstrumental. The local ethics committee approved the study, and all participants signed a detailed consent form before they were enrolled. Inclusion criteria were: primiparity, singleton term pregnancy, vertex presentation, noninstrumental vaginal delivery, neonatal weight >2500 g, competent Spanish, and a signed informed consent form. The following data were recorded: maternal age, gestational age, race, weight, height, fetal position, birth weight, pH umbilical cord blood sampling, use of epidural anesthesia, and OASIS rate. Perineal changes were investigated for each participant at the last possible moment of delivery (immediately before fetal head expulsion) and in contrast to the original configuration, i.e., when the participant was positioned on the bed (before active pushing) and the obstetrician applied the linear pattern with a paper model using a solution of gentian-violet in 1 % aqueous solution. The perineum at rest was marked with five lines of 3 cm at 0°, 30°, 45°, 60°, and 90° from the midline (line from urethra to anus), and every line had: (a) the same initial point in posterior fourchette, and (b) two marked dots—one at 2 cm (point A) and the other at 3 cm (point B) from the beginning of the line (Fig. 1a).

Two researchers attended all deliveries, and each woman was assisted by one obstetrician while the other took photographs of the perineum. Two digital pictures were taken: one at rest and the second at the time of fetal head crowning. A digital camera (10 megapixels) was used to analyze deformations of the perineal region. The camera was placed ~30 cm from the participant and at the posterior fourchette level. Standard hospital lighting was used without any disruptive flash. The patient was in the lithotomy position with her legs flexed at the hip joints at an angle of 90–100°, according to Kalis et al. [6]. The obstetrician's hands did not touch the perineum before the crowning of the fetal head. Then, if it was necessary, a mediolateral episiotomy was performed, and in all cases, the "hands-on" technique was used for manual perineal protection. Displacements were calculated for points A and B and line angle as it moved over time from a rest position to that at the time of crowning. Each photograph was analyzed using the PixelStick program (Version 2.8.), and we obtained the following parameters:

- At rest—distance from fourchette to A, B and angle for each line drawn
- In stress—angle and distance from cut-off in introitus to points A and B for the five lines drawn
- In stress—angle and distance from fourchette to points A and B of imaginary lines formed between these points
- In stress—distance each line moves in introitus from the fourchette

Statistical analysis was done using the SPSS version 20 (SPSS Inc., Chicago, IL, USA). Normality was checked using the Shapiro–Wilk method. Differences between dependent data were computed by the paired samples Student's test. A ρ value of less than 0.05 was considered to be statistically significant.

Results

During the study period, 45 consecutive women were recruited after being informed and signing the informed consent form; 14 women refused to participate. All women were Caucasian, with a mean age of 32.5 years and a gestational age of 280 days. The average birthweight was 3290 g, no fetus was in occipitoposterior position, and the pH was 7.24. Epidural rate was 91.1 % (Table 1).

At the time the fetal head is crowning and the perineum is distended, the origin points of the 30°, 45°, 60°, and 90° lines move laterally from posterior fourchette to 4.95, 8.01, 11.24, and 12.08 mm, respectively, into introitus. Only the 0° line remains in the fourchette without moving (Fig. 1b). Line angles drawn in the perineum at rest do not change significantly during crowning. Angles of segments that form between lines are not changed. Also, there were no significant differences in distances to points A and B in the lines drawn between at rest and when the perineum was stretched (Table 2).

However, if we compare the original configuration of lines drawn with an imaginary line from fourchette to points A and B before fetal head expulsion, the angle and distance increased statistically significantly. The angle to point A on the line of 30°, 45°, and 60° and to point B on the line of 30°, 45°, 60°, and 90° increased in a statistically significant way with respect to at rest. For the 45°-line at rest, the angle with fetal head crowning increases to 56.75° from fourchette to point A (2 cm at rest) and 60.33° to point B (3 cm at rest) (Table 2).

Overall, in this particular area of the perineum, we observe a lateral and ventral linear displacement, but no rotational movement, at the last possible moment of delivery (immediately before fetal head expulsion) (Fig. 1). Therefore, to place an episiotomy suture from the posterior fourchette with an angle of 45° and a length of 2 or 3 cm, from our study data, theoretically, we would have several incision options at the time of the fetal head crowning: (a) making a cut from introitus (~6 mm from fourchette) with an angle of 45° and a length of 2 or 3 cm, or (b) making a cut from the fourchette with an angle of ~57° and ~2.5 cm in length, or 60° and 3.5 cm for suture lengths of 2 and 3 cm. For other options

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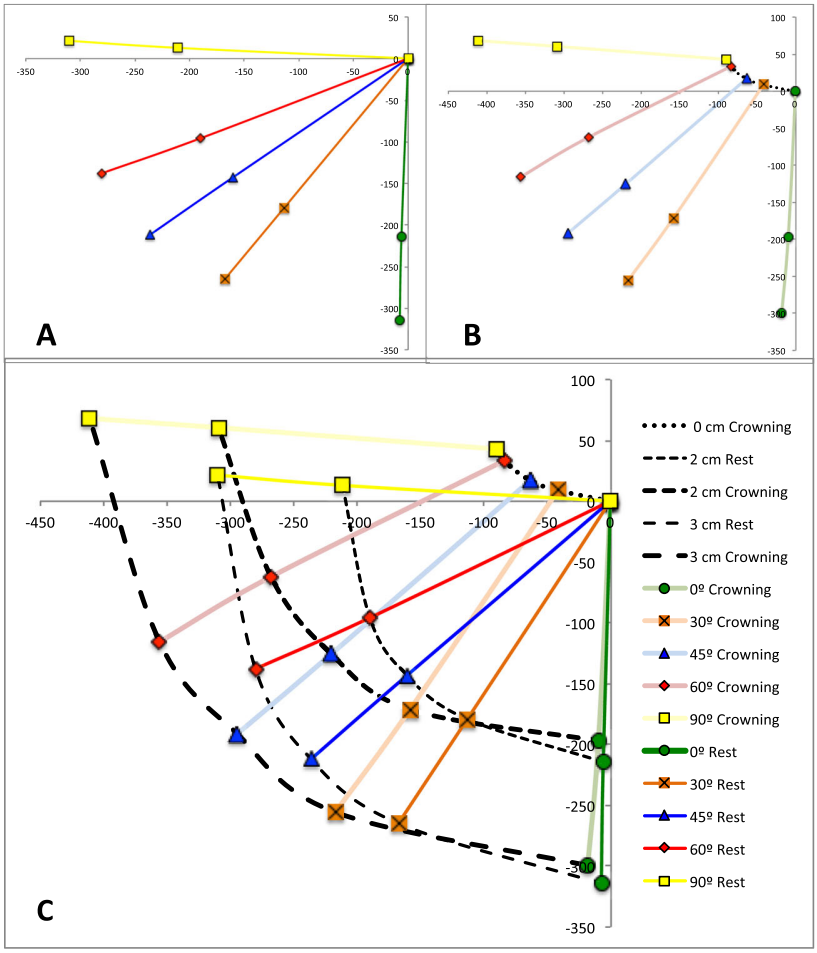

Fig. 1 Changes in linear pattern of perineum from the original configuration (at rest) to the last possible moment of delivery (at crowning). **a** *Lines* with their marks at rest (initial configuration): the initial point of each line was the posterior fourchette. **b** *Lines* with where their marks went at the time of fetal head crowning: initial points of the original configuration were moved from the posterior fourchette, except in the 0° line. **c** *Lines* in both **a** and **b** shown together

between the fourchette and 6 mm, the angle should be between 45° and 60°, with a sharper angle when the cutoff in introitus is closer to the posterior fourchette, and a shorter episiotomy length (Fig. 2).

Discussion

The soft tissues of the perineal region are highly heterogeneous materials, and their mechanical response is nonlinear and anisotropic [10]. The biomechanics of birth have been studied by clinical observation [6, 7, 11], magnetic resonance imaging (MRI) studies [12], and stereophotogrammetry [10]. The anal orifice has been found to dilate to 25 mm in the anteroposterior and transverse diameters during crowning, implying a circular dilatation [11]. Lien et al. [12] found a 2.5- to 3-fold increase in different parts of the levator muscle dimensions during birth. The largest stretch ratios of 300 % occurred in the most medial part of the pubococcygeus due to the location of its origins near the midline. It was uncertain whether the stretch would be transmitted to the caudal perineal body, which may be a passive structure. Stereophotogrammetry of the perineum has shown a maximum stretching of 177 % in the transverse diameter and 43 % in the anteroposterior diameter [10].

Table 1 Characteristics of women recruited for this study

Participant characteristics (*n* 45)	
Maternal age (years)[a]	32.5 (6.4)
Gestational age (days)[a]	280 (6)
Caucasian	100 %
Weight (kg)[a]	73.3 (5)
Height (cm)[a]	165 (5.5)
Occipitoposterior position	0 %
Birthweight (g)[a]	3290 (350)
pH umbilical cord blood sampling[a]	7.24 (0.91)
Epidural anesthesia	91.1 %
OASIS	0

OASIS obstetric anal sphincter injuries

[a] Mean (Standard deviation)

Table 2 Differences in distances and angles of lines drawn on the perineum of the 45 participants between original configuration at rest and the last possible moment of delivery (immediately before fetal head expulsion)

	Rest	Crowning	MD	SD	Student's*t* test	*P* value
Angle 0°	1.58	2	0.42	6.66	0.217	NS
Angle 30°	32.42	33.08	0.67	8.38	0.276	NS
Angle 45°	47.92	48.08	0.17	8.54	0.068	NS
Angle 60°	63.92	62.92	−1	9.53	−0.363	NS
Angle 90°	93.83	94.92	1.08	7.99	0.469	NS
Angle segment 1 (0–30°)	30.83	31.25	−0.42	6.03	−0.239	NS
Angle segment 2 (30–45°)	15.42	15.25	0.17	4.76	0,121	NS
Angle segment 3 (45–60°)	16.08	15.08	1	3.93	0.881	NS
Angle segment 4 (60–90°)	29.92	32.42	−2.5	4.77	−1.813	NS
Angle segment A (0–45°)	46.33	46.42	−0.08	7.94	−0.036	NS
Angle segment B (0–60°)	62.33	61.5	0.83	9.34	0.309	NS
Angle segment C (0–90°)	92.08	94	−1.92	8.07	−0.822	NS
Distance A–introitus (0°)	20.97	22.17	−12	66.42	−0.65	NS
Distance A–introitus (30°)	21.33	22.03	−7	60.7	−0.556	NS
Distance A–introitus (45°)	21.18	21.72	−5.39	65.73	−0.375	NS
Distance A–introitus (60°)	21.02	21.52	−5	59.2	−0.422	NS
Distance A–introitus (90°)	21.71	24.94	−32.33	85.12	−1.566	NS
Distance B–introitus (0°)	31.45	33.25	−18	87.31	−0.714	NS
Distance B–introitus (30°)	32.00	33.05	−10.5	79.7	−0.456	NS
Distance B–introitus (45°)	31.76	32.57	−8.08	74.7	−0.375	NS
Distance B–introitus (60°)	31.53	32.28	−7.5	67.01	−0.388	NS
Distance B–introitus (90°)	32.56	37.41	−48.5	95.12	−1.766	NS
Angle A–fourchette (0°)	1.58	2.42	0.83	7.51	0.384	NS
Angle A–fourchette (30°)	32.42	39.92	7.5	9.02	2.88	0.015
Angle A–fourchette (45°)	47.92	56.75	8.83	8.69	3.519	0.005
Angle A–fourchette (60°)	63.92	72.83	8.92	9.4	3.284	0.007
Angle A–fourchette (90°)	93.83	98.92	5.08	9.52	1.848	NS
Distance A–fourchette (0°)	31.45	34.57	−31.25	97.64	−1.109	NS
Distance A–fourchette (30°)	32.00	35.05	−30.5	86.99	−1.214	NS
Distance A–fourchette (45°)	31.77	36.63	−48.67	80.42	−2.096	0.06
Distance A–fourchette (60°)	31.53	39.00	−74.67	79.33	−3.26	0.008
Distance A–fourchette (90°)	32.56	43.59	−110.33	79.32	−4.818	0.001
Angle B–fourchette (0°)	1.58	2.58	1	8.15	0.425	NS
Angle B–fourchette (30°)	32.42	43.17	10.75	11.06	3.366	0.006
Angle B–fourchette (45°)	47.92	60.33	12.42	10.21	4.209	0.001
Angle B–fourchette (60°)	63.92	76.5	12.58	10.56	4.124	0.002
Angle B–fourchette (90°)	93.83	100.67	6.83	11.11	2.131	0.057
Distance B–fourchette (0°)	21.45	20.62	8.33	72.89	0.396	NS
Distance B–fourchette (30°)	22.00	24.38	−23.83	74.72	−1.105	0.042
Distance B–fourchette (45°)	21.77	26.62	−48.5	72.85	−2.306	0.007
Distance B–fourchette (60°)	21.53	28.73	−72	75.34	−3.31	0.000
Distance B–fourchette (90°)	22.56	32.86	−103	68.61	−5.2	NS
Distance fourchette–introitus (0°)	0	0	0			
Distance fourchette–introitus (30°)	0	4.95	−4.95	10.21	24.58	0.000
Distance fourchette–introitus (45°)	0	8.01	−8.01	9.55	62.48	0.000
Distance fourchette–introitus (60°)	0	11.24	−11.24	7.55	80.22	0.000
Distance fourchette–introitus (90°)	0	12.08	−12.08	11.14	94.72	0.000

Angle line 0°, 30°, 45°, 60°, 90°: Angle between each line with the midline. Angle segment 1, 2, 3, 4, A, B, C: angle formed between two lines (defined in parentheses). Distance A or B–introitus: measurement from point A or B. Angle A or B–fourchette: compares angle formed by line drawn in perineum at rest with the angle of an imaginary line between point A–B and posterior fourchette with fetal head crowning. Distance A or B–fourchette: from A or B to fourchette; at rest corresponds to distance of line drawn in perineum and with fetal head crowning corresponding to distance of imaginary line from A or B to fourchette. Distance fourchette–introitus: from posterior fourchette to starting point of each line in introitus with perineum distended by the fetal head

MD mean of differences, *SD* standard deviation, *NS* not significant, *angle* degree, *distance* mm, *Point A* to 2 cm from fourchette in every line at rest, *Point B* to 3 cm from fourchette in every line at rest

Kalis et al. were the first to report data on the difference between the incision and suture angle of the episiotomy [6, 7]. A 40° premarked episiotomy results in a postdelivery suture angle of 22°, while a 60° premarked episiotomy results in a suture angle of 45°. Similar degrees of perineal distension have also been observed on the opposite side of the episiotomy (intact side of the perineum), ruling out an effect of the episiotomy itself.

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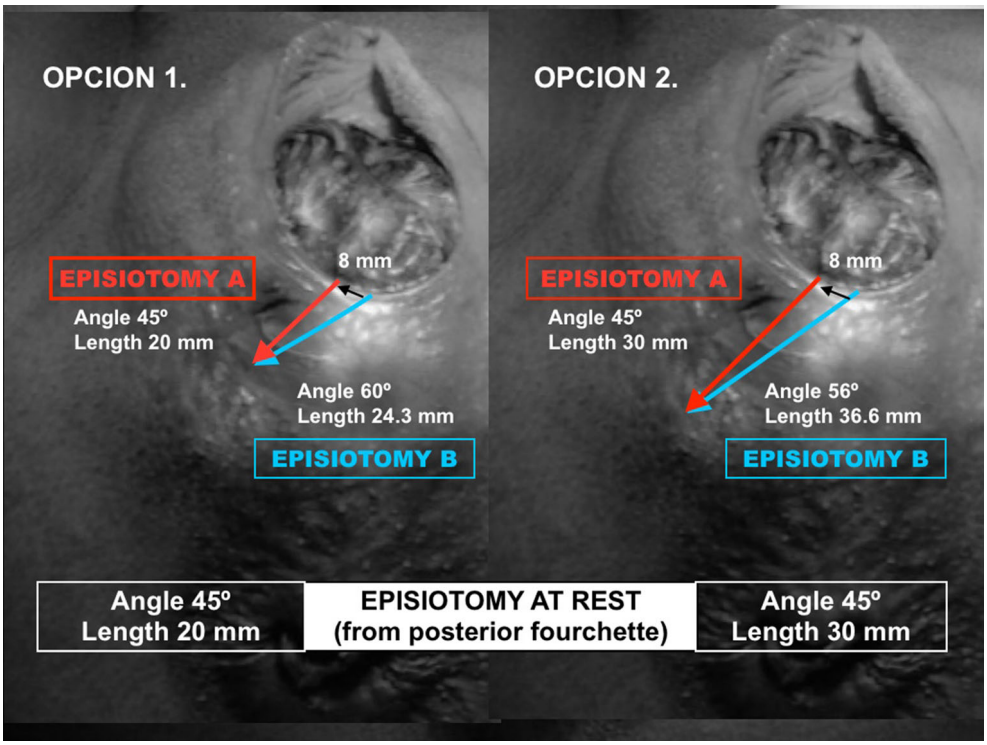

Fig. 2 Incision options at time of fetal head crowning to insert an episiotomy suture from posterior fourchette with an angle of 45° and a length of 2 ot 3 cm

This degree of perineal distension has been observed even when performing episiotomies at 60° with the Episcissors-60TM (Medinvent Ltd., Romsey, UK) in instrumental (43°) [13] and spontaneous (50°) deliveries [14]. From our study data, we explain these changes in angle due to perineal distension at the time of the crowning of the fetal head, which causes a linear displacement of the perineum in the ventral and lateral directions. Also, stereophotogrammetry data showed this linear distension in the same direction as our report in the studied area [10]. However, Eliashiv et al. [15] suggested a perineal distension in angular terms of 30° from the first stage of labor to crowning.

If a mediolateral episiotomy is performed to reduce anal sphincter injury, then this angle must be great enough that the incision and any potential subsequent tearing are far enough away from the anal sphincters that they are not injured [16]. If the angle at which the incision is made differs from that which exists after the repair, then which angle is the most appropriate? Following findings in our study, we suggest using specific angles when employing the mediolateral technique, depending on the distance to fourchette at which the incision is made. This is not a new observation, but its quantification depending on the distance to the fourchette and the length of episiotomy cut is. All this suggests a modification of episiotomy cut (with multiple options), which may increase accuracy for a suitable surgical wound suture angle of 45°.

This study has limitations. Comparison of 2D images for a description of the deformation of a 3D object does not seem to be sufficient. The results must therefore be interpreted with caution. As the studied measurements are collected before birth, we do not know whether they are similar to after birth. Perineal distension and edema (caused by fetal head crowning) creates changes in the perineum with respect to before active pushing, but measurements may be similar after a few days when these changes disappear in the immediate postpartum. Another limitation is that we only know changes that occur on each of the five lines drawn, not around the entire perineum.

In conclusion, perineal distension at the time of fetal head crowning causes a linear displacement of the perineum in ventral and lateral directions, and this is the cause of difference in episiotomy angle between incision and suture. Therefore, to perform an episiotomy suture from the posterior fourchette with an angle of 45°, theoretically, there are several incision options to use a less acute angle when the introitus cut is closer to the posterior fourchette (between 45° in 6 mm and ~60° in the fourchette) and a sharper angle for a longer episiotomy length. These results are consistent with the established definition of mediolateral episiotomy (with 3 mm of the midline in the posterior fourchette and directed laterally at an angle of at least 60° from the midline toward the ischial tuberosity) [17]. Our study opens new lines of research into options for episiotomy angle.

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Compliance with ethical standards

Financial disclaimer None.

Conflicts of interest None.

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Full length article

Which characteristics of the episiotomy and perineum are associated with a lower risk of obstetric anal sphincter injury in instrumental deliveries

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ABSTRACT

Objetive: Operative vaginal delivery (OVD) is the most important risk fact for obstetric anal sphincter injury (OASI). Knowledge of possible risk factors for their occurrence may therefore reduce the likelihood of faecal incontinence. The aim is to analyse the effect of mediolateral episitomy and perineum characteristics on the occurrence of OASI in OVD.
Study Design: Case-control study, which included 958 OVD that were reviewed in *Pelvic Floor and Puerperium Clinic*. The episiotomy and perineum characteristics of those women who experienced OASIs (n = 150) were compared with those who had no evidence of anal sphincter injury (n = 788).
Results: In multivariate logistic regression analysis the factors which were independently associated were nulliparity, persistent occipitoposterior position, birthweight >3500 g, an angle of episiotomy <30°, a distance episiotomy-fourchette <5 mm and a distance of perineal body <30 mm. The analysis of subgroups show that only the multiparous women does not benefit from any feature of the episiotomy, and an angle greater than 30° and a distance episiotomy-fourchette >5 mm are associated with a risk reduction of OASI in nulliparous, perineal bodies ≤30 mm and occipitoanterior position.
Conclusions: Two modifiable risk factors at the time of performing the episiotomy, the angle and distance episiotomy-fourchette, have been identified as the risk modification of OASI. It is necessary to achieve an adequate angle to reduce the probability of OASIs in OVD, and in nulliparous women with an anterior position and a distance of perineal body ≤30 mm could benefit from increasing the episiotomy-fourchette distance.

Introduction

Obstetric anal sphincter injuries (OASIs) are the leading cause of anal incontinence (AI) in women [1]. Thirty percent of women were symptomatic one year after OASI [2], and at 25-year revealed persistent AI in 40% [3].

Operative vaginal delivery (OVD) is used to facilitate childbirth and to avoid cesarean section delivery (CS) and its associated morbidities. Nevertheless, operative techniques are associated with a greater tendency for birth injury than spontaneous delivery [4]. OVD has been shown to be a significant contributor to the number of OASIs [5–7]. Episiotomy has traditionally been a routine component of OVD, the aim being to avoid injury to the anal sphincter and to minimise the risk of pelvic floor dysfunction in later life. In the only randomized clinical trial (RCT) comparing routine versus restrictive use of episiotomy for instrumental delivery, routine use of episiotomy was not associated with a statistically significant difference in the incidence of OASIs (8.1% vs. 10.9%) [8]. However, subsequently and with regard to the same population, Macleod et al. [9] found that restrictive use of episiotomy for instrumental delivery may increase immediate postpartum morbidity, in particular the incidence of perineal pain and stress urinary incontinence. The latest Cochrane review recommends that further research in instrumental delivery may help to clarify routine episiotomy is useful in this particular group [10].

Abbreviations: OVD, operative vaginal delivery; OASI, obstetric anal sphincter injury; AI, anal incontinence; CS, cesarean section delivery; RCT, randomized clinical trial.

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There is growing evidence that the exact placement of episiotomy plays an important role in the degree of perineal trauma [11–16]. This has also been evaluated in instrumental deliveries [17]. Mediolateral episiotomy is a compromise between midline and lateral episiotomy. The use of instrumental delivery in combination with midline episiotomy was associated with a significant increase OASIs risk in both primiparous and multiparous women [18,19]. However two large retrospective population-based register studies have suggested that mediolateral episiotomy reduces the risk of OASIS in instrumental delivery [20,21], and the lateral episiotomies are associated as a protective factor [22].

A wide variety in the clinical performance of mediolateral episiotomy has been observed between countries and institutions [23] as well as between the accoucheurs in the same institution [24–26]. Some authors have found an association between an angle too acute, or too wide [27] and the risk of OASIs, the instrumental deliveries with an acute angle was a also risk factor [17]. Stedenfeldt27 found that an episiotomy shorter or with introitus onset closer to fourchette is associated with an increased risk of anal sphincter injury. However in instrumental delivery there is no association with other episiotomy characteristics [17].

This study is designed to analyse the effect of characteristics of mediolateral episitomy and distances of perineum on the occurrence of anal sphincter injury in OVD using the data from our database.

Materials and methods

Study population

This is a observational retrospective case-control study, which included all OVDs which were reviewed in *Pelvic Floor and Puerperium Clinic* in a single tertiary centre from January 2012 to June 2017. The episiotomy features of these women who experienced OASIs and were diagnosed in the delivery room (the OASIs group), were compared with those who had no evidence of anal sphincter injury (the control group). OASI was defined as any rupture involving the anal sphincter muscles with or without rupture of the anal mucosa clinicallly diagnosed in the delivery room. Women without episiotomy or twin deliveries were excluded from analysis. The study protocol was approved by the local Research Ethics Board.

The indications for OVD at our center are prolonged second stage and non-reassuring fetal heart rate. We performed only low or outlet instrumental deliveries. The OVD were divided into three groups: a) Vacuum extractors (VE) (including: Ventouse/suction or Kiwi delivery); b) Forceps deliveries (including: Forceps or Thierry's spatulas), and c) Sequential deliveries (which include the different combinations of at least two types of instrumental deliveries). The choice of operative delivery for the initial attempt was left to the discretion of the attending physician. In the absence of epidural analgesia, local infiltration was usually added.

All instrumental deliveries were cited in *Pelvic floor and Puerperium Clinic* between the 8th and 12th weeks after delivery. On this visit, a history was taken and a complete examination were performed, including assessment of episiotomy and perineum. With the patient in lithotomy position and legs resting in knee holders, the perineum and episiotomy scar was assessed and the following characteristics were measured (Fig. 1): 1) Angle of episiotomy (angle between the episiotomy and the midline, which was measured using a digital goniometer in degrees), 2) Length of episiotomy, 3) Distance episiotomy-fourchette (the distance from the origin of the episiotomy scar in the introitus to the fourchette), 4) Distance of perineal body, and 5) Distance of genital hiatus. Distances were measured in millimetres. Two types of episiotomy in terms of their relationship to the anus can be observed (Fig. 1), the type I was defined when the end of episiotomy scar was below the anus, and the type II when above [17].

Data collection

Data for the study were drawn from the computerized puerperium records and their linked maternal hospital discharge records. All characteristics known from the literature as a possible risk factor, and available from the database, were analysed in this study as potential attributing factors for anal sphincter injury in assisted vaginal

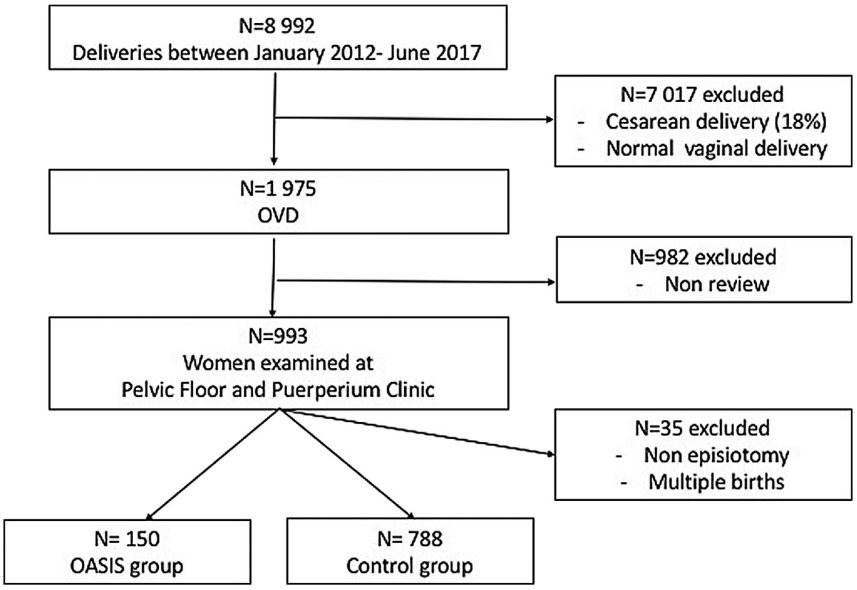

Fig. 1. The flow diagram of the included patients. OVD: Operative Vaginal Delivery. OASI: Obstetric Anal Sphincter Injuries.

deliveries. These factors were: matenal age, race, gestational diabetes, parity, gestational age, induction of labor, occipitoposterior position, mode of OVD, epidural anesthesia, duration of second stage, and fetal birthweight. The characteristics of the episiotomy (angle, length and distance to fourchette) and the distance of the perineal body and the genital hiatus were also collected.

Data analysis

Categorical variables were evaluated using a chi-square test analysis, and the Mann-Whitney U test was used for continuous non-parametric variables and the Student-t test for continuous parametric. The Kolmogorov-Smirnov test was used to evaluate continuous data for normality prior to significance testing.

In order to account for the potentially confounding effect of differences in demographic, delivery and episiotomy characteristics between groups, a logistic regression model to predict OASIS was created using factors found to be significant in bivariate analyses. Prior to this the continuous variables were transformed into a dichotomous variable. Receiver operating characteristic (ROC) curve analysis was used to determine optimal cut-off values for episiotomy characteristics to predict any OASI risk. We defined the best cut-off value as the value with the highest accuracy which maximizes the Youden index (sensitivity + specificity-1).

Subgroup analyses were performed for the characteristics of the episiotomy that were associated with OASIS by dividing group according to predictive factors of OASI in the multivariate analysis.

Differences were considered significant when the probability value was 0.05. All data were managed and analyzed using the SPSS software (version 20.0 for Mac; SPSS Inc, Chicago, IL).

Results

Demographic, obstetrical and delivery characteristics

During the study period at our center, 1975 out of a total 8992 deliveries (21%) were OVD. The overall rate of episiotomy in all births was 45%. The rate of episiotomies and OASIs for OVD was 97% and 7.85% respectively (the rate of OASI for sequential, Espatulas, Forceps, Vaccum and Kiwi: 26.7%, 17.4%, 5.6%, 8.16% and 5.1% respectively). During this period 958 women with OVD were examined at the *Pelvic Floor and Puerperium Clinic,* and were included in this study, 150 of whom in the OASIs group and 788 in the control group. Thirty-five women were excluded due to twin delivery or no episiotomy. Fig. 1 illustrates the selection of study participants as a flow diagram. The demographic, obstetrical and delivery characteristics of the women in the OASIs and control group are presented in Table 1. Women in the OASIs group were more likely to be nulliparous (95.6% vs 89.1%, p = 0.023), and delivered at a more advanced gestational age (281 vs 280 days, p = 0.049). The OASIs group was characterized by higher rates of persistent occiput posterior position (32.5% vs 22%, p = 0.03) and a significantly higher neonatal birth weight (3388 g vs 3292 g, p = 0.037). There were no differences between the groups with regard to maternal age, nationality, gestational diabetes, weight gain, labor induction, meconium, mode of OVD, experience of the obstetrician, epidural analgesia, duration of labor, fetal sex, umbilical pH or Apgar (Fig. 2) (Table 2).

Episiotomy characteristics

On univariate analysis of episiotomy characteristics, the OASIs group was characterized by lower angle of episiotomy (30° Vs 22°, p < 0.0001), lower distance of perineal body (30 mm Vs 32.5 mm, p < 0.0001) and lower distance episiotomy-fourchette (4 Vs 3 mm, p = 0.002). Women with episiotomy type I were significantly more common in OASIs group (34.8% vs 16.7, p < 0.0001).

Table 1
Characteristics of Operative Vaginal Delivery with and without OASI.

Characteristics	No OASI n = 788	OASI n = 150	ρ value
Patient characteristics			
Maternal age (years)*	33.22 (5.17)	32.01 (5.37)	0.03[a]
Spanish (%)	91.4	91.9	NS[c]
Gestational diabetes (%)	4.4	4.7	NS[c]
Nulliparity (%)	89.1	95.6	0.023[a]
Gestational age (days)**	280 (275-285)	281 (276-287)	0.049[b]
Weight gain (Kg)**	12 (10-16)	12 (10-15.25)	NS[b]
Delivery characteristics			
Prostaglandins Induction (%)	11.7	15.3	NS[c]
Meconium (%)	22.3	15.2	NS[c]
Occipitoposterior position (%)	22	32.5	0.03[c]
Mode of delivery (%)			NS[c]
Sequential	9.1	14.9	
Espatulas	2.9	1.2	
Forceps	45.2	50.3	
Vacuum	23.6	17.4	
kiwi	19.2	16.1	
Experience obstetrician >10 years (%)	52.9	57.8	NS[c]
Epidural anesthesia(%)	94.6	95.6	NS[c]
Duration of stage labor (min)			
1 st Stage labor**	240 (161-330)	240 (180-330)	NS[b]
2nd stage labor**	94 (30-150)	90 (45-135)	NS[b]
Neonatal characteristics			
Male (%)	55.7	58,8	NS[c]
Birthweight >3500 g (%)	27.3	37.8	0,007[c]
Apgar score <5 at 1 min (%)	5	7.6	NS[c]
Apgar score <7 at 5 min (%)	2	3.1	NS[c]
Umbilical artery pH < 7.20 (%)	37	34	NS[c]

[a] Student's test.
[b] Mann-Whitney U test.
[c] Chi-Square test.
* Mean(SD).
** Median(Interquartile range); NS: Not Significant.

Risk factors for oasis: multivariate analysis

In order to identify independent risk factors for OASIs, we used multivariate logistic regression analysis to control for potential confounders (Table 3). The factors that were independently associated with OASIs in OVD were the nulliparity, persistent occipitoposterior position, birthweight >3500 g, an angle of episiotomy <30°, a distance episiotomy-fourchette >5 mm and a distance of perineal body <30 mm.

The angle of episiotomy behaves as a factor associated to anal sphincter injury, so women with a mediolateral episiotomy and an angle of greater than 30° have an 81% less risk of having an OASIS (OR 0.19,95% CI 0.12–0.31). The odds ratio estimates show that there is a 48% (OR 0.52,95% CI 0.31–0.88) and 63% (OR 0.23,95% CI 0.23–0.58) reduced risk of sustaining an anal obstetric sphincter rupture when the distance episiotomy-fourchette was >5 mm and distance of perineal body was >30 mm, respectively.

Characteristics of episiotomy and perineum in subgroup analysis

In the analysis of subgroups (Table 4) to assess the association between the characteristics of episiotomy and perineum with the risk of OASIs, we found that an angle of the episiotomy greater than 30° behaves as a protective factor in all subgroups with a risk reduction of 80%, except in multiparous women, where there is no association with any characteristics. A length of episiotomy >30 mm and a distance of genital hiatus >25 mm, as in global analysis, are not associated with increased risk of OASIS in any subgroup. A distance episiotomy-fourchette >5 mm is associated with a risk reduction of OASIS of 50%, only in women with perineal body less than or equal to 30 mm (OR 0.46,95% CI 0.25–0.83), nulliparous (OR 0.46,95% CI 0.27–0.78) and occipitoanterior position(OR 0.54,95% CI 0.3–0.96). A lower distance of perineal

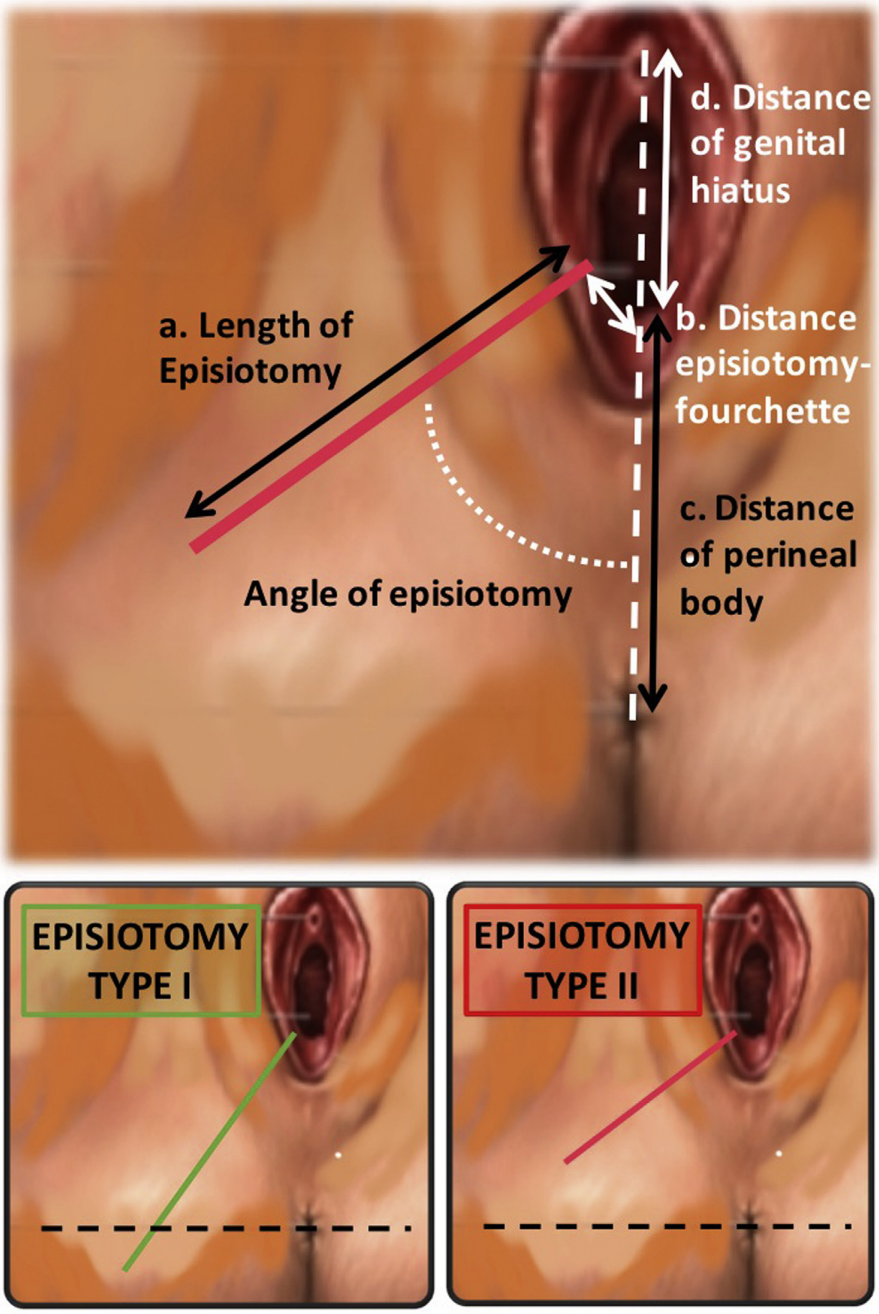

Fig. 2. Characteristics and types of episiotomies.

body is associated with an increased risk of OASIS, whether it is greater or less than 30 mm. However a distance of perineal body >30 mm is only associated with a reduction in the risk of sphincter injury in nulliparous women (OR 0.42,95% CI 0.27–0.65) and in occipitoanterior positions (OR 0.28,95% CI 0.17–0.46).

Discussion

Main findings

The main risk factors of OASIs in the OVD are nulliparity, persistent occipitoposterior position, birthweight >3500 g and a distance of perineal body ≤30 mm. We also find two protective factors which can be modified by the obstetrician at the time of performing the episiotomy, such as an angle of episiotomy >30° and a distance episiotomy-fourchette >5 mm. Except in the case of multiparous women, where they do not benefit from any feature of episiotomy to reduce the risk of OASIs, an adequate angle is the most important modifiable protective factor. In addition, the nulliparous women with an anterior position and a distance of perineal body ≤30 mm could benefit from increasing the episiotomy-fourchette distance to reduce the risk of sphincter injury.

This outcome is clinically relevant because episiotomy technique is relatively easy to modify, and our findings suggest that

Table 2
Characteristics of episiotomy with and without OASI in OVD.

Characteristics of episiotomy (Quantitative variables)	No OASI n = 788	OASI n = 150	ρ value
Angle			
Angle of episiotomy (º)*	32 (14)	23 (9)	<0,0001[a]
Angle of episiotomy >30º (%)	53.0	18.4	<0.0001[b]
Distance			
Length of episiotomy (mm): distance a*	35 (5)	30 (10)	NS[a]
Length of episiotomy >30 mm (%)	49.7	44.7	NS[b]
Distance episiotomy-fourchette (mm): distance b*	4 (5)	3 (4)	0.002[a]
Distance episiotomy-fourchette >5 mm (%)	29.9	19.2	0.007[b]
Distance of perineal body (mm): distance c*	35 (10)	30 (10)	<0.0001[a]
Distance of perineal body >30 mm (%)	52.1	34.5	<0.0001[b]
Distance of genital hiatus (mm): distance d*	25 (5)	25 (10)	0.004[a]
Distance of genital hiatus >25 mm (%)	47.4	40.8	NS[b]
Classification of episiotomies (%)			<0.0001[b]
Epsiotomy type I (%)	16.7	34.8	
Episiotomy type II (%)	83.3	65.2	

NS: Not Significant.
* Median(Interquartile range).
[a] Mann-Whitney U test.
[b] Chi-Square test.

Table 3
Factors that predict OASIS in OVD.

Factors	Wald	ρ value	OR* crude	IC 95%
Maternal age <35 years	1.12	NS		
Nulliparity	4.45	0.035	0.31	0.1-0.9
Gestational age >40 weeks	0.87	NS		
Occipitoposterior position	16.77	0.001	0.31	0.18-0.54
Birthweight >3500 g	7.34	0.007	0.62	0.43-0.87
Angle of episiotomy > 30º	44.68	0	0.19	0.12-0.31
Distance episiotomy-fourchette > 5 mm	5.76	0.016	0.52	0.31-0.89
Distance of perineal body > 30 mm	18.32	0	0.37	0.23-0.58

Values reflect the results of multivariate logistic regression analysis that controlled for the variables that are detailed in Tables 1 and 2.

modified practice would potentially lead to reduction in anal sphincter injury rates, especially in a risk group such as instrumental deliveries.

Strenghs and limitations

The strength of this study is the large number of analyzed deliveries collected in a prospective way. The weaknesses are the retrospective study design, the characteristics of mediolateral episitomy are collected weeks after delivery, only 50% of the OVD of the study period attended at *the pelvic floor and puerperium Clinic* and the small sample size of the multiparous subgroup. The results should therefore be interpreted with caution.

As the measures studied were collected a few weeks after birth, we do not know the true measures of the episiotomy at birth. The perineal distension and oedema caused by the crowning of the head and subsequent retraction by the healing process cause changes in episiotomy between at the time of incision and puerperium control. Therefore, the measurements in this study are necessarily smaller than at the time of performing the episiotomy. So we should consider three different angles of episiotomy in three periods: a) Incision, b) repair and c) scar. It has been shown that an average difference between angle at incision and repair of 15–20° [28–30,32]. Another study has shown that the angle varies as a function of the distance to fourchette at which the introitus episiotomy begins [31]. On the other hand, the length of the perineal body is modified increasing up to 50% from the first stage to crowning [33,34].

Despite the weaknesses of this study, the evident and considerable protective effect of the episiotomy angle and the distance episiotomy-fourchette clearly is of clinical importance.

Interpretation

Tincello et al. [24] were the first to question the technique of mediolateral episiotomy and to raise the issue of the degree of force relief upon the perineum related to the angle of episiotomy. Later on, Andrews et al. [25] with an observational study and Eogan et al. [13] and Stedenfeldt et al. [27] with case–control studies showed differences in the characteristics of episiotomies in women with anal sphincter injury. Eogan et al. [13] only studied the angle of episiotomy. Andrews et al. [25] also studied the length and depth but only finding differences in the angle. Stedenfeldt et al. [27] added distance episiotomy-fourchette and found an association with that distance, the depth and length of the episiotomy, but not in the angle or the perineal body. A recent random study in nulliparous found 2.4% OASI when the episiotomy angle was performed at 60° versus 5.5% if it were 40°, although the difference was not statistically significant due to the small sample size [30].

Finally a prospective case-control study also found that when a mediolateral episiotomy is performed in OVD, the technique has a strong effect on the occurrence of OASIs, and an angle greater than 20° have an 87% lower risk [17], but no association with other characteristics of the episiotomy was found. Our study confirms the important relationship between the angle of the episiotomy and the risk of OASI in OVD and also finds association with other parameters, such as distance to fourchette.

Conclusions

OVD is the most important risk fact for OASI. In daily obstetric practice, the use of OVD is necessary in the case of fetal distress or prolonged second stage of labor. Knowledge and modification of attributive risk factors may help reduce the number of anal sphincter injuries during OVD, may therefore reduce the likelihood of faecal incontinence. The obstetrician determines two factors when performing an episiotomy which can modify the risk of OASI: the angle and the episiotomy-fourchette distance. Only the multiparous subgroup does not benefit from any feature of the episiotomy. It is necessary to achieve an adequate angle >30° to reduce the probability of OASIs in OVD, as well as an adequate

Table 4
Characteristics of episiotomy in subgroup analysis.

Characteristics	Univariate analysis			Multivariate analysis		
	OR	95% CI	ρ-value	Adjusted[a] OR	95% CI	ρ-value
Perineal body						
				≤30 mm		
Angle of episiotomy > 30°	0.19	0.11–0.33	0.000	0.16	0.09–0.3	0.000
Length of episiotomy > 30 mm			NS			
Distance episiotomy-fourchette > 5 mm	0.5	0.29–0.87	0.014	0.46	0.25–0.83	0.01
Distance of perineal body (mm)	0.91	0.86–0.96	0.001	0.9	0.84–0.97	0.005
Distance of genital hiatus > 25 mm			NS			
				>30 mm		
Angle of episiotomy > 30°	0.22	0.1–0.45	0.000	0.17	0.07–0.4	0.000
Length of episiotomy > 30 mm			NS			
Distance episiotomy-fourchette > 5 mm			NS			
Distance of perineal body (mm)	0.088	0.8–0.97	0.011	0.85	0.76–0.95	0.000
Distance of genital hiatus > 25 mm			NS			
Parity						
				Nulipara		
Angle of episiotomy > 30°	0.20	0.13–0.31	0.000	0.21	0.13–0.34	0.000
Length of episiotomy > 25 mm			NS			
Distance episiotomy-fourchette > 5 mm	0.51	0.32–0.8	0.004	0.46	0.27–0.78	0.004
Distance of perineal body > 30 mm	0.47	0.32–0.68	0.000	0.42	0.27–0.65	0.000
Distance of genital hiatus > 25 mm			NS	NS		
				Multipara		
Angle of episiotomy > 30°			NS			
Length of episiotomy > 25 mm			NS			
Distance episiotomy-fourchette > 5 mm			NS			
Distance of perineal body > 30 mm			NS			
Distance of genital hiatus > 25 mm			NS			
Fetal head position						
				Occipitoposterior		
Angle of episiotomy > 30°	0.22	0.09–0.55	0.001	0.19	0.07–0.54	0.002
Length of episiotomy > 25 mm			NS			
Distance episiotomy-fourchette > 5 mm			NS			
Distance of perineal body > 30 mm			NS			
Distance of genital hiatus > 25 mm			NS			
				Occipitoanterior		
Angle of episiotomy > 30°	0.19	0.11–0.31	0.000	0.17	0.1–0.3	0.000
Length of episiotomy > 25 mm			NS			
Distance episiotomy-fourchette > 5 mm	0.63	0.37–0.95	0.071	0.54	0.3–0.96	0.035
Distance of perineal body > 30 mm	0.35	0.22–0.54	0.000	0.28	0.17–0.46	0.000
Distance of genital hiatus > 25 mm			NS			

Characteristics	Univariate analysis			Multivariate analysis			Univariate analysis			Multivariate analysis		
	OR	95% CI	ρ-value	OR	95% CI	ρ-value	OR	95% CI	ρ-value	OR	95% CI	ρ-value
Perineal body			≤30 mm						>30 mm			
Angle of episiotomy > 30°	0.19	0.11–0.33	0.000	0.16	0.09–0.3	0.000	0.22	0.1–0.45	0.000	0.17	0.07–0.4	0.000
Length of episiotomy > 30 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm	0.5	0.29–0.87	0.014	0.46	0.25–0.83	0.01			NS			
Distance of perineal body (mm)	0.91	0.86–0.96	0.001	0.9	0.84–0.97	0.005	0.088	0.8–0.97	0.011	0.85	0.76–0.95	0.000
Distance of genital hiatus > 25 mm			NS						NS			
Parity			Nulipara						Multipara			
Angle of episiotomy > 30°	0.20	0.13–0.31	0.000	0.21	0.13–0.34	0.000			NS			
Length of episiotomy > 25 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm	0.51	0.32–0.8	0.004	0.46	0.27–0.78	0.004			NS			
Distance of perineal body > 30 mm	0.47	0.32–0.68	0.000	0.42	0.27–0.65	0.000			NS			
Distance of genital hiatus > 25 mm			NS	NS					NS			
Position			Occipitoposterior						Occipitoanterior			
Angle of episiotomy > 30°	0.22	0.09–0.55	0.001	0.19	0.07–0.54	0.002	0.19	0.11–0.31	0.000	0.17	0.1–0.3	0.000
Length of episiotomy > 25 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm			NS				0.63	0.37–0.95	0.071	0.54	0.3–0.96	0.035
Distance of perineal body > 30 mm			NS				0.35	0.22–0.54	0.000	0.28	0.17–0.46	0.000
Distance of genital hiatus > 25 mm			NS						NS			

CI, confidence interval; OR, odds ratio.
[a] Adjusted for: maternal age, parity, daytime obstetrics, birthweight, fetal head position.

distance to fourchette (>5 mm) in nulliparous, perineal bodies ≤30 mm and occipitoanterior position.

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Contribution to authorship

- E Gonzalez Díaz: Conception and Design, Data collection, Data analysis, Manuscript writing
- C Fernández Fernández: Manuscript writing
- JM Gonzalo Orden: Supervision
- A Fernández Corona: Supervision

All authors assisted in the critical revision of the manuscript and have read and approved the final version of the article.

Ethical approval

The *Comité Etico de Investigacion Clinica de Leon* approved the study protocol.

Disclosure of Interests

None declared.

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CLINICAL ARTICLE

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Incidence of obstetric anal sphincter injuries after implementing the Triepi-45 tool to improve episiotomy angle in instrumental deliveries

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Abstract

Objective: To assess the impact of Triepi-45—a tool that enables an episiotomy angle of 45° to be marked on the perineum at rest—on the incidence of obstetric anal sphincter injuries (OASIS) during operative vaginal delivery (OVD).

Method: A retrospective–prospective cohort study was performed among successive women who underwent OVD at Complejo Asistencial Universitario de de León, Spain, between 2011 and 2013 (preintervention cohort, n=986) and between 2014 and 2016 (intervention cohort, n=986) after implementation of an interventional programme in 2013 to improve the episiotomy angle, including use of Triepi-45, in OVD.

Results: The intervention cohort had a lower incidence of OASIS than the preintervention cohort (70/986 [7.1%] vs 93/986 [9.4%]), but the difference was not significant, owing to the low use of Triepi-45 in the intervention cohort (n=375). However, the OASIS incidence was significantly lower in the Triepi-45 cohort than in the preintervention cohort (18/375 [4.8%] vs 93/986 [9.4%]; odds ratio, 0.47; 95% confidence interval, 0.26–0.86).

Conclusion: Use of Triepi-45 had a positive impact on reducing OASIS in OVD. It remains essential to raise obstetricians' awareness of the importance of the episiotomy angle and to implement the systematic use of tools to reduce the incidence of OASIS.

KEYWORDS

Episiotomy angle; Obstetric anal sphincter injuries; Operative vaginal delivery; Triepi-45

1 | INTRODUCTION

Despite adequate primary repair at delivery, approximately 30%–50% of women with a clinically recognized third- or fourth-degree perineal laceration experience long-lasting symptoms of anal incontinence.[1,2] The complications after obstetric anal sphincter injuries (OASIS) may be devastating; therefore, reducing the incidence of this condition and its associated sequelae by raising standards of clinical practice is an important step in improving the quality of obstetric care.[3]

Operative vaginal delivery (OVD) is associated with a high risk of obstetric injury relative to spontaneous delivery, and is a significant contributor to OASIS.[4–6] Episiotomy, which aims to avoid anal sphincter injury, is often a routine component of OVD. Whereas the combination of instrumental delivery and midline episiotomy has been associated with an increased risk of OASIS,[7,8] mediolateral[9,10] and lateral[11] episiotomies have a lower risk.

There is wide variation in the technique used for mediolateral episiotomy between countries and institutions,[12] and even among different healthcare professionals in the same institution.[13–15] Furthermore, the exact placement of this type of episiotomy has been shown to be important in the resulting degree of perineal trauma.[14,16,17] In instrumental deliveries, in particular, the angle

of the episiotomy has been associated with the risk of sphincter injury,[18,19] so that a suture angle greater than 30° has an 80% lower risk of OASIS during a OVD.[19]

Perineal distension at the moment of fetal head crowning leads to displacement of the perineum, resulting in a difference in the angle between the episiotomy incision and suture.[20–22] Therefore, at the study institution, it was considered that the appropriate angle to obtain a suture angle of 45° should be marked on the perineum at rest, and the incision should be made above this line when the fetal head is crowning. The aim of the present study was to assess the impact of an interventional programme to optimize the episiotomy angle of OVD to reduce the incidence of OASIS.

2 | MATERIALS AND METHODS

The present retrospective–prospective cohort study was conducted among women who delivered by OVD at the Complejo Asistencial Universitario de León (CAULE), León, Spain; a hospital with an average of 2000 deliveries per year, 21% of which are instrumental deliveries. Data were collected from two cohorts: a retrospective cohort who delivered before (November 10, 2011, to, November 31, 2013), and a prospective cohort who delivered after (February 1, 2014, to March 3, 2016) implementation of an interventional program designed to improve the angle of the episiotomy using Triepi-45, a tool that enables a 45 degree angle to be marked in the perineum. The study protocol was approved by the local Research Ethics Board (Comite Etico de Investigacion Clinica de Leon). All data were analyzed anonymously.

In November 2013, the preliminary results of a case–control study[18] at the study institution demonstrated that the episiotomy angle in OVD is an important risk factor for sphincter injury. As a result, it was considered how clinical practice might be improved to reduce the incidence of OASIS, especially during OVD. The institution's protocols for making obstetricians aware of the importance of an adequate mediolateral episiotomy technique were reviewed, and systematic use of Triepi-45 in OVD was implemented.

The Triepi-45 tool enables an appropriate angle to be marked on the perineum (Fig. 1). It is a paper square of 30 mm, which is bent along a diagonal to create two straight isosceles triangles. One triangle is

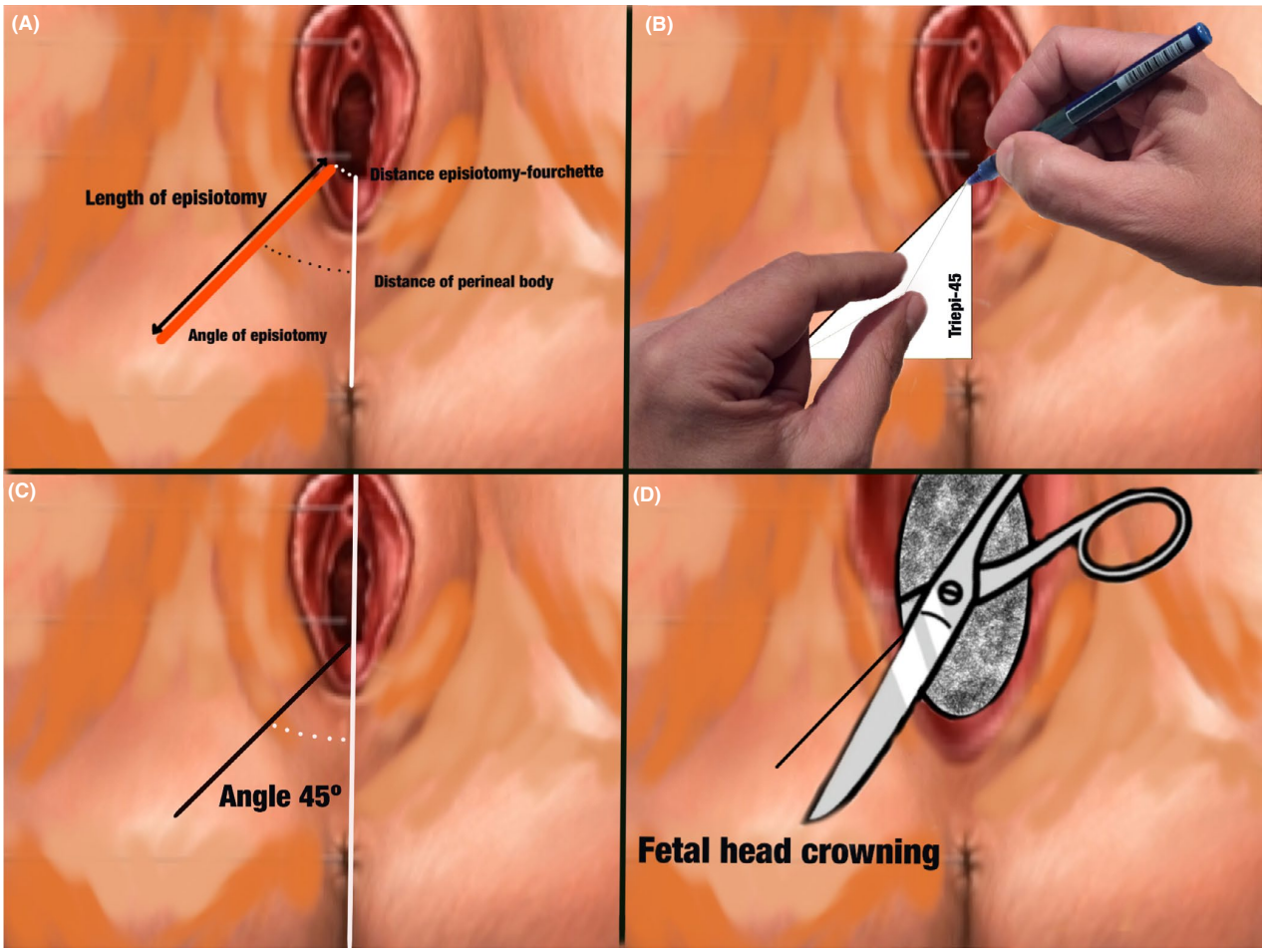

FIGURE 1 Use of Triepi-45. (A) Characteristics of the perineum and episiotomy. (B) Placement of Triepi-45 on the perineum at rest for marking. (C) Perineum at rest marked with an angle of 45°. (D) Incision made on the previously marked line at the time of head crowning.

placed on the perineum at rest (while the other triangle is used to hold it in place), with one side on the midline and one vertex at the level of the vulvar fourchette (Fig. 1B). A line is then drawn with a marker on the diagonal side from the fourchette to the end of the triangle (Fig. 1C). When the fetal head is crowning, the episiotomy incision is made above the marked line (Fig. 1D).

Between December 2013 and January 2014, the whole Obstetrics Department of CAULE completed an educational program including information about the preliminary results of the study,[18] the changes made to delivery protocols, and the use of Triepi-45 in OVD. The changes made to the protocols were implemented from January 1, 2014, onward.

At CAULE, the indications for OVD are prolonged second stage and non-reassuring fetal heart rate, and instrumental delivery is performed only for low or outlet head positions. For the present analysis, OVDs were classified into two groups: vacuum extraction, including Ventouse/suction and Kiwi delivery; and forceps delivery including forceps and Thierry spatulas. The choice of OVD was made by the attending physician. In the absence of epidural analgesia, local infiltration was usually given.

The attending physician also evaluated and classified the degree of perineal tear. In cases of OASIS, standardized surgical repair was performed under the direct surveillance of an experienced obstetrician. OASIS was defined as any degree of injury in the anal sphincter muscle classified as follows: 3A (<50% of the external anal sphincter depth torn), 3B (>50% of the external anal sphincter depth torn), 3C (internal anal sphincter torn, with or without torn external anal sphincter), and 4 (injury of the anal sphincter complex and anorectal epithelium).[23]

Women with OVD were followed up at the Pelvic Floor and Puerperium Clinic at 8–12 weeks postpartum. The women underwent a complete examination, including assessment of the episiotomy scar and perineum in the lithotomy position with legs resting in knee holders. The following characteristics were recorded (Fig. 1A): angle of episiotomy (between the episiotomy and the midline, measured by a digital goniometer in degrees; length of episiotomy (in mm); episiotomy–fourchette distance (from the origin of the episiotomy scar in the introitus to the fourchette, in mm); and length of perineal body (in mm).

For the analysis, the sample size was calculated on the basis of a prevalence of OASIS in instrumental deliveries of 8.5% before implementation of the intervention. It was assumed that this prevalence would remain unchanged in the control group, and there would need to be a reduction of 40% or greater in the incidence of third- or fourth-degree tears in the intervention group to observe a statistically significant difference. Thus, a sample size of 986 participants per group was needed to achieve 80% power to detect a significant difference with a two-sided type I error rate of 5%.

For the control group, data were collected retrospectively from 986 consecutive women with OVD between November 10, 2011, and November 30, 2013. For the intervention cohort, data were collected prospectively from 986 consecutive women with OVD between February 1, 2014, and March 3, 2016. Preterm deliveries (<34 gestational weeks) and failed instrumental deliveries in which a cesarean was performed were excluded (Fig. 2).

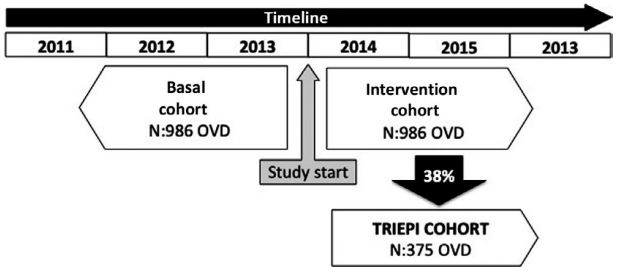

FIGURE 2 Timeline of the two cohorts. OVD: Operative Vaginal Delivery.

Data were obtained from the hospital's obstetric database and puerperium records. Potential risk factors for OASIS in assisted vaginal deliveries[19] that were available from the database were analyzed, including maternal age, gestational age, weight gain, race, parity, previous cesarean delivery, twin pregnancy, type of OVD, episiotomy, epidural analgesia, induction of labor, occipitoposterior position, induced labor, duration of first and second stage labor, fetal sex, birthweight, Apgar score, and umbilical artery pH. Episiotomy characteristics (angle, length, and distance to fourchette) and length of perineal body were also collected.

Data from the preintervention cohort were compared with those of the intervention cohort, and those of the cohort of deliveries using Triepi-45 (Triepi-45 cohort). The primary outcome was OASIS incidence. The null hypothesis was that the incidence of OASIS in the two study periods would be the same.

All data were managed and analyzed by using SPSS version 20.0 for Mac (IBM, Armonk, NY, USA). Categoric variables were evaluated by χ^2 test; continuous variables were evaluated by Mann-Whitney *U* test (non-parametric variables) or Student *t* test (parametric variables). Kolmogorov-Smirnov test was used to evaluate continuous data for normality prior to significance testing. Differences were considered significant when the *P* value was 0.05 or less.

3 | RESULTS

The preintervention cohort included 986 successive OVDs; similarly, the intervention cohort included 986 OVDs. During the two time periods, the rate of OVD among all deliveries was 21.54% (986/4577) and 21.45% (986/4597), respectively ($P>0.05$).

In the intervention cohort, the Triepi-45 tool was used only for 375 (38.0%) of the 986 OVDs. The reasons for this low adherence were varied, but the three most frequent causes were physician confidence in their mediolateral episiotomy technique, emergency OVD, and the decision for instrumentation was made when the fetal head was crowning and the perineum was distended.

None of the demographic or obstetric characteristics differed between the preintervention and intervention cohorts, including maternal age at delivery, gestational age, weight gain, race, parity, previous cesarean, twin pregnancy, mode of OVD, episiotomy, epidural analgesia, induction of labor, occipitoposterior position, duration of

first and second stage labor, fetal sex, birthweight, Apgar score, and umbilical artery pH. Similarly, there were no differences in the demographic and obstetric characteristics between the preintervention cohort and the Triepi-45 cohort (Table 1).

Regarding episiotomy characteristics (Table 1), the angle of episiotomy was smaller in the preintervention cohort than in the intervention cohort (25.4° vs 29.8°, *P*=0.002), and the difference was even greater between the preintervention cohort and the Triepi-45 cohort

TABLE 1 Demographic characteristics of the study women by preintervention and intervention groups.[a]

Characteristics	Preintervention cohort (n=986)	Intervention cohort (n=986)	*P* value	Triepi cohort (n=375)	*P* value[b]
Maternal characteristics					
Age, y	32.8 ± 5.2	32.8 ± 5.5	NS	33.0 ± 5.8	NS
Gestational age, d	276.1 ± 9.6	275.4 ± 9.3	NS	275.3 ± 9.2	NS
Weight gain, kg	11.7 ± 4.8	11.9 ± 4.9	NS	11.5 ± 4.7	NS
Spanish	924 (93.7)	928 (94.1)	NS	351 (93.7)	NS
Nulliparity	779 (81.3)	58 (5.9)	NS	299 (79.8)	NS
Previous cesarean	65 (6.5)	75 (7.6)	NS	30 (8.1)	NS
Twin pregnancy	25 (2.5)	20 (2.0)	NS	8 (2.0)	NS
Delivery characteristics					
Instrumental delivery					
Vacuum/Kiwi	542 (53.8)	551 (55.9)	NS	258 (58.9)	NS
Forceps/spatulas	444 (46.2)	435 (44.1)		117 (41.1)	
Episiotomy	963 (97.8)	968 (98.2)	NS	368 (98.4)	NS
Epidural analgesia	929 (94.2)	968 (93.6)	NS	354 (94.4)	NS
Occipitoposterior position	207 (21.0)	259 (26.3)	NS	88 (23.5)	NS
Induced labor	305 (30.9)	321 (32.6)	NS	128 (34.1)	NS
Duration of stage, min					
1st stage	300 (210)	232.2 (172.8)	NS	232.2 (172.8)	NS
2nd Stage	75 (90)	90 (135)	NS	90 (135)	NS
Episiotomy characteristics					
Angle, °	25.4 ± 11.3	29.8 ± 9.5	0.002	33.8 ± 7.4	<0.001
Angle >30°	205 (20.8)	379 (38.4)	0.017	281 (75.0)	<0.001
Length, mm	30 (8.5)	35 (10)	NS	35 (10)	NS
Distance episiotomy–fourchette, mm	4 (5)	3 (4)	NS	4 (6)	NS
Distance of perineal body, mm	30 (10)	30 (5)	NS	30 (11)	NS
Distance of perineal body >30 mm	426 (43.2)	404 (41.0)	NS	197 (52.0)	NS
Neonatal characteristics					
Male	631 (64.0)	535 (54.3)	NS	204 (54.3)	NS
Birhweight, g	3361 ± 570	3305 ± 456	NS	3287 ± 442	NS
Umbilical artery pH <7.20	182 (18.5)	159 (16.1)	NS	(16.7)	NS
Apgar score <6 at 1 min	60 (6.1)	104 (10.6)	NS	36 (9.5)	NS
Apgar score <7 at 5 min	30 (3.1)	48 (4.9)	NS	20 (5.4)	NS
OASIS	93 (9.4)	70 (7.1)	0.103	18 (4.8)	0.009
Rupture grade			NS		NS
3a	55 (59.1)	33 (47.1)		9 (50.0)	
3b	30 (32.2)	33 (47.1)		8 (44.4)	
3c	6 (6.4)	2 (2.8)		1 (5.5)	
4	2 (2.1)	2 (2.8)		0 (0.0)	

Abbreviations: OASIS, obstetric and anal injuries; NS, not significant.
[a]Values are given as mean ± SD, median (interquartile range) or number (percentage).
[b]Groups were compared by Student test for mean values, Mann-Whitney *U* test for median values, and χ^2 test for percentages.

(25.4° vs 33.8°, *P*<0.001). The number of episiotomies with an angle greater than 30° was also higher in the intervention cohort than in the preintervention cohort (38.4% vs 20.8%, *P*=0.017), and even higher in the Triepi-45 cohort (75.0% vs 20.8%, *P*<0.001). Other episiotomy characteristics and length of perineal body did not differ among the three cohorts.

The proportion of instrumental deliveries with OASIS was 9.4% (93/986) before and 7.1% (70/986) after the intervention, but the difference was not significant. However, the rate of OASIS was significantly lower in the Triepi-45 cohort than in the preintervention cohort (4.8% vs 9.4%, *P*=0.009; odds ratio [OR], 0.47; 95% confidence interval [CI], 0.26–0.86). These data were used to calculate the "number needed to treat," which showed that use of the Triepi-45 tool would prevent one case of sphincter rupture for every 21.7 women treated. There was no difference in the distribution of the different grades of rupture among the cohorts.

Rates of OASIS were also compared between the preintervention cohort and the Triepi-45 cohort for different subgroups of the study population (Table 2). The OASIS incidence was not higher in the Triepi-45 group in any of the subgroups. For the following subgroups, the incidence was significantly lower in Triepi-45 cohort: women younger than 35 years, nulliparous women, women with a neonate weighing less than 3500 g, those with vacuum/Kiwi delivery, and those with a longer (>30 mm) or shorter (≤30 mm) perineal body length (Table 2).

4 | DISCUSSION

The present analysis found that an intervention programme to improve the angle of episiotomy in OVD was associated with a lower incidence of OASIS; however, statistical significance was not observed owing to the use of the Triepi-45 in only 38% of OVDs. However, comparison of the preintervention cohort with the Triepi-45 cohort showed significantly lower rates of OASIS for the Triepi-45 deliveries. Subgroup analysis showed that Triepi-45 is especially useful in reducing OASIS for younger women, nulliparous women, and those with any perineal body length, in addition to deliveries with a birthweight less than 3500 g and those by vacuum/Kiwi.

Of the risk factors for anal sphincter injuries in instrumental deliveries,[19] only the angle of the episiotomy was modified after the start of the intervention, and this change in angle had a more positive impact on reducing OASIS when Triepi-45 was used. Therefore, this improvement in the angle of episiotomy may be the cause of the reduction of sphincter injuries in OVD.

TABLE 2 Incidence of OASIS stratified by maternal and delivery characteristics of women and logistic regression analysis.[a]

Incidence of OASIS	Preintervention (n=986)	Intervention (n=375)	*P* value	Adjusted OR (95% CI)[a]
Overall	93 (9.4)	18 (4.8)	0.01	0.47 (0.26–0.86
Age at birth				
Maternal age <35 y	68/662 (10.2)	8/252 (3.2)	0.004	0.3 (0.13–0.68)
Maternal age >35 y	25/324 (7.7)	10/122 (7.5)	NS	
Parity				
Multiparity	10/83 (4.7)	2/76 (1.6)	NS	
Nulliparity	83/779 (10.4)	16/299 (5.3)	0.023	0.48 (0.26–0.90
Birthweight				
<3500 g	58/647 (9.0)	9/267 (3.4)	0.000	0.17 (0.06–0.45)
>3500 g	35/339 (10.2)	9/108 (8.3)	NS	
Fetal position				
Occipitoposterior	23/207 (11.2)	7/88 (7.9)	NS	
Occipitoanterior	70/779 (8.9)	11/287 (3.8)	0.000	0.19 (0.08–0.46)
Instrumental delivery				
Vacuum/Kiwi	35/542 (6.5)	8/258 (2.3)	0.044	0.34 (0.12–0.97)
Forceps/spatulas	35/444 (8.0)	10/117 (8.0)	NS	
Episiotomy				
No episiotomy	3/22 (13.0)	1/7 (14.2)	NS	
Episiotomy	90/964 (9.3)	17/368 (4.6)	0.017	0.45 (0.23–0.86)
Distance of perineal body				
≤30 mm	60/560 (10.7)	11/178 (6.2)	0.001	0.18 (0.07–0.49)
>30 mm	36/426 (8.45)	7/197 (3.55)	0.002	0.13 (0.04–0.47)

Abbreviations OASIS, obstetric anal sphincter injuries; NS, not significant.
[a]Logistic regression adjusted for age, birthweight, and parity. Presented as OASIS(n)/OVD(n).

The main strength of the study is that it is based on prospective implementation of an intervention in OVD in the context of a quality improvement framework. However, the study also has limitations. First, a historical cohort was used for comparison. In theory, the intervention focused on the episiotomy angle, and other aspects of OVD should not have changed between the preintervention and intervention periods. Nevertheless, differences in procedure may have evolved over time and residual confounding cannot be excluded.

Second, Triepi-45 was used in only 38.0% of OVDs after the start of the protocol. This low adherence possibly accounts for the lack of significant results in the total intervention cohort and its main causes were, first, the belief of some obstetricians that they already have an "unbeatable" mediolateral episiotomy technique and the training program did not convince them to improve it (although the study data show that use of Triepi-45 improved the angle of the mediolateral episiotomy); and second, the limitations of using Triepi-45 when the fetal head is crowning because the marked 45° angle does not have the same validity as it does at rest.[20–22] To improve this limitation, a new tool called Triepi-60 has been designed that facilitates perineal marking of a 60° angle for cases when the fetal head is crowning and the introitus is opening more than 2 cm (Supplementary Video S1). Last, up to 25% of episiotomies performed using Triepi-45 had an angle less than or equal to 30°; therefore, it is necessary to improve clinician training to optimize these results.

A randomized controlled trial would be the optimal study design to evaluate a reduction in OASIS due to an intervention to improve episiotomy angle during OVD; however, it would be difficult to carry this out during delivery due to issues with blinding of patients and staff, and contamination of methods in the different study arms.[24,25]

OASIS can cause a significant morbidity[1,2] and its prevention is the first step in reducing this. However, many known risk factors for OASIS such as parity, length of perineal body, and fetal weight are nonmodifiable. Among the risk factors for OASIS in OVD are the characteristics of the episiotomy, such as the episiotomy angle and the episiotomy–fourchette distance.[19] The angle of episiotomy proves to be of crucial importance, but there is no definition of the ideal angle of mediolateral episiotomy and it is generally determined by the experience of the operator. A previous study reported that the incidence of OASIS in OVD was 32.82% in cases with a post-suturing angle of less than 20°, but 3.95% in cases with a post-suturing angle higher than 20°.[18] An acute episiotomy angle is an important risk factor for anal sphincter injury in OVD, and an angle above 30° has been shown to have an 81% less risk of OASIS (OR, 0.19; 95% CI, 0.12–0.31).[19] But this protective effect is lost when the angle of the post-suturing episiotomy is greater than 60 ° because the episiotomy will have failed to relieve pressure in the perineum. Therefore, it seems reasonable to assume that the ideal suture angle is between 30° and 60°.

Due to the way the perineum expands, there is a difference in the episiotomy angle between the cut and the post-suturing. Therefore, a suture angle of 45° from fourchette, is theoretically possible to obtain with different angle incision options (between 45° and 60°), with a less acute angle when the introitus cut is closer to the fourchette (45° to 8 mm and 60° in the fourchette).[20]

Currently, most clinicians judge the incision by eye, which makes it very difficult to accurately position the angle in OVD, where the instrument makes it hard to perform the incision. Andrews et al.[14] found that 0% midwives and only 22% of doctors cut a truly mediolateral episiotomy with an adequate angle (between 40° and 60°). The difficulty in accurately estimating angles has been demonstrated in model situations, where only 12%–25% of clinicians cut an episiotomy at the recommended angle[15,26,27] and even up to 28% of doctors marked an angle at less than the angle of suture in cases with fetal head crowning.[15] Therefore, to avoid this human error in estimating the angle required for mediolateral episiotomies, we designed Triepi-45 for use at rest, prior to the perineal distention caused by fetal head crowning.

To our knowledge, the present study is the first to evaluate the prevention of sphincter injuries with the use of Triepi-45 in a high-risk group such as OVD. However, there are other devices that aim to optimize the episiotomy angle such as Episcissors-60™[28]: This pair of episiotomy scissors was designed specifically to attain a post-suturing angle of 40°–60°. It has a guide limb that is directed toward the anus in the vertical plane so that the scissors maintain a constant angle of 60°. A recent systematic review on the effect of Episcissors-60™ on the OASIS rate, showed promising results in terms of a possible reduction in OASIS, even though the studies were small in size and of low quality.[29] When comparing 797 patients who had episiotomies with Episcissors-60™ to 1122 patients who had episiotomies with other scissors, there was a significant reduction in OASIS, and the number needed to treat was 25.[29]

In summary, OASIS may have devastating consequences; therefore, reducing its incidence and associated sequelae by raising standards of clinical practice is an important step in improving the quality of obstetric care. The episiotomy angle is a modifiable factor at the time of delivery and, with its optimization close to 45°, will have an important impact in reducing OASIS and thus diminish the long-term morbidity of this condition, especially for high-risk groups of women. For this reason, it is essential to raise awareness among obstetricians about the importance of the episiotomy angle, and to implement the systematic use of tools to adjust this angle. Use of Triepi-45 achieves these objectives and has been shown to have a positive impact on reducing OASIS in OVD.

AUTHOR CONTRIBUTIONS

EG-D contributed to conception and design, data collection and analysis, and manuscript writing. CFF contributed to manuscript writing. JMGO and AFC supervised the study. All authors critically revised the manuscript and read and approved the final version.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Video S1. The Triepi-45 and Triepi-60 tools to improve the episiotomy angle in operative vaginal delivery.

E. COMPENDIO DE PUBLICACIONES

E.1. HIPÓTESIS DE TRABAJO Y PRINCIPALES OBJETIVOS DE INVESTIGACION

Las características de la episiotomía mediolateral, el tipo mas utilizado en nuestro medio, varían de manera importante entre los distintos profesionales que atienden un parto (Gonzalez-Diaz et al, 2016), debido a la falta de una definición uniforme para la misma, la dificultad técnica para conseguir un determinado patrón *in vivo* y a los cambios anatómicos que se producen en el momento del expulsivo en el parto. Esta variabilidad puede causar una gran repercusión, ya que algunas características van a condicionar la aparición de patología de suelo pélvico en el puerperio, fundamentalmente de los OASIs (Gonzalez-Diaz et al, 2015).

Dentro de estas características que definen una episiotomía incluiríamos: el *ángulo* que forma con la línea media, la *distancia* a la que se inicia en introito desde horquilla vulvar, y *longitud* de la episiotomía, así como las características especificas del periné de cada mujer, el tamaño del *cuerpo perineal* y del *hiato genital*. Estas van a ser diferentes en función de si las consideramos en el momento de la incisión con la cabeza coronando o tras suturarla en el puerperio precoz debido a los cambios causados por el paso de la cabeza fetal en el periné.

Nuestra hipótesis de trabajo principal es que algunas características de las episiotomía son un factor protector de la aparición de OASIs, así como que el uso de un patrón determinado en el momento de la incisión podría condicionar una disminución de su incidencia.

Así partiendo de estas hipótesis, los objetivos principales los podemos dividir en tres:

A.) Establecer una correlación entre las características de las episiotomía en el momento de la incisión (cuando se realiza el corte) y de la sutura de la misma en el puerperio precoz.

B.) Establecer que características de la episiotomía mediolateral en el postparto inmediato se asocian a un menor riesgo de OASIs en los partos instrumentales.

C.) Valorar si la modificación de las características de la episiotomía en el momento de la incisión pueden repercutir en una disminución de la incidencia de los OASIs, principalmente en el grupo de los parto instrumentales donde las episiotomías se realizan de manera liberal debido al elevado riesgo de lesión. O dicho de otra manera, valorar si la optimización de las características de la episiotomía puede prevenir los OASIs en los partos instrumentales.

E.2. APORTACIONES DEL DOCTORANDO

Las contribuciones del doctorando al conocimiento aportan una visión global respecto del problema del uso de la episiotomía en la prevención de los desgarros obstétricos del esfínter anal fundamentalmente en los partos instrumentales.

Para ello aborda en primer lugar, el problema técnico al que nos enfrentamos los obstetras a la hora de realizar una episiotomía respecto a las diferencias que experimenta entre el momento de su incisión y el de su sutura. Este punto es muy importante, ya que por un lado, nosotros disponemos fundamentalmente de la información de las características de las episiotomías en el puerperio cuando

es posible su valoración de manera fehaciente, pero la aplicación practica de cualquier medida requiere su adaptación al momento de la incisión en el periné y estas varían respecto a la sutura.

Hasta el momento el estudio de estos cambios se había limitado al comportamiento de algunos parámetros (como el ángulo) y para un rango muy limitado de valores (45º). En nuestro caso pretendimos hacer una valoración mas amplia que permitiera dar una solución técnica y así conseguir una incisión correcta para cualquier patrón de sutura que nos propusiéramos obtener. Para ello hemos mejorado el conocimiento del comportamiento del periné en el momento del expulsivo, fundamentalmente del cuerpo perineal que es donde asientan las episiotomías.

En segundo lugar, a partir de los datos disponible de un estudio previo realizado por el doctorando (Gonzalez-Diaz E et al, 2015), ampliamos los conocimientos respecto al patrón de la episiotomía mediolateral que se asocia a un menor riesgo de OASIs en los partos instrumentales. Se seleccionaron los partos instrumentales porque es un subgrupo de partos con un alto riesgo de lesión perineal grave, en los cuales el uso liberal de la episiotomía se ha asociado a un menor riesgo de estas lesiones y en las cuales no había estudios previos específicos sobre como afectaban las variaciones de la episiotomía en el riesgo de OASIs. Este primer estudio realizado por el doctorando sentó las bases de la importancia del problema, especialmente del ángulo de la episiotomía, pero tenia la limitación del tamaño muestral que no permitía extraer conclusiones adecuadas respecto al resto de características de la episiotomía y el periné. Por ello se diseño una estudio mucho mas amplio que pudiera mejorar conocimiento sobre la influencia de todos estos parámetros en el riesgo de OASIs, y así como poder establecer el patrón de episiotomía ideal para los partos instrumentales, es decir, el que se asocia a un menor riesgo de lesión esfinteriana.

En ultimo lugar, y como punto fundamental, el doctorando innova una solución original que permite aplicar los conocimientos previamente adquiridos para reducir las lesiones esfinterianas

durante los partos instrumentales. Dicha solución es denominada **Triepi-45**, se trata de una pieza de papel cuadrada de 3 cm de lado que se pliega diagonalmente y que permite el marcado del periné en reposo con un ángulo de 45º. De esta manera el profesional que atiende el parto dispone de una referencia en el momento del expulsivo para orientar la episiotomía con el ángulo correcto. Actualmente existen otros dispositivo con el mismo fin que **Triepi-45**, como Episcissors-60™ (Una tijera con una guía que se dirige hacia el ano en el plano vertical para que se mantengan a un ángulo constante de 60°) o Episiometer (Un dispositivo de plástico transparente que se pega en periné para guiar el ángulo y la longitud de la episiotomía en el momento de realizarla). Todos estos dispositivos al igual que el nuestro pretenden optimizar el ángulo de la episiotomía para de esa manera reducir las posibilidades de sufrir una lesión esfinteriana. A diferencia de **Triepi-45**, el resto de dispositivos no dispone de estudios amplios que puedan avalar su uso en la actualidad. Las otras dos grandes ventajas de **Triepi-45** serian que se trata de un dispositivo barato, ya en que se realiza en papel, siendo así también un material fácilmente reciclable.

Uno de las mayores limitaciones del uso de **Triepi-45** fue la imposibilidad de uso una vez que la cabeza estaba coronando (ya que el marcado de un ángulo de 45º en esas circunstancia implicaría un menor ángulo de sutura y por tanto un mayor riesgo de lesión), para solucionarlo diseñamos **Triepi-60** que permite el marcado de un ángulo de 60º para ser usado en estas condiciones.

E.3. METODOLOGÍA UTILIZADA

La tesis doctoral presentada ha sido realizada por compendio de publicaciones, estando constituida por un conjunto de trabajos justificados por su unidad temática. Para cumplirlos objetivos planteados en el primer epígrafe (D.1.), se realizaron tres trabajos de investigación que han sido publicados independientemente en tres artículos diferentes en revistas científicas de relevancia.

Los protocolos de cada estudio fueron aprobados por el Comité Ético de Investigación local (Comité Ético de Investigación Clínica de León). Todos los datos se gestionaron y analizaron utilizando el software SPSS (versión 20.0 para Mac; SPSS Inc, Chicago, IL).

Esta fue la metodología seguida en cada uno de los trabajos que forman parte de esta tesis:

E.3.1. *Behavior of perineum during delivery before fetal head expulsion.*

Comportamiento del periné durante el parto antes de la expulsión de la cabeza fetal.

<u>Estudio prospectivo descriptivo.</u>

Para el primer objetivo de la tesis, la valoración de las modificaciones en las características de la episiotomía desde el momento en que se realiza la incisión con la cabeza fetal coronando (abombando el periné) a el reposo del periné una vez finalizado el parto, se realizo un *estudio prospectivo descriptivo* que incluyo: *mujeres primíparas*, *a término*, sometidas a *parto vaginal no instrumental*, entre el *1 de septiembre de 2009* y el *1 de septiembre de 2010*. De los 1919 partos vaginales durante este período, 1497 (78%) no fueron instrumentales. Todas las participantes firmaron un formulario de consentimiento detallado antes de participar en el estudio.

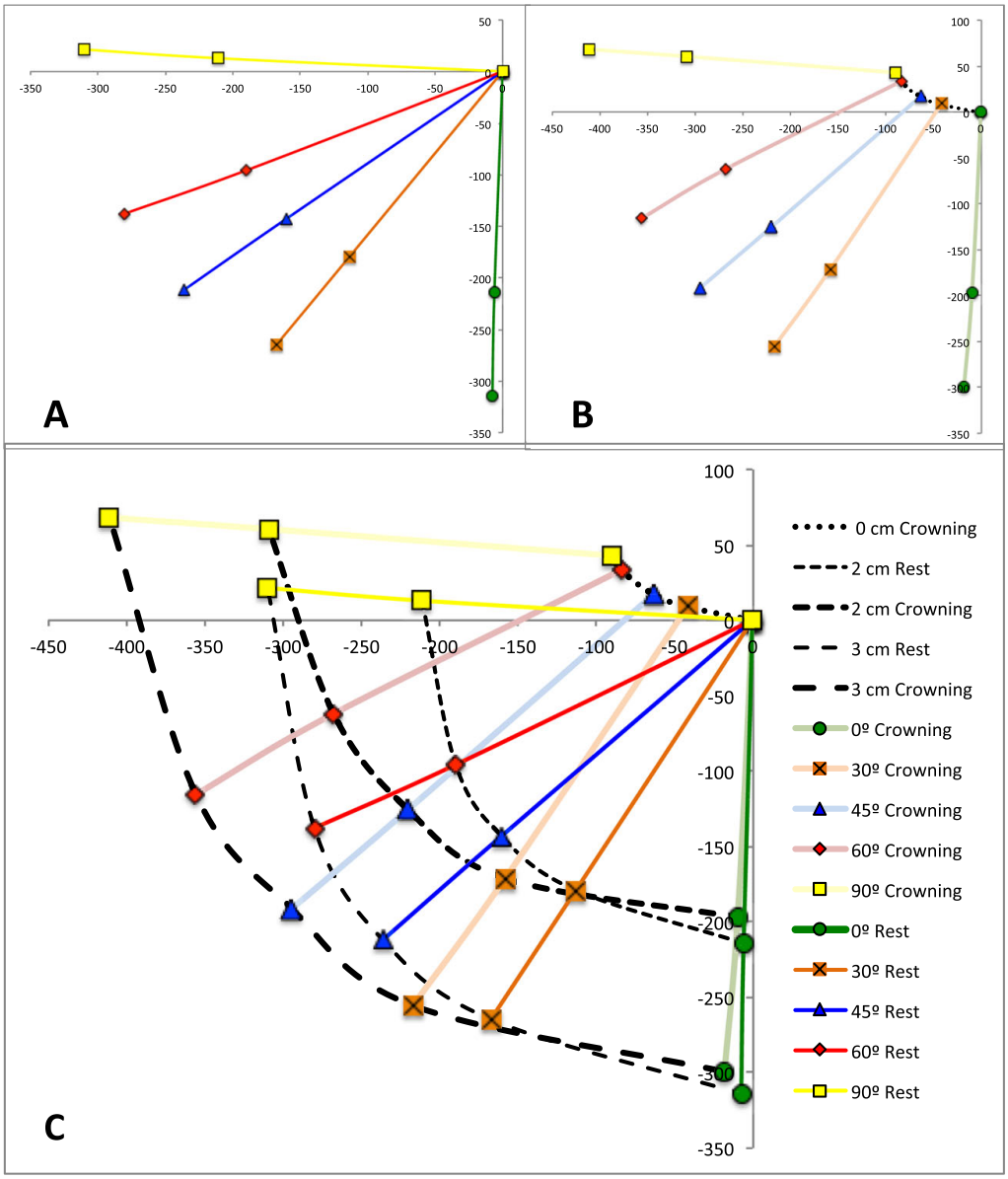

Figura 5. Cambios en el patrón lineal del periné desde la configuración original (en reposo) hasta el último momento posible antes de parto (en la coronación). **A.** Líneas con sus marcas en reposo (configuración inicial): el punto inicial de cada línea era la horquilla posterior. **B.** Líneas y marcas donde se ubicaron en el momento de la coronación de la cabeza del feto: los puntos iniciales de la configuración original se movieron desde la horquilla posterior, excepto en la línea de 0°. **C.** Las líneas en A y B se muestran juntas (Gonzalez-Diaz E et al, 2017)

Se registraron los siguientes datos: edad materna, edad gestacional, raza, peso, altura, posición fetal, peso al nacer, pH de sangre del cordón umbilical, uso de anestesia epidural y tasa de OASIS. Se investigaron los cambios superficiales del perine para cada participante entre el último momento posible antes del parto (inmediatamente antes de la expulsión de la cabeza fetal) y la configuración

original, es decir, cuando la participante estaba con el periné en reposo (antes de empujar activamente) y el obstetra realizo el marcado del periné.

Este marcado del periné en reposo, se realizo usando una solución de violeta de genciana en solución acuosa al 1% sobre un modelo de papel con un patrón lineal, este incluía cinco líneas de 3 cm a: 0°, 30°, 45°, 60° y 90° desde la línea media (línea desde la uretra hasta el ano), y cada línea tenía: (a) el mismo punto de inicio en la horquilla vulvar y (b) dos puntos marcados, uno a 2 cm (punto A) y el otro a 3 cm (punto B) desde el comienzo de la línea (Figura 5.A).

Dos investigadores asistieron cada uno de los partos, uno lo atendía y mientras que el otro tomaba las fotografías del periné. Se tomaron dos fotografías digitales: una en reposo y la segunda en el momento de la coronación de la cabeza fetal. Se usó una cámara digital (10 megapíxeles), que se coloco a unos 30 cm de cada participante. La iluminación estándar del hospital se utilizó sin ningún flash disruptivo. La paciente se situaba en posición de litotomía con las piernas flexionadas en las articulaciones de la cadera en un ángulo de 90-100°. Las manos del obstetra no tocaron el periné antes de la coronación de la cabeza fetal. Luego, si era necesario, se realizó una episiotomía mediolateral y, en todos los casos, se usó la técnica *Hand-on* para la protección perineal manual. Los desplazamientos se calcularon para los puntos A y B y el ángulo de cada línea a medida que se movía con el tiempo desde una posición de descanso al de la coronación. Cada fotografía se analizó utilizando el programa PixelStick (Versión 2.8.), y así obtuvimos los siguientes parámetros:

- *En reposo:* la distancia desde la horquilla vulvar hasta el punto A y B y el ángulo para cada línea dibujada (Figura 5.A).
- *En tensión:* el ángulo y la distancia desde su inicio en introito hasta los puntos A y B para las cinco líneas dibujadas (Figura 5.B).
- *En tensión:* el ángulo y la distancia desde la horquilla hasta los puntos A y B de las líneas imaginarias formadas entre estos puntos (Figura 5.B).

-*En tensión*: distancia que cada línea desde introito hasta la horquilla vulvar (Figura 5.B).

La normalidad se verificó utilizando el método de Shapiro-Wilk. Las diferencias entre los datos dependientes se calcularon mediante la prueba de t-Student para muestras pareadas. Un valor de ρ de menos de 0.05 se consideró estadísticamente significativo.

E.3.2. *Which characteristics of the episiotomy and perineum are associated with a lower risk of obstetric anal sphincter injury in instrumental deliveries.*

Que características de la episiotomía y el periné se asocian con menor riesgo de lesiones de obstétricas del esfínter anal en partos instrumentales.

Estudio retrospectivo de casos y controles.

El segundo objetivo planteado fue la valoración de aquellas características de la episiotomía que se asocian a un menor riesgo de OASI, en aquellas mujeres con un mayor riesgo de sufrirlo como son aquellas que precisaron de un parto instrumental. Para ello se realizo un *estudio observacional de casos y controles* con un diseño retrospectivo a partir de los partos instrumentales del paritorio del Complejo Asistencial Universitario de León desde enero de 2012 hasta junio de 2017. Las características de las episiotomías de aquellas mujeres que experimentaron una OASIs y fueron diagnosticadas en la sala de partos (Grupo OASIs), se compararon con aquellas que no tenían evidencia de lesión del esfínter anal (Grupo control). OASI se definió como cualquier ruptura que involucre a los músculos del esfínter anal con o sin ruptura de la mucosa anal diagnosticada clínicamente en la sala de partos. Las mujeres sin episiotomía o los partos gemelares fueron excluidas del análisis.

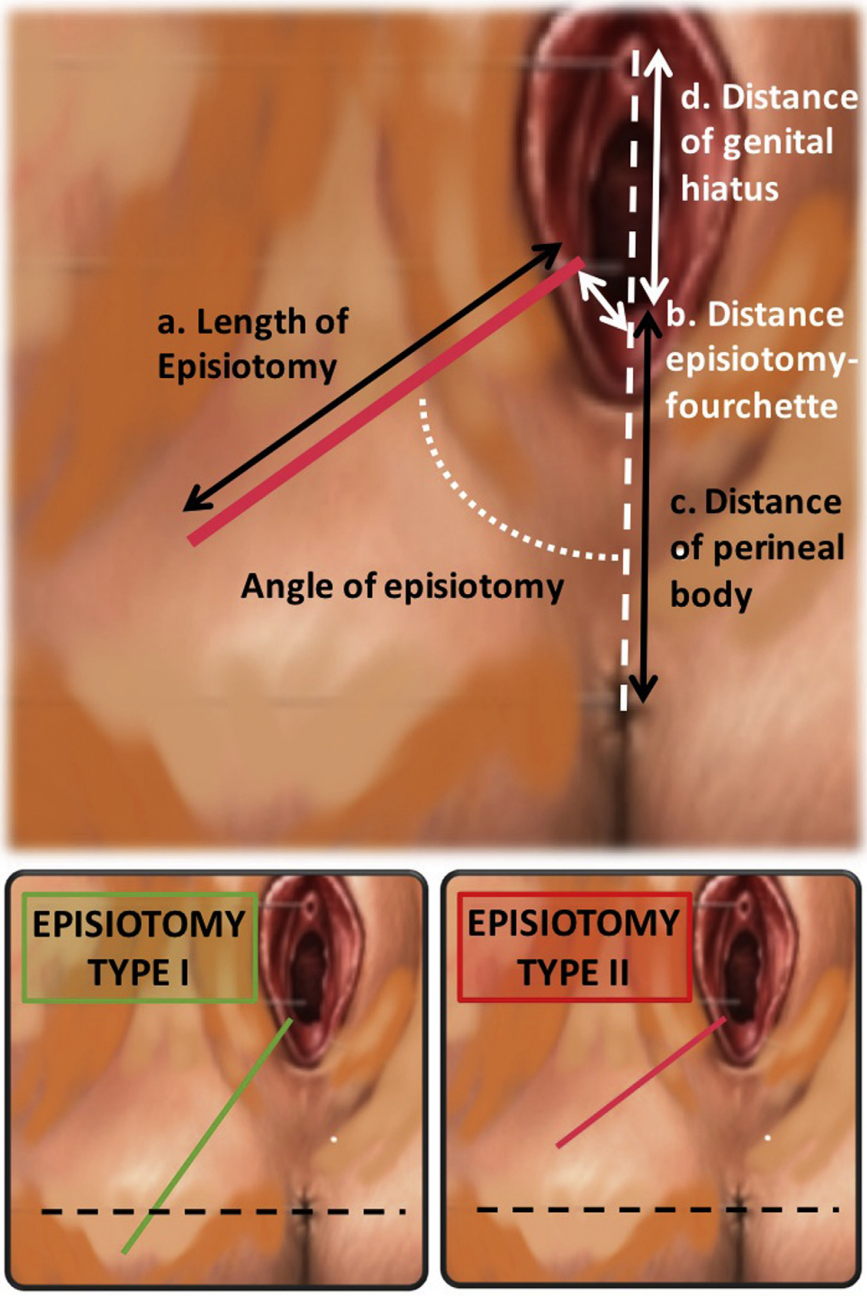

Figura 6. Características y tipo de episiotomía mediolateral

Las indicaciones para un parto instrumental en nuestro centro son una segunda etapa prolongada y la frecuencia cardíaca fetal no tranquilizadora. Solo realizamos partos instrumentales bajos o de salida. En ausencia de analgesia epidural, generalmente se usa anestesia local.

Todos los partos instrumentales fueron citadas en la *consulta de suelo pélvico y puerperio* entre las 8 y 12 semanas postparto. En esta visita, se realizo una historia clínica y un examen completo, incluida

la medición de la episiotomía y el periné. Con el paciente en posición de litotomía y las piernas apoyadas en las rodilleras se midieron las siguientes características (Figura 6): 1) Ángulo de la episiotomía (ángulo entre la episiotomía y la línea media, que se midió en grados utilizando un goniómetro digital), 2) Longitud de la episiotomía, 3) Distancia episiotomía-horquilla (la distancia desde el origen de la cicatriz de episiotomía en el introito hasta la horquilla vulvar), 4) Distancia del cuerpo perineal y 5) Distancia del hiato genital. Las distancias se midieron en milímetros. Se pueden distinguir dos tipos de episiotomía en función de su relación con el ano (Figura 6), el **tipo I** se definió cuando el final de la cicatriz de episiotomía estaba debajo una línea horizontal que pase por el ano y el **tipo II** cuando estaba por encima.

Los datos para el estudio se obtuvieron de los registros computarizados del puerperio y de los registros de alta hospitalaria materna vinculados. Todas las características conocidas en la literatura como posibles factores de riesgo disponibles en la base de datos, se analizaron en este estudio como posibles factores predisponentes para la lesión del esfínter anal en partos vaginales asistidos. Estos factores fueron: edad materna, raza, diabetes gestacional, paridad, edad gestacional, inducción del trabajo de parto, posición occipito-posterior, tipo de instrumental, anestesia epidural, duración de la segunda etapa y peso fetal al nacimiento. También se recogieron las características de la episiotomía (ángulo, longitud y distancia a horquilla), la distancia del cuerpo perineal y del hiato genital.

Las variables categóricas se evaluaron mediante un análisis de prueba Chi-cuadrado, y la prueba U de Mann-Whitney se utilizó para variables continuas no paramétricas y la prueba t de Student para paramétricas continuas. La prueba de Kolmogorov-Smirnov se usó para evaluar los datos continuos de normalidad antes de las pruebas de significación. Para tener en cuenta el efecto potencialmente de confusión de las diferencias en las características demográficas, de parto y de la episiotomía entre los grupos, se creó un modelo de regresión logística para predecir OASIS utilizando factores que fueron significativos en los análisis bivariados. El análisis de la curva de características operativas del receptor (ROC) se usó para determinar los valores de corte óptimos para las características de episiotomía para

predecir cualquier riesgo de OASI. Definimos el mejor valor de corte como el valor con la mayor precisión que maximiza el índice de Youden (sensibilidad + especificidad-1).

Se realizo un análisis de subgrupos para las características de la episiotomía que se asociaron con OASIs, dividiendo el grupo de acuerdo con los factores predictivos de OASI en el análisis multivariado.

E.3.3. *Incidence of obstetric anal sphincter injuries after implementing the Triepi-45 tool to improve episiotomy angle in instrumental deliveries.*

Incidencia de lesiones obstétricas del esfínter anal después de implementar la herramienta Triepi-45 para mejorar el ángulo de la episiotomía en los partos instrumentales.

Estudio de cohortes prospectivo (con una cohorte histórica).

El tercer objetivo de la tesis fue valorar si la adecuación de alguna de las características estudiadas previamente podrían asociarse a una disminución real de la incidencia de OASIs en los partos instrumentales. De todas las características de la episiotomía seleccionamos para actuar el ángulo de la misma, ya que era el parámetro mas consistente entre nuestros resultados de la fase previa y la literatura disponible. Y nos propusimos como objetivo conseguir un ángulo de las episiotomías lo mas próximo a los 45º en el momento de la sutura, y para conseguirlo diseñamos un dispositivo que denominamos **Triepi-45**, una herramienta que permite marcar un ángulo de 45º en el periné en reposo. Para evaluar el efecto el uso de **Triepi-45**, o sea la optimización del ángulo de la episiotomía, se realizo un *estudio de cohorte retrospectivo-prospectivo* a partir de los datos de los partos instrumentales en el Complejo Asistencial Universitario de León (CAULE). Los datos se obtuvieron de dos cohortes: una *cohorte retrospectiva* (del 10 de noviembre de 2011 al 31 de noviembre de 2013) y una *cohorte*

prospectiva (del 1 de febrero de 2014 al 3 de marzo de 2016) tras la implementación de un programa diseñado para mejorar el ángulo de la episiotomía utilizando para ello **Triepi-45**.

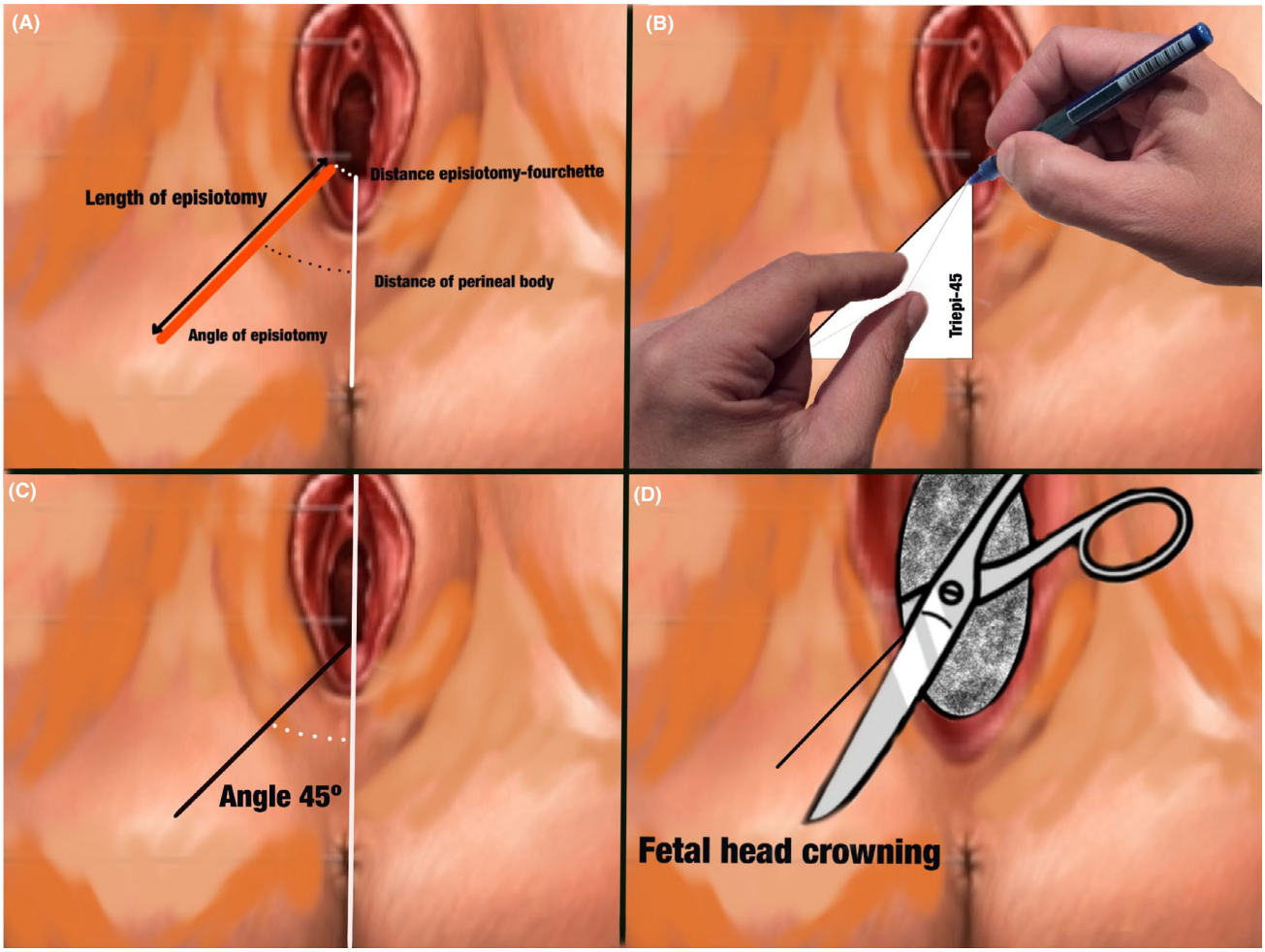

Figura 7. Uso de **Triepi-45**. **A)** Características de el periné y la episiotomía, **B)** Colocación de Triepi-45 para el marcado en el periné en reposo, **C)** Periné en reposo marcado con un ángulo de 45º, **D)** Incisión por encima de la línea previamente marcada realizada en el momento que corona la cabeza fetal.

En noviembre de 2013, los resultados preliminares de un estudio de casos y controles realizado en nuestro centro (Gonzalez-Diaz E et al, 2015) demostraron que el ángulo de episiotomía en los partos instrumentales es un factor de riesgo importante para la lesión del esfínter anal. A partir de estos datos, se revisaron los protocolos de la institución con el fin de sensibilizar a los obstetras sobre la importancia de una técnica adecuada de episiotomía mediolateral, y se implementó el uso sistemático de **Triepi-45** en los partos instrumentales.

La herramienta **Triepi-45** permite marcar un ángulo apropiado en el periné (Figura 7). Se trata de un cuadrado de papel de 30 mm de lado, que se dobla a lo largo de su eje diagonal para crear dos triángulos rectos isósceles. Se aplica uno de los triángulos en el periné en reposo (mientras que el otro se usa para mantenerlo en su lugar), con un lado en la línea media y el vértice al nivel de la horquilla vulvar (Figura 7.B). Luego se dibuja una línea con un marcador en el lado diagonal desde la horquilla hasta el final del triángulo (Figura 7.C). Cuando la cabeza fetal está coronando, se realiza la incisión de la episiotomía que debe finalizar por encima de la línea marcada (Figura 7.D).

Entre diciembre de 2013 y enero de 2014, todo el Servicio de Obstetricia de CAULE completó un programa educativo que incluía información sobre los resultados preliminares del estudio realizado en nuestro centro (Gonzalez-Diaz E et al 2015), los cambios realizados en los protocolos del centro y acerca del uso de Triepi-45 en los partos instrumentales. Los cambios en el protocolo entraron en vigor oficialmente en Enero del 2014.

Las mujeres con partos instrumentales fueron seguidas en la *Consulta de suelo pélvico y puerperio* a las 8-12 semanas después del parto, realizándolas un examen completo, que incluyó la evaluación de la cicatriz de la episiotomía y el periné.

Para el análisis, el tamaño de la muestra se calculó sobre la base de una prevalencia de OASIS en los partos instrumentales del 8,5% antes de la implementación de la intervención. Se supuso que esta prevalencia se mantendría sin cambios en el grupo de control y que se necesitaría una reducción del 40% o más en la incidencia de desgarros de tercer o cuarto grado en el grupo de intervención para observar una diferencia estadísticamente significativa. Por lo tanto, se necesitaba un tamaño de muestra de 986 participantes por grupo para lograr una potencia del 80% para detectar una diferencia significativa con una tasa de error tipo I del 5%.

Para el grupo de control, los datos se recolectaron retrospectivamente de 986 partos instrumentales consecutivos entre el 10 de noviembre de 2011 y el 30 de noviembre de 2013. Para la cohorte de intervención, los datos se recolectaron prospectivamente de 986 partos instrumentales consecutivos

realizados entre el 1 de febrero de 2014 y el 3 de marzo 2015. Se excluyeron los partos prematuros (<34 semanas de gestación) y los partos instrumentales fallidos en los que se realizó una cesárea (Figura 8).

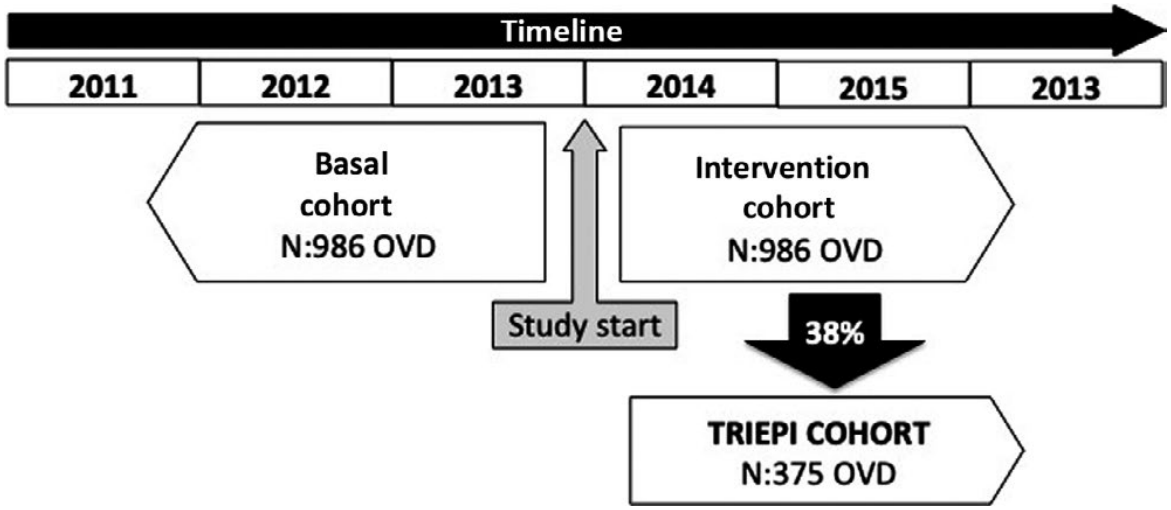

Figura. 8. Time-line de ambas cohortes. OVD: partos instrumentales

E.4. PRINCIPALES RESULTADOS

E.4.1. *Behavior of perineum during delivery before fetal head expulsion.*

Comportamiento del periné durante el parto antes de la expulsión de la cabeza fetal.

Participant characteristics (*n* 45)	
Maternal age (years)[a]	32.5 (6.4)
Gestational age (days)[a]	280 (6)
Caucasian	100 %
Weight (kg)[a]	73.3 (5)
Height (cm)[a]	165 (5.5)
Occipitoposterior position	0 %
Birthweight (g)[a]	3290 (350)
pH umbilical cord blood sampling[a]	7.24 (0.91)
Epidural anesthesia	91.1 %
OASIS	0

OASIS obstetric anal sphincter injuries
[a] Mean (Standard deviation)

Tabla 1. Características de la mujeres reclutadas para este estudio (Gonzalez-Diaz E et al, 2017)

Durante el período de estudio, fueron reclutadas 45 mujeres de manera consecutiva después de ser informadas y firmar el consentimiento informado; 14 mujeres se negaron a participar. Todas las mujeres eran caucásicas, con una edad media de 32,5 años y una edad gestacional media de 280 días. El peso promedio al nacer fue de 3290 g, ningún feto estaba en posición occipito-posterior y el pH fue de 7.24. La tasa epidural fue del 91,1% (Tabla 1).

En el momento en que la cabeza fetal está coronando y el perine está distendido, los puntos de origen de las líneas de 30°, 45°, 60° y 90° se mueven lateralmente desde la horquilla posterior a 4.95, 8.01, 11.24 y 12.08 mm, respectivamente en introito. Solo la línea de 0° permanece en la horquilla sin moverse (Figura 5). Los ángulos de línea dibujados en el periné en reposo no cambian significativamente durante la coronación. Los ángulos de los segmentos que se forman entre líneas no

cambian. Además, no hubo diferencias significativas en las distancias a los puntos A y B en las líneas trazadas entre en reposo y cuando se estiraba el periné (Tabla 2).

	Rest	Crowning	MD	SD	Student's*t* test	*P* value
Angle 0°	1.58	2	0.42	6.66	0.217	NS
Angle 30°	32.42	33.08	0.67	8.38	0.276	NS
Angle 45°	47.92	48.08	0.17	8.54	0.068	NS
Angle 60°	63.92	62.92	−1	9.53	−0.363	NS
Angle 90°	93.83	94.92	1.08	7.99	0.469	NS
Angle segment 1 (0–30°)	30.83	31.25	−0.42	6.03	−0.239	NS
Angle segment 2 (30–45°)	15.42	15.25	0.17	4.76	0,121	NS
Angle segment 3 (45–60°)	16.08	15.08	1	3.93	0.881	NS
Angle segment 4 (60–90°)	29.92	32.42	−2.5	4.77	−1.813	NS
Angle segment A (0–45°)	46.33	46.42	−0.08	7.94	−0.036	NS
Angle segment B (0–60°)	62.33	61.5	0.83	9.34	0.309	NS
Angle segment C (0–90°)	92.08	94	−1.92	8.07	−0.822	NS
Distance A–introitus (0°)	20.97	22.17	−12	66.42	−0.65	NS
Distance A–introitus (30°)	21.33	22.03	−7	60.7	−0.556	NS
Distance A–introitus (45°)	21.18	21.72	−5.39	65.73	−0.375	NS
Distance A–introitus (60°)	21.02	21.52	−5	59.2	−0.422	NS
Distance A–introitus (90°)	21.71	24.94	−32.33	85.12	−1.566	NS
Distance B–introitus (0°)	31.45	33.25	−18	87.31	−0.714	NS
Distance B–introitus (30°)	32.00	33.05	−10.5	79.7	−0.456	NS
Distance B–introitus (45°)	31.76	32.57	−8.08	74.7	−0.375	NS
Distance B–introitus (60°)	31.53	32.28	−7.5	67.01	−0.388	NS
Distance B–introitus (90°)	32.56	37.41	−48.5	95.12	−1.766	NS
Angle A–fourchette (0°)	1.58	2.42	0.83	7.51	0.384	NS
Angle A–fourchette (30°)	32.42	39.92	7.5	9.02	2.88	0.015
Angle A–fourchette (45°)	47.92	56.75	8.83	8.69	3.519	0.005
Angle A–fourchette (60°)	63.92	72.83	8.92	9.4	3.284	0.007
Angle A–fourchette (90°)	93.83	98.92	5.08	9.52	1.848	NS
Distance A–fourchette (0°)	31.45	34.57	−31.25	97.64	−1.109	NS
Distance A–fourchette (30°)	32.00	35.05	−30.5	86.99	−1.214	NS
Distance A–fourchette (45°)	31.77	36.63	−48.67	80.42	−2.096	0.06
Distance A–fourchette (60°)	31.53	39.00	−74.67	79.33	−3.26	0.008
Distance A–fourchette (90°)	32.56	43.59	−110.33	79.32	−4.818	0.001
Angle B–fourchette (0°)	1.58	2.58	1	8.15	0.425	NS
Angle B–fourchette (30°)	32.42	43.17	10.75	11.06	3.366	0.006
Angle B–fourchette (45°)	47.92	60.33	12.42	10.21	4.209	0.001
Angle B–fourchette (60°)	63.92	76.5	12.58	10.56	4.124	0.002
Angle B–fourchette (90°)	93.83	100.67	6.83	11.11	2.131	0.057
Distance B–fourchette (0°)	21.45	20.62	8.33	72.89	0.396	NS
Distance B–fourchette (30°)	22.00	24.38	−23.83	74.72	−1.105	0.042
Distance B–fourchette (45°)	21.77	26.62	−48.5	72.85	−2.306	0.007
Distance B–fourchette (60°)	21.53	28.73	−72	75.34	−3.31	0.000
Distance B–fourchette (90°)	22.56	32.86	−103	68.61	−5.2	NS
Distance fourchette–introitus (0°)	0	0	0			
Distance fourchette–introitus (30°)	0	4.95	−4.95	10.21	24.58	0.000
Distance fourchette–introitus (45°)	0	8.01	−8.01	9.55	62.48	0.000
Distance fourchette–introitus (60°)	0	11.24	−11.24	7.55	80.22	0.000
Distance fourchette–introitus (90°)	0	12.08	−12.08	11.14	94.72	0.000

Angle line 0°, 30°, 45°, 60°, 90°: Angle between each line with the midline. Angle segment 1, 2, 3, 4, A, B, C: angle formed between two lines (defined in parentheses). Distance A or B–introitus: measurement from point A or B. Angle A or B–fourchette: compares angle formed by line drawn in perineum at rest with the angle of an imaginary line between point A–B and posterior fourchette with fetal head crowning. Distance A or B–fourchette: from A or B to fourchette; at rest corresponds to distance of line drawn in perineum and with fetal head crowning corresponding to distance of imaginary line from A or B to fourchette. Distance fourchette–introitus: from posterior fourchette to starting point of each line in introitus with perineum distended by the fetal head

MD mean of differences, *SD* standard deviation, *NS* not significant, *angle* degree, *distance* mm, *Point A* to 2 cm from fourchette in every line at rest, *Point B* to 3 cm from fourchette in every line at rest

Tabla 2: Diferencias en las distancias y ángulos de líneas trazadas en el periné de los 45 participantes entre la configuración original en reposo y el momento previo a la expulsión de la cabeza fetal (Gonzalez-Diaz E et al, 2017)

Sin embargo, si comparamos la configuración original de las líneas dibujadas con una línea imaginaria desde horquilla hasta los puntos A y B antes de la expulsión de la cabeza fetal, el ángulo y la distancia aumentaron de manera estadísticamente significativa. El ángulo al punto A en la línea de 30°, 45° y 60° y al punto B en la línea de 30°, 45°, 60° y 90° aumentó de manera estadísticamente significativa con respecto al reposo. Para la línea de 45° en reposo, el ángulo con coronación de la cabeza fetal aumenta a 56.75° desde la horquilla vulvar al punto A (2 cm en reposo) y 60.33° al punto B (3 cm en reposo) (Tabla 2).

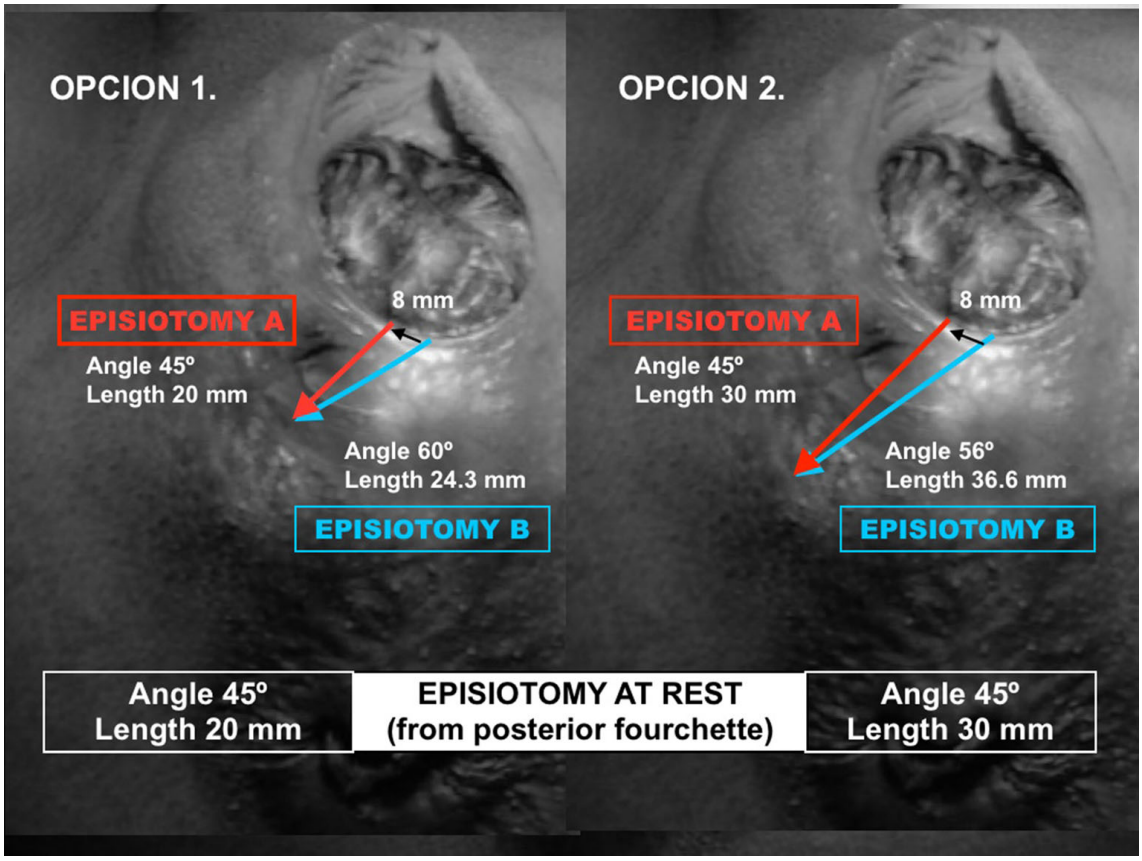

Figura 9: Opciones de incisión en el momento de la coronación de la cabeza fetal para conseguir una sutura de episiotomía desde la horquilla posterior con un ángulo de 45° y una longitud de 2 a 3 cm (Gonzalez-Diaz E et al, 2017)

En general, en esta área particular del periné, observamos un desplazamiento lineal lateral y ventral, pero sin movimiento de rotación, en el momento previo a la expulsión de la cabeza fetal (Figura 5). Por lo tanto, para colocar una episiotomía suturada desde la horquilla posterior con un ángulo de 45°

y una longitud de 2 o 3 cm, a partir de los datos de nuestro estudio, en teoría, tendríamos varias opciones de incisión en el momento de la coronación de la cabeza fetal: a) haciendo un corte de introito a aproximadamente a 6 mm de la horquilla vulvar con un ángulo de 45° y una longitud de 2 o 3 cm, o b) haciendo un corte desde la horquilla con un ángulo de 57 ° y 2.5 cm en longitud, o 60° y 3,5 cm para suturas de 2 y 3 cm, respectivamente. Para otras opciones entre la horquilla y 6 mm, el ángulo debería estar entre 45° y 60°, con un ángulo más agudo cuando el corte en introito está más cerca de la horquilla posterior, y una longitud de episiotomía más corta (Figura 9).

E.4.2. *Which characteristics of the episiotomy and perineum are associated with a lower risk of obstetric anal sphincter injury in instrumental deliveries.*

Que características de la episiotomía y el periné se asocian con menor riesgo de lesiones de obstétricas del esfínter anal en partos instrumentales.

E.4.2.1. Características demográficas, obstétricas y de los partos.

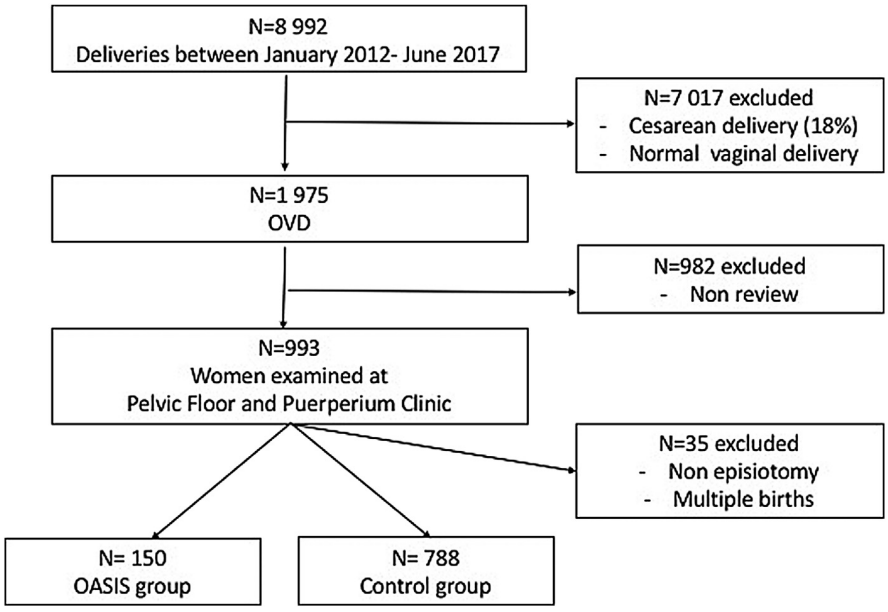

Figura 10. Diagrama de flujo de las pacientes incluidas en el estudio. OVD: partos instrumentales. (Gonzalez-Diaz E et al, 2019)

Durante el período de estudio en nuestro centro, 1975 de un total de 8992 partos (21%) fueron instrumentales. La tasa general de episiotomía en todos los nacimientos fue del 45%. La tasa de episiotomías y OASI para los partos instrumentales fue de 97% y 7.85% respectivamente (la tasa de OASI para los partos secuenciales, espátulas, fórceps, ventosa obstétrica y ventosa kiwi fueron de: 26.7%, 17.4%, 5.6%, 8.16% y 5.1% respectivamente). Durante este período, 958 mujeres con partos instrumentales fueron examinadas en la *Consulta de suelo pélvico y puerperio*, y fueron incluidas en este estudio, 150 de las cuales en el grupo de OASI y 788 en el grupo de control. Treinta y cinco mujeres fueron excluidas por parto gemelar o sin episiotomía. La figura 10 ilustra la selección de los participantes del estudio con un diagrama de flujo. Las características demográficas, obstétricas y de los partos de las mujeres en el grupo OASI y control se presentan en la Tabla 3.

Characteristics	No OASI n = 788	OASI n = 150	ρ value
Patient characteristics			
Maternal age (years)*	33.22 (5.17)	32.01 (5.37)	0.03[a]
Spanish (%)	91.4	91.9	NS[c]
Gestational diabetes (%)	4.4	4.7	NS[c]
Nulliparity (%)	89.1	95.6	0.023[a]
Gestational age (days)**	280 (275-285)	281 (276-287)	0.049[b]
Weight gain (Kg)**	12 (10-16)	12 (10-15.25)	NS[b]
Delivery characteristics			
Prostaglandins Induction (%)	11.7	15.3	NS[c]
Meconium (%)	22.3	15.2	NS[c]
Occipitoposterior position (%)	22	32.5	0.03[c]
Mode of delivery (%)			NS[c]
Sequential	9.1	14.9	
Espatulas	2.9	1.2	
Forceps	45.2	50.3	
Vacuum	23.6	17.4	
kiwi	19.2	16.1	
Experience obstetrician >10 years (%)	52.9	57.8	NS[c]
Epidural anesthesia(%)	94.6	95.6	NS[c]
Duration of stage labor (min)			
1 st Stage labor**	240 (161-330)	240 (180-330)	NS[b]
2nd stage labor**	94 (30-150)	90 (45-135)	NS[b]
Neonatal characteristics			
Male (%)	55.7	58,8	NS[c]
Birthweight >3500 g (%)	27.3	37.8	0,007[c]
Apgar score <5 at 1 min (%)	5	7.6	NS[c]
Apgar score <7 at 5 min (%)	2	3.1	NS[c]
Umbilical artery pH < 7.20 (%)	37	34	NS[c]

[a] Student's test.
[b] Mann-Whitney U test.
[c] Chi-Square test.
* Mean(SD).
** Median(Interquartile range); NS: Not Significant.

Tabla 3. Características de los partos instrumentales con y sin OASI (Gonzalez-Diaz E et al, 2019)

Las mujeres en el grupo OASI tenían más probabilidades de ser nulíparas (95.6 % vs 89.1%, p = 0.023), y una edad gestacional más avanzada (281 vs 280 días, p = 0.049). El grupo OASI se caracterizó por tasas más altas de posiciones occipito-posteriores persistentes (32.5% vs 22%, p = 0.03) y un peso neonatal al nacer significativamente mayor (3388 g frente a 3292 g, p = 0.037). No hubo diferencias entre los grupos con respecto a la edad materna, nacionalidad, diabetes gestacional, ganancia ponderal durante la gestación, inducción del parto, meconio, tipo de parto instrumental, experiencia del obstetra, analgesia epidural, duración del trabajo de parto, sexo fetal, pH umbilical o Apgar (Tabla 3).

Characteristics of episiotomy (Quantitative variables)	No OASI n = 788	OASI n = 150	ρ value
Angle			
Angle of episiotomy (º)*	32 (14)	23 (9)	<0,0001[a]
Angle of episiotomy >30º (%)	53.0	18.4	<0.0001[b]
Distance			
Length of episiotomy (mm): distance a*	35 (5)	30 (10)	NS[a]
Length of episiotomy >30 mm (%)	49.7	44.7	NS[b]
Distance episiotomy-fourchette (mm): distance b*	4 (5)	3 (4)	0.002[a]
Distance episiotomy-fourchette >5 mm (%)	29.9	19.2	0.007[b]
Distance of perineal body (mm): distance c*	35 (10)	30 (10)	<0.0001[a]
Distance of perineal body >30 mm (%)	52.1	34.5	<0.0001[b]
Distance of genital hiatus (mm): distance d*	25 (5)	25 (10)	0.004[a]
Distance of genital hiatus >25 mm (%)	47.4	40.8	NS[b]
Classification of episiotomies (%)			<0.0001[b]
Epsiotomy type I (%)	16.7	34.8	
Episiotomy type II (%)	83.3	65.2	

NS: Not Significant.
* Median(Interquartile range).
[a] Mann-Whitney U test.
[b] Chi-Square test.

Tabla 4. Características de la episiotomía en los partos instrumentales con y sin OASIS (Gonzalez-diaz E et al, 2019)

E.4.2.2. Características de la episiotomía

En el análisis univariante de las características de la episiotomía, el grupo OASI se caracterizó por un ángulo de episiotomía más agudo (30º Vs 22º, p <0,0001), una menor distancia del cuerpo perineal (30 mm Vs 32,5 mm, p <0,0001) y una menor distancia a horquilla vulvar (4 Vs 3 mm, p=0,002). Las mujeres con episiotomía **tipo I** fueron significativamente más comunes en el grupo de OASI (34.8% vs 16.7, p <0.0001) (Tabla 4).

E.4.2.3. Factores de riesgo para oasis: análisis multivariante

Factors	Wald	ρ value	OR* crude	IC 95%
Maternal age <35 years	1.12	NS		
Nulliparity	4.45	0.035	0.31	0.1-0.9
Gestational age >40 weeks	0.87	NS		
Occipitoposterior position	16.77	0.001	0.31	0.18-0.54
Birthweight >3500 g	7.34	0.007	0.62	0.43-0.87
Angle of episiotomy > 30º	44.68	0	0.19	0.12-0.31
Distance episiotomy-fourchette > 5 mm	5.76	0.016	0.52	0.31-0.89
Distance of perineal body > 30 mm	18.32	0	0.37	0.23-0.58

Tabla 5. Factores predictores de OASIs en partos instrumentales (Gonzalez-Diaz E et al, 2019)

Para identificar factores de riesgo independientes para los OASIs, utilizamos un análisis de regresión logística multivariante para controlar posibles factores de confusión (Tabla 5). Los factores que se asociaron independientemente con los OASIs en los partos instrumentales fueron la *nuliparidad*, la *posición occipitoposterior persistente*, el *peso al nacer> 3500 g*, un *ángulo de la episiotomía <30º*, una *distancia episiotomía-horquilla <5 mm* y una *distancia del cuerpo perineal <30 mm*.

El ángulo de la episiotomía se comporta como un factor asociado a la lesión del esfínter anal, por lo que las mujeres con una episiotomía mediolateral y un ángulo mayor de 30º tienen un 81% menos de riesgo de tener un OASIS (OR 0.19; IC del 95%: 0.12-0.31). Las estimaciones de Odds ratio muestran que hay una reducción riesgo de sufrir una ruptura del esfínter obstétrico anal del 48% (OR 0.52; IC del 95%: 0.31–0.88) y 63% (OR 0.23; IC del 95%: 0.23–0.58) cuando la distancia episiotomía-horquilla fue > 5 mm y la distancia del cuerpo perineal fue > 30 mm, respectivamente.

E.4.2.4. Características de la episiotomía y el periné en el análisis de subgrupos.

Characteristics	Univariate analysis			Multivariate analysis			Univariate analysis			Multivariate analysis		
	OR	95% CI	ρ-value	OR	95% CI	ρ-value	OR	95% CI	ρ-value	OR	95% CI	ρ-value
Perineal body	≤30 mm						>30 mm					
Angle of episiotomy > 30°	0.19	0.11–0.33	0.000	0.16	0.09–0.3	0.000	0.22	0.1–0.45	0.000	0.17	0.07–0.4	0.000
Length of episiotomy > 30 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm	0.5	0.29–0.87	0.014	0.46	0.25–0.83	0.01			NS			
Distance of perineal body (mm)	0.91	0.86–0.96	0.001	0.9	0.84–0.97	0.005	0.088	0.8–0.97	0.011	0.85	0.76–0.95	0.000
Distance of genital hiatus > 25 mm			NS						NS			
Parity	Nulipara						Multipara					
Angle of episiotomy > 30°	0.20	0.13–0.31	0.000	0.21	0.13–0.34	0.000			NS			
Length of episiotomy > 25 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm	0.51	0.32–0.8	0.004	0.46	0.27–0.78	0.004			NS			
Distance of perineal body > 30 mm	0.47	0.32–0.68	0.000	0.42	0.27–0.65	0.000			NS			
Distance of genital hiatus > 25 mm			NS	NS					NS			
Position	Occipitoposterior						Occipitoanterior					
Angle of episiotomy > 30°	0.22	0.09–0.55	0.001	0.19	0.07–0.54	0.002	0.19	0.11–0.31	0.000	0.17	0.1–0.3	0.000
Length of episiotomy > 25 mm			NS						NS			
Distance episiotomy-fourchette > 5 mm			NS				0.63	0.37–0.95	0.071	0.54	0.3–0.96	0.035
Distance of perineal body > 30 mm			NS				0.35	0.22–0.54	0.000	0.28	0.17–0.46	0.000
Distance of genital hiatus > 25 mm			NS						NS			

CI, confidence interval; OR, odds ratio.
[a] Adjusted for: maternal age, parity, daytime obstetrics, birthweight, fetal head position.

Tabla 6. Características de la episiotomías en el análisis de subgrupos (Gonzalez-Diaz et al, 2019)

En el análisis de subgrupos (Tabla 6) para evaluar la asociación entre las características de la episiotomía y el periné con el riesgo de OASIs, encontramos que un ángulo de la episiotomía mayor de 30º se comporta como un factor protector en todos los subgrupos con una reducción del riesgo del 80%, excepto en mujeres multíparas, donde no hay asociación con ninguna característica. Ni la longitud de episiotomía >30 mm ni una distancia del hiato genital >25 mm están asociados con un mayor riesgo de OASIS en ningún subgrupo. Una distancia episiotomía-horquilla >5 mm se asocia con una reducción del riesgo de OASIS del 50%, solo en mujeres con cuerpo perineal menor o igual a 30 mm (OR 0.46; IC del 95%: 0.25-0.83), nulíparas (OR 0.46; IC del 95%: 0.27–0.78) y posición occipitoanterior (OR 0.54; IC del 95%: 0.3–0.96). Una menor distancia del cuerpo perineal se asocia con un mayor riesgo de OASIS, ya sea mayor o menor de 30 mm. Sin embargo, una distancia del cuerpo perineal> 30 mm solo se asocia con una reducción en el riesgo de lesión del esfínter en mujeres nulíparas (OR 0.42; IC de 95%: 0.27–0.65) y en posiciones occipitoanteriores (OR 0.28; IC del 95%: 0.17–0.46) .

E.4.3. *Incidence of obstetric anal sphincter injuries after implementing the Triepi-45 tool to improve episiotomy angle in instrumental deliveries.*

Incidencia de lesiones obstétricas del esfínter anal después de implementar la herramienta Triepi-45 para mejorar el ángulo de la episiotomía en los partos instrumentales.

La cohorte de preintervención incluyó 986 partos instrumentales sucesivos; de manera similar, la cohorte de intervención incluyó 986 partos operatorios. Durante los dos períodos de tiempo, la tasa de instrumentación fue del 21.54% (986/4577) y del 21.45% (986/4597), respectivamente (P> 0.05).

En la cohorte de intervención, la herramienta **Triepi-45** se usó solo para 375 (38.0%) de los 986 partos instrumentales. Las razones de esta baja adherencia fueron variadas, pero las tres causas más frecuentes fueron la confianza del médico en su técnica en la episiotomía mediolateral, los partos instrumentales de emergencia y la toma de decisión de instrumentación con la cabeza fetal coronando y el periné distendido.

Ninguna de las características demográficas u obstétricas difirió entre las cohortes de preintervención e intervención, incluida la edad materna al parto, la edad gestacional, el ganancia ponderal, la raza, la paridad, las cesáreas previas, el embarazo gemelar, el tipo de parto instrumental, la analgesia epidural, la inducción de trabajo de parto, posición occipitoposterior, la duración de la primera y segunda fase del trabajo de parto, sexo fetal, peso al nacer, puntaje de Apgar y pH de la arteria umbilical. Del mismo modo, no hubo diferencias en las características demográficas y obstétricas entre la cohorte preintervención y la cohorte **Triepi-45** (Tabla 7).

Con respecto a las características de la episiotomía (**Tabla 1**), el ángulo de la episiotomía fue menor en la cohorte de preintervención que en la cohorte de intervención (25.4° vs 29.8°, P = 0.002), y la diferencia fue mayor entre la cohorte de preintervención y la cohorte Triepi-45 (25.4° vs 33.8°, P

<0.001). El número de episiotomías con un ángulo mayor de 30° también fue mayor en la cohorte de intervención que en la cohorte preintervención (38.4% vs 20.8%, P = 0.017), e incluso aun mayor en la cohorte **Triepi-45** (75.0% vs 20.8% , P <0,001). Otras características de episiotomía y la longitud del cuerpo perineal no difirieron entre las tres cohortes.

Characteristics	Preintervention cohort (n=986)	Intervention cohort (n=986)	*P* value	Triepi cohort (n=375)	*P* value[b]
Maternal characteristics					
Age, y	32.8 ± 5.2	32.8 ± 5.5	NS	33.0 ± 5.8	NS
Gestational age, d	276.1 ± 9.6	275.4 ± 9.3	NS	275.3 ± 9.2	NS
Weight gain, kg	11.7 ± 4.8	11.9 ± 4.9	NS	11.5 ± 4.7	NS
Spanish	924 (93.7)	928 (94.1)	NS	351 (93.7)	NS
Nulliparity	779 (81.3)	58 (5.9)	NS	299 (79.8)	NS
Previous cesarean	65 (6.5)	75 (7.6)	NS	30 (8.1)	NS
Twin pregnancy	25 (2.5)	20 (2.0)	NS	8 (2.0)	NS
Delivery characteristics					
Instrumental delivery					
Vacuum/Kiwi	542 (53.8)	551 (55.9)	NS	258 (58.9)	NS
Forceps/spatulas	444 (46.2)	435 (44.1)		117 (41.1)	
Episiotomy	963 (97.8)	968 (98.2)	NS	368 (98.4)	NS
Epidural analgesia	929 (94.2)	968 (93.6)	NS	354 (94.4)	NS
Occipitoposterior position	207 (21.0)	259 (26.3)	NS	88 (23.5)	NS
Induced labor	305 (30.9)	321 (32.6)	NS	128 (34.1)	NS
Duration of stage, min					
1st stage	300 (210)	232.2 (172.8)	NS	232.2 (172.8)	NS
2nd Stage	75 (90)	90 (135)	NS	90 (135)	NS
Episiotomy characteristics					
Angle, °	25.4 ± 11.3	29.8 ± 9.5	0.002	33.8 ± 7.4	<0.001
Angle >30°	205 (20.8)	379 (38.4)	0.017	281 (75.0)	<0.001
Length, mm	30 (8.5)	35 (10)	NS	35 (10)	NS
Distance episiotomy–fourchette, mm	4 (5)	3 (4)	NS	4 (6)	NS
Distance of perineal body, mm	30 (10)	30 (5)	NS	30 (11)	NS
Distance of perineal body >30 mm	426 (43.2)	404 (41.0)	NS	197 (52.0)	NS
Neonatal characteristics					
Male	631 (64.0)	535 (54.3)	NS	204 (54.3)	NS
Birhweight, g	3361 ± 570	3305 ± 456	NS	3287 ± 442	NS
Umbilical artery pH <7.20	182 (18.5)	159 (16.1)	NS	(16.7)	NS
Apgar score <6 at 1 min	60 (6.1)	104 (10.6)	NS	36 (9.5)	NS
Apgar score <7 at 5 min	30 (3.1)	48 (4.9)	NS	20 (5.4)	NS
OASIS	93 (9.4)	70 (7.1)	0.103	18 (4.8)	0.009
Rupture grade			NS		NS
3a	55 (59.1)	33 (47.1)		9 (50.0)	
3b	30 (32.2)	33 (47.1)		8 (44.4)	
3c	6 (6.4)	2 (2.8)		1 (5.5)	
4	2 (2.1)	2 (2.8)		0 (0.0)	

Abbreviations: OASIS, obstetric and anal injuries; NS, not significant.
[a]Values are given as mean ± SD, median (interquartile range) or number (percentage).
[b]Groups were compared by Student test for mean values, Mann-Whitney *U* test for median values, and χ^2 test for percentages.

Tabla 7. Características demográficas de la cohorte preintervencion, de la cohorte postintevencion y de la cohorte de **Triepi-45** (Gonzalez-Diaz E et al, 2020)

La proporción de partos instrumentales con OASIS antes de la intervención fue del 9,4% (93/986) y del 7,1% (70/986) después de su inicio, pero la diferencia no fue significativa. Sin embargo, la tasa de OASIS fue significativamente menor en la cohorte Triepi-45 que en la cohorte previa a la intervención (4.8% vs 9.4%, P = 0.009; Odds ratio [OR], 0.47; IC del 95%: 0.26–0.86). Estos datos se usaron para calcular el "número necesario a tratar", lo que mostró que el uso de la herramienta Triepi-45 evitaría un caso de ruptura del esfínter por cada 21.7 mujeres tratadas. No hubo diferencias en la distribución de los diferentes grados de ruptura entre las cohortes.

Incidence of OASIS	Preintervention (n=986)	Intervention (n=375)	*P* value	Adjusted OR (95% CI)[a]
Overall	93 (9.4)	18 (4.8)	0.01	0.47 (0.26–0.86
Age at birth				
Maternal age <35 y	68/662 (10.2)	8/252 (3.2)	0.004	0.3 (0.13–0.68)
Maternal age >35 y	25/324 (7.7)	10/122 (7.5)	NS	
Parity				
Multiparity	10/83 (4.7)	2/76 (1.6)	NS	
Nulliparity	83/779 (10.4)	16/299 (5.3)	0.023	0.48 (0.26–0.90
Birthweight				
<3500 g	58/647 (9.0)	9/267 (3.4)	0.000	0.17 (0.06–0.45)
>3500 g	35/339 (10.2)	9/108 (8.3)	NS	
Fetal position				
Occipitoposterior	23/207 (11.2)	7/88 (7.9)	NS	
Occipitoanterior	70/779 (8.9)	11/287 (3.8)	0.000	0.19 (0.08–0.46)
Instrumental delivery				
Vacuum/Kiwi	35/542 (6.5)	8/258 (2.3)	0.044	0.34 (0.12–0.97)
Forceps/spatulas	35/444 (8.0)	10/117 (8.0)	NS	
Episiotomy				
No episiotomy	3/22 (13.0)	1/7 (14.2)	NS	
Episiotomy	90/964 (9.3)	17/368 (4.6)	0.017	0.45 (0.23–0.86)
Distance of perineal body				
≤30 mm	60/560 (10.7)	11/178 (6.2)	0.001	0.18 (0.07–0.49)
>30 mm	36/426 (8.45)	7/197 (3.55)	0.002	0.13 (0.04–0.47)

Abbreviations OASIS, obstetric anal sphincter injuries; NS, not significant.
[a]Logistic regression adjusted for age, birthweight, and parity. Presented as OASIS(n)/OVD(n).

Tabla 8. Incidencia de OASIs estatificado según las características maternales y obstétricas y análisis de regresión logística[a] (Gonzalez-Diaz E et al, 2020)

Las tasas de OASIS también se compararon entre la cohorte preintervención y la cohorte **Triepi-45** para los diferentes subgrupos de las poblaciones de estudio (Tabla 8). La incidencia de OASIS no fue mayor en el grupo Triepi-45 en ninguno de los subgrupos. Para los siguientes subgrupos, la incidencia fue significativamente menor en la cohorte **Triepi-45**: mujeres menores de 35 años, mujeres nulíparas,

mujeres con un recién nacido que pesa menos de 3500 g, aquellas con parto con ventosa/kiwi y aquellas con una longitud del cuerpo perineal largo (> 30 mm) o corto (≤ 30 mm) (Tabla 8).

E.5. DISCUSION

La distensión perineal en el momento de la coronación de la cabeza fetal durante el parto provoca un desplazamiento lineal en el periné en dirección ventral y lateral, y esta es la causa de la diferencia en las características de la episiotomía entre la incisión y la sutura. Por lo tanto, para conseguir una sutura de la episiotomía desde la horquilla posterior con un ángulo de 45°, teóricamente, hay varias opciones de incisión, necesitando un mayor ángulo cuando el corte en introito está más cerca de la horquilla posterior (entre 45° en 6 mm y 60° en la horquilla). Estos resultados son consistentes con la definición establecida de episiotomía mediolateral (situada a menos de 3 mm de la línea media y dirigida lateralmente en un ángulo de al menos 60° hacia la tuberosidad isquiática).

El parto instrumental es el factor de riesgo más importante para los OASIs. En la práctica obstétrica diaria, el uso de los partos instrumentales es necesario en aquellos casos de sufrimiento fetal o de segundas etapas de parto prolongadas. El conocimiento y la modificación de los factores de los riesgo atribuidos pueden ayudar a reducir el número de lesiones del esfínter anal durante los partos operatorios, por lo tanto, podrían reducir la probabilidad de incontinencia fecal. El obstetra determina dos factores a la hora de realizar una episiotomía que pueden modificar el riesgo de OASIs: el *ángulo* y la *distancia episiotomía-horquilla*. Solo en el subgrupo de multíparas no se beneficiarían de ninguna característica de la episiotomía.

Para reducir la probabilidad de OASIs en los partos instrumentales es necesario lograr un ángulo de sutura de al menos 30º y con una longitud de entre 1-2 cm. Además en aquellas mujeres nulíparas, con cuerpos perineales menores de 30 mm y con posiciones fetales en occipitoanterior se pueden beneficiar de una lateralización de la episiotomía aumentando la distancia a la horquilla vulvar (>5mm). Por tanto teniendo en cuenta los conocimientos adquiridos en el primer trabajo, precisaríamos una incisión

realizada desde la horquilla vulvar con un ángulo de al menos 60º y una longitud de entre 2-3 cm en el momento de la coronación de la cabeza fetal, y en caso de precisar una lateralización de la episiotomía, para conseguir al menos 5 mm, el inicio de la incisión se debería separar al menos 15 mm de la horquilla vulvar.

Por ultimo, siendo el ángulo de episiotomía un factor modificable en el momento del parto, su optimización entre los 30-45° tiene un impacto importante en la reducción de los OASIs, y por lo tanto, disminuye la morbilidad a largo plazo de esta afección, especialmente en los grupos de mujeres de alto riesgo. Por esta razón, es esencial crear conciencia entre los obstetras sobre la importancia del ángulo de episiotomía e implementar el uso sistemático de herramientas que mejoren su precisión en el momento de la incision. Con este fin diseñamos el dispositivo **Triepi-45**, que permite el marcado del periné en reposo con un ángulo de 45º, cuyo uso logra estos objetivos demostrando que tiene un impacto positivo con una reducción de hasta el 50% de los OASIs en los partos instrumentales.

E.6. CONCLUSIONES FINALES

1. Con el fin de reducir el riesgo de lesión obstétrica del esfínter anal en los partos instrumentales es necesario lograr un ángulo de sutura de la episiotomía de al menos 30º, y en aquellas mujeres nulíparas, con cuerpos perineales menores de 30 mm y con posiciones fetales en occipitoanterior también se pueden beneficiar de una lateralización de la episiotomía (aumentando la distancia a la horquilla vulvar a >5mm).

2. La distensión del periné por la cabeza fetal durante el expulsivo provoca un desplazamiento lineal causando diferencias en las características de la episiotomía entre la incisión y su sutura. Así en los partos instrumentales, precisaríamos una incisión en el momento de la coronación de la cabeza fetal con inicio en horquilla vulvar, un ángulo de al menos 60º, y en caso de precisar una lateralización de la episiotomía, para conseguir al menos 5 mm, el inicio de la incisión se debería separar al menos 15 mm de la horquilla vulvar y con una angulación de 45º.

3. El uso del dispositivo Triepi-45, permite el marcado del periné en reposo con un ángulo de 45º, ha demostrando que tiene un impacto positivo con una reducción de hasta el 50% de las lesiones obstétricas del esfínter anal en los partos instrumentales.

E.7. PERSPECTIVAS

En base a los resultados satisfactorios que se presentan en esta tesis, se debe crear conciencia entre todos los obstetras acerca de la importancia de las características de la episiotomía y el periné en el riesgo de lesiones esfinterianas durante el parto instrumental, y con el fin de optimizar la técnica de incisión de la episiotomía favorecer el uso de aquellos dispositivos que colaboren en este sentido, como es el caso de Triepi-45.

Es necesario mas investigaciones, por un lado, que nos permita conocer si la optimización de otros parámetros, como distancia episiotomía-horquilla, conllevaría una disminución del riesgo del OASIs, y por el otro, diseñar nuevos dispositivos (como Triepi-60) que puedan ayudar técnicamente en el momento de la realización de la episiotomía, y así como comprobar su eficacia clínicamente.

Por ultimo, seria preciso conocer si los resultados obtenidos en partos instrumentales podrían ser extrapolables a los partos eutócicos, o sea, si la mejora de las características de las episiotomías realizadas en partos normales conllevaría una reducción del número de lesiones del esfínter anal dentro de las políticas restrictivas actuales.

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G. APENDICES

G.1. APENDICE 1: Trigonometric characteristics of episiotomy and risks for obstetric anal sphincter injuries in operative vaginal delivery.

G.2. APENDICE 2: Differences in characteristics of mediolateral episiotomy in proffesionals at the same hospital.

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ORIGINAL ARTICLE

Trigonometric characteristics of episiotomy and risks for obstetric anal sphincter injuries in operative vaginal delivery

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Abstract
Introduction and hypothesis The objective of this study was to investigate the association between the trigonometric properties of episiotomy in operative vaginal delivery (OVD) and obstetric anal sphincter injuries (OASIS).
Methods The study included 72 primiparous women who had an OVD and episiotomy. Cases (n=36) had sustained OASIS at birth, while controls (n=36) had not. The groups were matched for instrumental delivery. The episiotomy scar was identified and its trigonometric characteristics were measured at 8–12 weeks postpartum. Data were analysed using conditional logistic analysis.
Results The angle of episiotomy behaves as a factor associated with anal sphincter injury, so women with a mediolateral episiotomy and an angle greater than 20° have an 87 % less risk of having an OASIS (odds ratio 0.13, 95 % confidence interval 0.03–0.58). The study showed that scarred episiotomies at 8–12 weeks after OVD with an angle≤20°, depth and distance between the episiotomy and anus≤15 mm, total upper triangle perimeter≤75 mm, para-anal triangle perimeter≤15 mm and areas between scar and midline≤250 mm^2 were significantly associated with higher risk of OASIS.
Conclusions When a mediolateral episiotomy is performed in OVD the technique has a strong effect on the occurrence of OASIS. Additional research is needed to determine if the optimal technique for mediolateral episiotomies produces less OASIS than deferring the performance of episiotomy.

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Keywords Episiotomy · Episiotomy technique · Obstetric anal sphincter injuries · Operative vaginal delivery

Introduction

Obstetric anal sphincter injuries (OASIS) are the most established and potentially most modifiable risk factor for developing faecal incontinence after vaginal delivery. The most important treatment is prevention [1], but there are few interventions shown to reduce risk. The increased risk of third- and fourth-degree tears in association with instrumental vaginal delivery is well described [2–4]. What is less clear is whether the use of episiotomy or its characteristics plays a role in preventing anal sphincter damage.

Traditionally, episiotomy has been a routine component of operative vaginal delivery (OVD), the aim being to avoid injury to the anal sphincter and to minimise the risk of traumatic birth for the baby. The published data are limited and contradictory regarding evaluation of episiotomy use in relation to instrumental vaginal delivery. Some studies show the performance of an episiotomy appears to increase the risk of perineal trauma [5–9] and other researchers found otherwise [10–13]. When assessing the type of episiotomy in each study, the midline episiotomies always behave as a risk factor [5, 6], the lateral episiotomies are associated as a protective factor [11] and the results of mediolateral episiotomies are conflicting [10, 12, 13].

There is only one pilot randomised controlled trial (RCT) [14] comparing restrictive use of episiotomy with routine use during operative vaginal birth, which does not provide conclusive evidence of which one is the best option. A longitudinal prospective cohort study embedded within a two-centre RCT [15] found that a restrictive approach to the use of episiotomy at OVD may increase rates of urinary morbidity, in particular stress incontinence and perineal pain, in the immediate postpartum period.

The angle at which an episiotomy can be made is a continuous variable (0–90°). Which angle should we choose? Kalis et al. [16] reported that definitions of mediolateral episiotomy used in European hospitals had a low degree of agreement and a vast range of individual interpretations. Other studies have shown that health professionals perform mediolateral episiotomies differently, causing some episiotomies to lie closer to the midline than intended [17–19]. This discrepancy in definition and technique highlights the question as to whether inaccurate conclusions might have been drawn, and if it might be misleading to compare reports [17, 20]. Studies evaluating the episiotomy technique revealed that the angle is significantly associated with OASIS and that such injuries seem to occur more often when the angle of the mediolateral episiotomy is <40° [19, 21–24].

We decided to investigate episiotomy characteristics in OVD defined by angle, distances, perimeters and areas. The aim of this study was to determine the impact of the angle of episiotomy on anal sphincter injury and whether a smaller angle of incision was associated with a higher incidence of third-degree perineal tears. The secondary aim was to determine the association between other episiotomy characteristics and OASIS in OVD.

Methods

Design and study population

Women included in this study delivered their children (between January 2012 and December 2012) at the Department of Obstetrics and Gynaecology at the Complejo Asistencial Universitario de León (CAULE), Spain, a referral medical centre.

We performed a matched case–control study. The cases were selected from successive OASIS diagnosed in the delivery room during the study period. The inclusion criteria were: single primiparous pregnancies with cephalic presentation, more than 35 weeks gestation and OVD with episiotomy. Controls were randomly selected from those instrumental deliveries in which OASIS was excluded and with the same inclusion criteria as the cases (ratio of 1:1). Also, the groups were matched for instrumental delivery (vacuum, forceps or both).

A power calculation using results from Andrews et al. [22] was undertaken for episiotomy angle, with an anticipated difference of 11° between groups, with a standard deviation of 13°, giving a significance level of 5 % and power of 90 %. The sample size required 31 women in each group. Due to anticipated loss to follow-up, a final sample size of 36 per group was established.

Techniques and data collection

Each participant was evaluated between 8 and 12 weeks postpartum for data collection. The measurements were determined for the lines and angle given between the fixed points of the posterior fourchette, the episiotomy and the most anterior point of the anal epithelium as well as the perimeters and areas of triangles formed in the perineum between the episiotomy scar and the midline. We distinguished two types of triangles: anus-independent and anus-dependent. Anus-independent triangles are right triangles formed between the episiotomy and midline, regardless of the location of the anus, and include total upper triangle and upper triangle (Fig. 1). Anus-dependent triangles (which consider the anus to draw the triangle) include the protective triangle (right triangle formed between the episiotomy and the midline, and that the lower side is not below the anus), double-double episiotomy-anus triangle (triangle formed by the fourchette, the caudal end of the episiotomy and the anus), double-single episiotomy-anus triangle (in the type 1 episiotomy corresponds to the protective triangle, while type 2 corresponds to the double-double episiotomy-anus triangle) and para-anal triangle (Figs. 1 and 2). We distinguished two types of episiotomy, according to their relationship to the anus, and defined as type 1 in which the caudal end of the episiotomy in the axial plane is below the anus and type 2 if it is above.

The unique examiner was blinded to cases and controls. At the physical examination, the vaginal introitus/perineum was assessed for the episiotomy scar. With the patient in lithotomy position and legs resting in knee holders, the following lengths (in mm and with a transparent ruler) were measured (Fig. 1): episiotomy scar, perineal body length (line drawn from the posterior fourchette to the outer edge of the anal epithelium), distance between the episiotomy and fourchette (the distance from the fourchette to the proximal end of the episiotomy) and distance between the episiotomy and anus (the shortest distance from the caudal end of the episiotomy to the midpoint of the anal canal). The other distances were calculated using trigonometric formulas and include (Fig. 1): (a) depth of episiotomy (line from the caudal end of the episiotomy to the crossing point in the perineal body perpendicularly or the shortest distance from the distal end of the episiotomy to the midline), (b) total length (line of episiotomy from the caudal end to the crossing point in the midline), (c) height to the fourchette (midline from the fourchette to cutoff of depth), (d) total height (midline between the crossing point of depth to the crossing point of total length) and (e) height to anus (midline from the depth of the episiotomy to the anus).

To measure the angle between the episiotomy and the midline (refers to x/360° of a full circle), we used the application Episiotomy© (episiotomy.uspcaule.es), a program developed by us for Apple devices, with a focal length of 10 cm. This same application also allowed us to calculate the remaining distances, perimeters and areas (Figs. 1 and 2) from the previous data and using trigonometric formulas for triangles formed in the perineum between the scar and the midline. The local Ethics Committee gave approval for the study and all participants gave their informed consent to participate.

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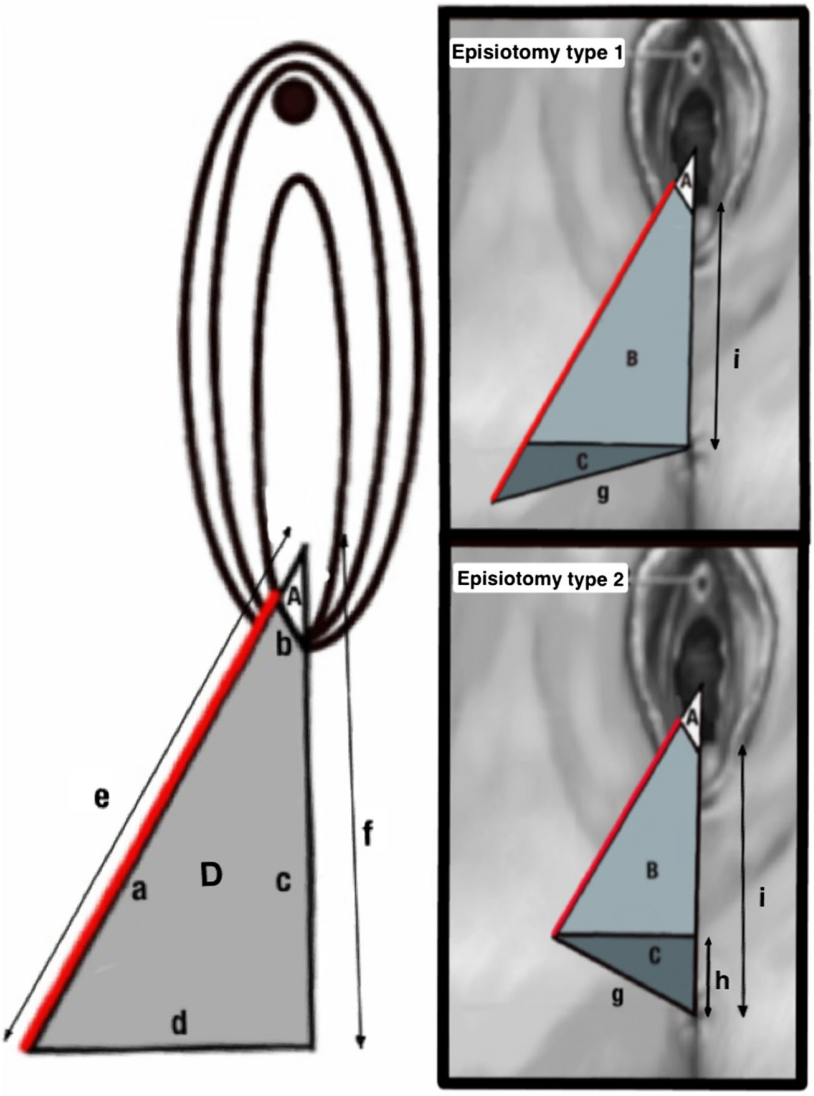

Fig. 1 Episiotomy characteristics. Distances (mm): **a** length of episiotomy, **b** distance between episiotomy and fourchette, **c** height to fourchette, **d** depth of episiotomy, **e** total length, **f** total height, **g** distance between episiotomy and anus, **h** height to anus, **i** perineal body length. Type of episiotomy: type 1: distance c>i, type 2: distance c <i. Perimeters (mm): total upper triangle perimeter: e+d+f, upper triangle perimeter: a+b+c+d, para-anal triangle perimeter: d+h+g, total triangle perimeter: a+b+i+g, protective triangle perimeter: type 1: a+b+i+depth from anus to episiotomy and type 2: a+b+c+d. Areas (mm^2): 1: total upper triangle area: area D+A, 2: upper triangle area: area D, 3: para-anal triangle area: area C, 4: double-single episiotomy-anus triangle area: type 1: area B and type 2: area B+C, 5: double-double episiotomy-anus triangle area: area B+C, 6: protective triangle area: area B

Statistics

A conditional logistic regression model was used to assess differences between cases and controls and to calculate crude odds ratio (OR) for OASIS. A significance level of 0.05 was set throughout. To look at associations between OASIS and ranges of episiotomy characteristics, we transformed the continuous variables into a dichotomous variable. Crude OR were estimated. Data were computerised and analysed using SPSS version 20 (SPSS Inc., Chicago, IL, USA).

In this case–control study, the proportion of women with third-degree tear was 51.47 %, whereas the incidence of third-degree tear in the institution is 7.56 %. Of itself, the case–control study only provided estimates of relative risks; however, absolute risks of third-degree tear for different angles of episiotomy were calculated by weighting the data appropriately to correspond to an overall population risk of 7.56 %.

Results

During the study period, 1,782 women gave birth vaginally (a total of 2,248 births with a caesarean section rate of 20.72 % and 476 needed an OVD). Routine mediolateral episiotomy is practised in OVD and the overall incidence of third-degree perineal tears was 2.13 % (in the group of OVD, it was 7.56 %) [25]. A total of 36 women with clinically identified OASIS during OVD and consecutively a total of 36 controls who met the inclusion criteria were selected. The characteristics of the cases and control groups are summarised in Table 1; no significant differences were found between groups.

Of 36 patients selected for each group, 35 cases and 33 controls agreed to participate in the study. Univariate conditional logistic regression analyses, considering both continuous and categorised variables (Tables 2 and 3), revealed significant differences between cases and controls. The angle

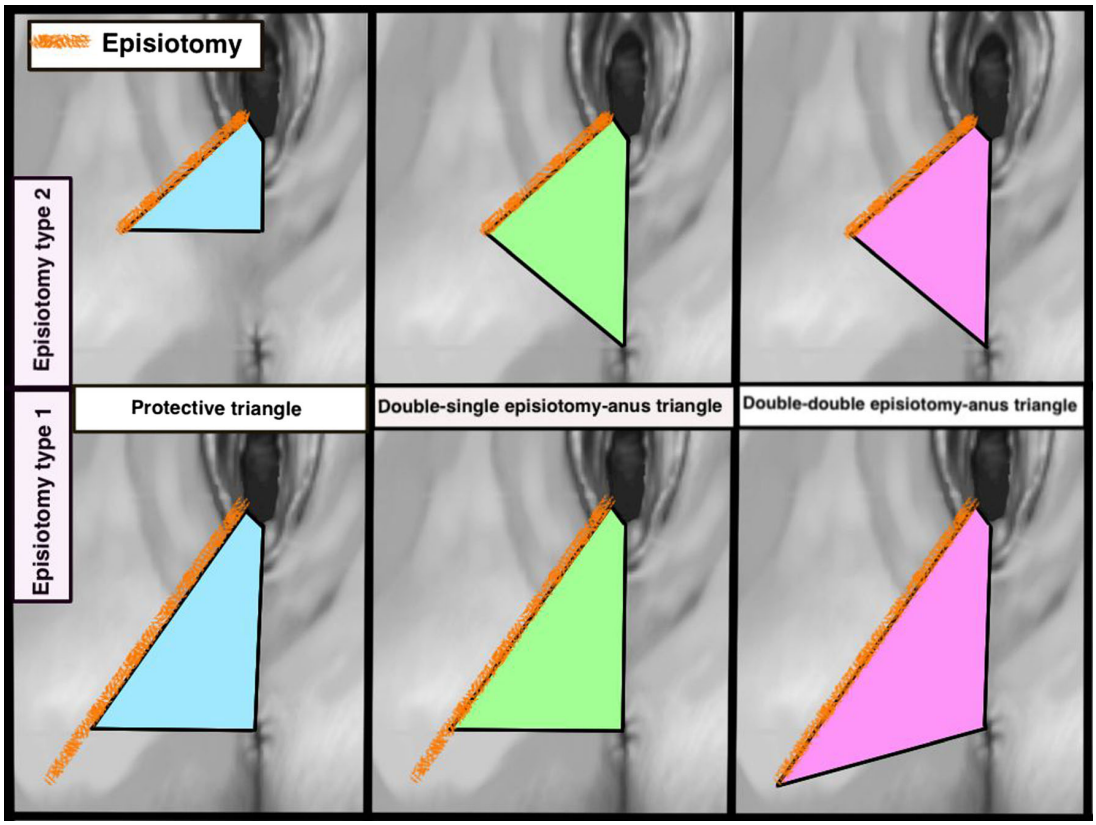

Fig. 2 Anus-dependent triangles: protective triangle, double-single episiotomy-anus triangle, double-double episiotomy-anus triangle and para-anal triangle*

Table 1 General characteristics

	OASIS (n=36)	No OASIS (n=36)	p value
Patient characteristics			
Maternal age (years)[a]	32.03±5.45	32.50±5.29	NS[e]
Gestational age (days)[a]	280±5.49	277±5.29	NS[e]
Delivery characteristics			
Vacuum extraction[c]	10 (28.57 %)	10 (29.41 %)	NS[d]
Forceps extraction[c]	19 (54.28 %)	18 (52.94 %)	NS[d]
Both vacuum and forceps extraction[c]	6 (17.14 %)	6 (17.65 %)	NS[d]
Use of PGE_2[c]	8 (22.2 %)	3 (8.3 %)	NS[d]
Epidural anaesthesia[c]	35 (97.2 %)	35 (97.2 %)	NS[d]
Clear amniotic fluid[c]	32 (88.9 %)	24 (66.7 %)	NS[d]
Duration first stage (h)[a]	4.72±2.8	4.44±3.09	NS[e]
Duration second stage (h)[a]	1.79±1.1	1.10±1.08	NS[e]
Occipitoposterior position[c]	11 (30.6 %)	12 (33.4 %)	NS[d]
Neonatal characteristics			
Male (%)[c]	22 (61.1 %)	25 (69.4 %)	NS[d]
Birthweight (g)[a]	3,371.94±376.6	3,342.19±393.5	NS[e]
Apgar ≤6 after 1 min[c]	6 (16.7 %)	4 (11.1 %)	NS[d]
Apgar ≤9 after 5 min[c]	11 (30.6 %)	01 (27.8 %)	NS[d]
pH umbilical cord blood sampling[a]	7.22±0.91	7.25±0.93	NS[e]

PGE_2 prostaglandin E_2 [a] Mean ± SD
[b] Median (p25–p75)
[c] *n* (%)
[d] McNemar's test
[e] Paired samples Student's test

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Table 2 Trigonometric characteristics of episiotomy in primiparous with OVD and OASIS risk

Characteristic of episiotomy (quantitative variables)	No OASIS (n=33)	OASIS (n=35)	p value	OR crude[a]	Wald	95 % CI
Angle						
Angle of episiotomy (°)	26.88 (5.3)[b]	20 9 (5.1)[b]	0.005[a]	0.81	7.99	0.7–0.94
Distances (Fig. 1)						
Length of episiotomy (mm): distance a	32.32 (5.6)[b]	29.86 (6.1)[b]	NS[a]			
Distance episiotomy-fourchette (mm): distance b	3.97 (4.7)[b]	2.74 (4.3)[b]	NS[a]			
Total length (mm): distance e	36.08 (6.93)[b]	33.24 (8.73)[b]	NS[a]			
Depth of episiotomy (mm): distance d	16.23 (4.2)[b]	11.96 (4.6)[b]	0.006[a]	0.74	7.63	0.60–0.92
Total height (mm): distance f	32.06 (6.4)[b]	30.88 (7.9)[b]	NS[a]			
Height to fourchette (mm): distance c	25.12 (6.9)[b]	25.21 (5.9)[b]	NS[a]			
Distance episiotomy-anus (mm): distance g	17.6 (4.6)[b]	13.39 (4.9)[b]	0.005[a]	0.79	7.77	0.67–0.93
Height to anus (mm): distance h	2.35 (6.8)[b]	1.64 (6.1)[b]	NS[a]			
Distance of perineal body (mm): distance i	27.47 (1.8)[b]	26.86 (2.6)[b]	NS[a]			
Perimeters (Fig. 1)						
Total upper triangle perimeter (mm)	84.36 (16.3)[b]	76.09 (20.4)[b]	NS[a]			
Upper triangle perimeter (mm)	77.64 (13.3)[b]	69.78 (15.1)[b]	NS[a]			
Para-anal triangle perimeter (mm)	18.09 (5.9)[b]	13.5 (5.1)[b]	0.01[a]	0.85	6.65	0.75–0.96
Total triangle perimeter (mm)	81.37 (10.8)[b]	72.85 (13.5)[b]	0.01[a]	0.94	6.03	0.89–0.98
Protective triangle perimeter (mm)	73.5 (10.9)[b]	65.29 (11.5)[b]	NS[a]			
Areas (Fig. 1)						
Total upper triangle area (mm^2)	267.28 (95.8)[b]	197.38 (121.9)[b]	0.02[a]	0.99	5.68	0.98–0.99
Upper triangle area (mm^2)	253.57 (95.8)[b]	185.88 (107.3)[b]	0.02[a]	0.99	5.19	0.98–0.99
Para-anal triangle area (mm^2)	46.48 (38.5)[b]	34.27 (39.3)[b]	NS[a]			
Double-single episiotomy-anus triangle area (mm^2)	286.5 (107.3)[b]	206.51 (117)[b]	0.01[a]	0.99	6.04	0.98–0.99
Double-double episiotmy-anus triangle area (mm^2)	272.96 (107.4)[b]	192.87 (103.5)[b]	0.01[a]	0.99	6.25	0.98–0.99
Protective triangle area (mm^2)	229.88 (92.1)[b]	162.34 (85.2)[b]	0.01[a]	0.99	6.25	0.98–0.99
Episiotomy type 1	12 (33.3 %)[c]	11 (30.6 %)[c]	NS[d]			

[a] Conditional logistic regression

[b] Mean (DT)

[c] n (%)

[d] McNemar's test

of episiotomy behaves as a factor associated with anal sphincter injury, so women with a mediolateral episiotomy and an angle of greater than 20° have an 87 % less risk of having an OASIS [OR 0.13, 95 % confidence interval (CI) 0.03–0.58]. Mean depth of the episiotomy and mean distance between the episitomy and anus were shorter in the case group (11.96 and 13.39 mm) than in the control group (16.23 and 17.6 mm). This was also the case for mean para-anal triangle perimeter (13.5 versus 18.09 mm) as well as mean total triangle perimeter (72.85 versus 81.37 mm). All studied areas, except para-anal triangle area, showed a significant difference between the groups. The mean length, total length, total height, height to fourchette, height to anus and distance of perineal body did not differ between the two groups. No difference was found between the types of episiotomy in each group.

The odds ratio estimates show that there is a 63 % (OR 0.27, 95 % CI 0.09–0.80) and 87 % (OR 0.13, 95 % CI 0.03–0.58) reduced risk of sustaining an anal obstetric sphincter rupture when the depth of the episiotomy was >15 mm and the distance between the episiotomy and anus was >15 mm, respectively. In addition, if the total upper triangle perimeter was >75 mm or para-anal triangle perimeter >15 mm, the risk for an OASIS decreased by 67 % (OR 0.33, 95 % CI 0.11–1.03) and 79 % (OR 0.21, 95 CI 0.06–0.75). Also, there are 81, 71, 77 and 67 % reduced risk of obstetric anal injuries when the total upper triangle area, upper triangle area, protective triangle area and double-double episiotomy-anus triangle area are >250 mm^2, and there is 83 % reduced risk of sustaining such injury when the double-single episiotomy-anus triangle area is >200 mm^2.

When the data of episiotomy angle were broken down into angle>or≤20° and scaled to a 7.56 % overall risk of third-degree tear in women with OVD, the risk of third-degree tear decreased substantially from 32.82 % in women with an angle of episiotomy less than 20° to 3.95 % in women with episiotomies exceeding 20°.

Table 3 Categorical trigonometric characteristics of episiotomy in primiparous with OVD and OASIS risk

Characteristic of episiotomy (categorical variables)	No OASIS (n=33)[a]	OASIS (n=35)[a]	p value[b]	Wald	OR crude[b]	95 % CI
Angle						
Angle of episiotomy (≤20°)	3 (8.3 %)	19 (52.8 %)	0.007	7.16	0.13	0.03–0.58
Distances						
Depth of episiotomy (≤15 mm)	15 (41.7 %)	27 (75 %)	0.019	5.52	0.27	0.09–0.80
Distance episiotomy-anus (≤15 mm)	11 (30.6 %)	25 (69.4 %)	0.007	7.16	0.13	0.03–0.58
Perimeters						
Total upper triangle perimeter (≤75 mm)	11 (30.6 %)	21 (58.3 %)	0.057	3.62	0.33	0.11–1.03
Para-anal triangle perimeter (≤15 mm)	11 (30.6 %)	23 (63.9 %)	0.015	5.86	0.21	0.06–0.75
Areas						
Total upper triangle area (≤250 mm^2)	15 (41.7 %)	29 (80.6 %)	0.008	7.08	0.19	0.05–0.64
Upper triangle area (≤250 mm^2)	15 (41.7 %)	26 (72.2 %)	0.027	4.88	0.29	0.09–0.87
Protective triangle area (≤250 mm^2)	20 (55.6 %)	31 (86.1)	0.022	5.24	0.23	0.06–0.81
Double-single episiotomy-anus triangle area (≤200 mm^2)	8 (22.2 %)	20 (55.6 %)	0.02	5.50	0.17	0.03–0.74
Double-double episiotomy-anus triangle area (≤250 mm^2)	16 (44.4 %)	27 (75 %)	0.03	4.52	0.33	0.12–0.92

[a] n(%)

[b] Conditional logistic regression

Discussion

There has been limited research addressing the optimal conduct of instrumental deliveries [19, 23, 26], in particular approaches to the use of episiotomy [5]. To date, the characteristics of episiotomy had been studied in spontaneous vaginal deliveries, but they had not been in OVD. This case–control study is the first one to demonstrate that the angle of episiotomy in OVD is associated with anal sphincter injury. In addition, other trigonometric characteristics, such as depth, distance between the episiotomy and anus, para-anal and total triangle perimeters and triangle areas, are associated with OASIS. This outcome is clinically relevant because episiotomy technique is relatively easy to modify, and our findings suggest that modified practice would potentially lead to reduction in anal sphincter injury rates, especially in a risk group such as instrumental deliveries. The absolute risk of a third-degree tear in a spontaneous delivery with an episiotomy under 25° [21] is three times lower than in instrumental delivery with an episiotomy less than 20° (9.7 vs 32.82 %).

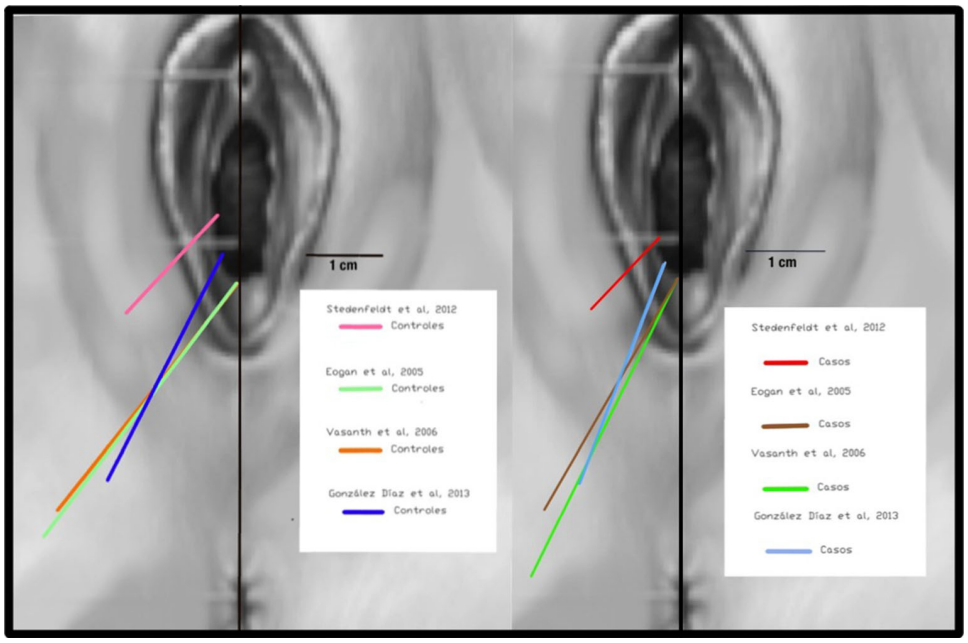

Fig. 3 Characteristic episiotomies in several studies

Tincello et al. [17] were the first to question the technique of mediolateral episiotomy and to raise the issue of the degree of force relief upon the perineum related to the angle of episiotomy. Later, Andrews et al. [22] with an observational study in the immediate postpartum period and Eogan et al. [21] and Stedenfeldt et al. [24] with case–control studies in the postpartum period showed differences in the characteristics of episiotomies in those patients with anal sphincter injury. Eogan et al. [21] studied only the angle of episiotomy. Andrews et al. [22] also studied the length, depth and distance from the anal canal, finding only differences in the angle. Finally, Stedenfeldt et al. [24] added the distance from the point of incision in the labia minora to the fourchette and found an association with that distance, the depth and length of the episiotomy, but not in the angle and the distance of the perineal body or with distance from the anus to episiotomy.

If we represent the episiotomy from each study (based on the mean of each variable) on the same perineal model (Fig. 3), we find that they are very different. So the OASIS group in Stedenfeldt et al. [24] has an average angle of 43° compared with 30 and 26° of Eogan et al. [21] and Andrews et al. [22] and 21° in our study. These variances in the angles (and associations) may involve differences in the incidence of damage to the sphincter in diverse institutions. In lateral episiotomies (as in Stedenfeldt et al. [24]), the angle is less important for the sphincter injury, whereas other parameters such as the length of the episiotomy and the distance from the fourchette to the incision gain importance, and yet, in the mediolateral episiotomies, the angle is the most decisive factor in the risk of sphincter injury. Therefore, the risk exists with different angles, and this risk may be modulated by the other variables.

In daily practice, the accoucheur determines three factors when performing an episiotomy: the angle, the distance from the posterior fourchette to start cutting the perineum and the length of the episiotomy. Also there is another constitutional factor to consider, the perineal body. A shortened perineal body length in primiparous women is associated with an increased risk of anal sphincter tear at the time of first delivery [27, 28]. The perimeters and areas are interesting because there is a strong association with the occurrence of OASIS and also because they allow one to analyse the risk of anal sphincter injury for the combination of all these measures (such as length, angle, perineal body, fourchette distance) into a unique parameter. More research is needed to assess which of these parameters has a greater association with the risk of OASIS.

This study has limitations. With 36 women in each group it is a small study. The results must therefore be interpreted with caution. As the measures studied were collected some time after birth, we do not know the true measures of the episiotomy at birth. At the time of birth, the perineal distension and oedema caused by the crowning of the head cause the perineum to be larger than at the time of repair and postnatal control. Therefore, the measurements in this study will necessarily be smaller than at the time of performing the episiotomy. Poor correlation between the angle of episiotomy at the time of the cut and the scarred episiotomy angle measured at the postnatal visit is reported in two studies. According to Kalis et al. [29], there is an episiotomy shrinkage of 12° after 6 months. A similar shrinkage was observed by van Dillen et al. [19]. The authors inspected episiotomies in 25 women immediately after birth and compared them with measurements made at a postnatal control. The mean angle of episiotomy was 38.6± 7.8° compared with 31.2±11.5°, respectively. Another factor to consider is that episiotomy is a three-dimensional structure, and all studies evaluated only one of the planes, without quantifying the effect of the remaining planes on the risk of OASIS.

When a mediolateral episiotomy is performed in OVD, the technique has a strong effect on the occurrence of OASIS. Additional research is needed to determine which is the optimal technique for episiotomies and if this practice produces less OASIS than deferring the performance of episiotomy.

Conflicts of interest None.

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ORIGINAL ARTICLE

Differences in characteristics of mediolateral episiotomy in proffesionals at the same hospital

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Abstract

Objectives: The objective of our study was to compare the theoretical concept of the accoucheur in our institution with regard to the characteristics of the mediolateral episiotomy (MLE), with a crowning head and after a delivery.
Methods: We devised two simple pictorial questionnaires (one with a crowning head and the other in rest after a delivery) in order to explore possible differences in clinical practice between the accoucheurs of our institution with respect to the MLE characteristics.
Results: With a crowning head, we found more acute angles when the age of accoucheurs was greater than 35 years old and more than 15 years of experience, but no with the perineum at rest. No difference was found between doctors and midwives, nor between males and females. 28.1% of accoucheurs indicated an acuter episiotomy angle with a crowning head.
Conclusion: This study confirmed that the individual interpretation of MLE differed widely among professionals at the same hospital. These differences which have been shown could predispose women to a greater risk of anal sphincter injuries. For this reason, there is a need to standardize this practice, to make the technique more homogeneous, particularly in the context of future research into the risks and benefits of episiotomy with respect to major perineal trauma.

Keywords

Episiotomy technique, mediolateral episiotomy, obstetric anal sphincter injuries

History

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Introduction

Episiotomy is a surgical enlargement of the vaginal orifice by an incision to the perineum during the last part of the second stage of labor or delivery [1,2]. When an episiotomy is needed, some clinicians choose a mediolateral rather than a midline episiotomy, primarily to reduce the chance of anal sphincter rupture since it is well established that the midline episiotomy carries a higher risk of sphincter laceration. This is a highly relevant issue because sphincter lacerations increase the chance that a woman may suffer fecal incontinence.

There is no current consensus on the definition of mediolateral episitomy (MLE). Kalis et al. [3] revealed that individual interpretation of MLE differed widely among European hospitals. Furthermore, 48% of the hospitals surveyed did not have a definition, had only an incomplete definition, or interchanged different types. The distribution of the three most frequent answers (no definition, ischial tuberosity, 45°) was distributed evenly across Europe with no obvious geographical concentration. Tincello [4] demonstrated differences in the reporting of the episiotomy practice by doctors and midwives working in the same institutions. Theoretically, all these differences demonstrated could predispose to a greater risk of anal sphincter injuries.

Recent researchers have established that the angle of episiotomy is an important determinant of the risk of obstetric anal sphincter injury (OASIS) [5–8]. Also there are differences between the angle at which the incision is made during the crowning of the head (when the perineum is stretched), and the angle of the surgical wound once the infant has been delivered [9]. Evidence suggests that correct execution of the episiotomy incision might have significant implications on the degree of perineal trauma. The results of studies evaluating whether MLE increases or reduces the risk of OASIS have conflicting results [10,11], which suggest that the reason for this difference could be a suboptimal incision [5].

There are studies that suggest a standardized definition of each type of episiotomy in order to establish uniformity going forward, so that future studies are amenable to comparison and meta-analysis [12].

The objective of our study was to compare the theoretical concept of the accoucheur in our institution with regard to the characteristics of the episiotomy, with a crowning head and after a delivery,

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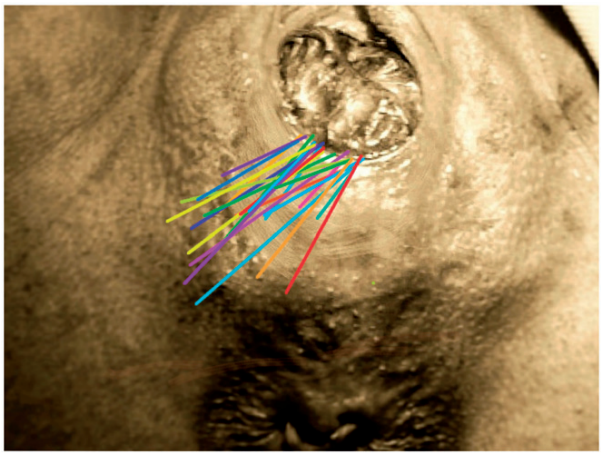

Figure 1. Graphical representation of mediolateral episiotomies with a crowning head.

Figure 2. Graphical representation of mediolateral episiotomies after delivery.

Methods

We devised two simple pictorial questionnaires in order to explore possible differences in clinical practice between the accoucheurs of our institution with respect to the MLE characteristics.

In the first pictorial questionnaire (Figure 1), there was a perineum with a crowning head (when the perineum is stretched) and, in the second picture (Figure 2), the perineum was in rest after a delivery (once the infant has been delivered without episiotomy). Both diagrams were taken from the same primiparous woman during childbirth.

Every clinician was asked to mark the size and site of an episiotomy on both pictures, assuming that an episiotomy was clinically indicated. For this test, we used a tablet computer (Ipad) to show the pictures and an app to measure the episiotomy drawn (Episiotomy®; available in Itunes, https://itunes.apple.com/app/episiotomy/id808441891?ign-mpt=uo%3D5. Cupertino, CA). The questionnaire also asked for details regarding profession, sex, age and professional experience.

Completed questionnaires were analyzed by drawing a line in the sagittal plane from the clitoris to mid-anus and measuring the following distances: (a) the angle subtended by the mark to the sagittal plane; (b) the length of the mark; and (c) distance episiotomy-fourchette (the distance from the union of sagittal plane and introitus to the origin of the episiotomy mark upon the introitus or the distance from the fourchette to the proximal end of the episiotomy) (Figures 1 and 2). Distances were measured in millimeters, and the drawing was with real scale so these figures correspond to anatomical measurements. Also, we calculated the difference between angles and distances of both figures: (d) Angle difference, (e) Length difference and (f) Fourchette distance difference. In addition, we determined the episiotomies with an angle difference $<0^\circ$ (Angle in the first picture with a crowning head was acuter than in the second).

The episiotomies were categorized into two groups: MLE and nonclassifiable, and the MLE had to meet all the following criteria: (a) during the crowning of the fetal head, the direction of the cut must be directed laterally at an angle of at least 60° (between 50 and 70°) from the midline towards the ischial tuberosity [9], and (b) the angle of the surgical wound must be of 45° (between 35 and 55°) and the distance to fourchette (mm) should be less than 3 mm [12].

First, we compared the episiotomy characteristics between the perineum in stretched and rest, and second, we compared this characteristic according to different variables: Occupation (Doctors/Midwives), Age ($\geq$35 years old/<35 years old), Professional experience (>15 years/<15 years), and Sex (Female/Male).

Statistical calculations were performed with SPSS version 20 (SPSS Inc., Chicago, IL). Univariate analyses were performed using chi-squared in dichotomous variables and Student's test in independent continuous variables or paired sample Student's test in continuous variables of matched pairs; a p value of <0.05 was chosen as the level of statistical significance.

Results

The two questionnaires were piloted on a sample of 32 midwives and doctors who were working at Complejo Asistencial Universitario of León (CAULE), a large tertiary referral hospital. Tests were performed in June 2012. Sixty-four forms were completed, 40 from doctors and 24 from midwives, and they are represented in Figures 1 and 2. Five (25%) of the doctors were resident gynecologists, and 15 (75%) were staff. Average age was 42.16 years old (75% were $\geq$ 35 years old), with 24 (75%) of the accoucheurs having an experience of at least 15 years.

Only 28.1% of the accoucheurs drew episiotomies that met the requirements for mediolateral episiotomy for this study. No differences were found between different groups (Table 1).

Angle, episiotomy length and distance episiotomy-fourchette in both pictures were different, and this difference was statistically significant (Table 1). In the first picture (perineum with a crowning head) (Figure 1), the average angle was 54.1° with no difference between doctors and midwives, nor between males and females. However, we have found significant differences, with acuter angles when age was greater than 35 years old and more than 15 years of experience (Table 1).

Table 1. Characteristics of mediolateral episiotomy: with a crowning head (1) and after delivery (2).

	N	%	Non-classifiable	Angle 1	Angle 2	Angle diff	Angle diff<0°	Length 1	Length 2	Length diff	Fourchette dist 1	Fourchette dist 2	Fourchette dist diff
General	32	100%	71.9%	54.1° (12.67) ((42-63)) <0.001***	43.1° (11.04) ((35-52))	10.9° (13.99)	28.1%	18.9 (5.84) ((15-22)) <0.001***	14.5 (4.22) ((11-17))	4.3 (4.6)	3.3 (2.97) ((0,1-6)) <0.001***	0.7 (1.11) ((0-1,1))	2.6 (2.6)
Occupation													
Doctors	20	62.5%	75.0%	53.9°	46.2°	7.7°	25.0%	18.7	14.8	3.9	3.4	0.7	2.6
Midwives	12	37.5%	66.7%	54.1°	41.2°	12.9°	33.3%	18.9	14.3	4.6	3.5	0.7	2.6
		p value	NS*	NS*	NS**	NS**	NS*	NS**	NS**	NS**	NS**	NS**	NS**
Age: 42.16 years (18.1)													
≥35 years	24	75%	75.0%	51.0°	40.9°	10.2°	0.0%	18.4	14.6	3.7	3.2	0.7	2.5
<35 years	8	25%	62.5%	63.1°	49.6°	13.5°	37.5%	20.4	14.0	6.3	3.8	0.9	2.9
		p value	NS*	0.005*	NS**	NS**	0.04*	NS**	NS**	NS**	NS**	NS**	NS**
Experience													
<15 years	15	46.9%	66.7%	60.8°	45.5°	15.4°	6.7%	20.9	14.3	6.7	2.4	0.6	1.8
>15 years	17	53.1%	76.5%	48.0°	40.9°	7.1°	47.1%	17.1	14.8	2.3	4.2	0.8	3.3
		p value	NS*	0.003*	NS**	NS**	0.01*	NS**	NS**	0.006**	NS**	NS**	NS**
Sex													
Female	22	68.8%	68.8%	54.7°	44.5°	10.23°	22.7%	19.7	14.8	4.8	3.5	0.8	2.7
Male	10	31.3%	80,00%	52.6°	39.9°	12.64°	40%	17.1	13.7	3.4	2.9	0.5	2.3
		p value	NS*	NS*	NS**	NS**	NS*	NS**	NS**	NS**	NS**	NS**	NS**

diff: difference; dist: distance; (): Standard deviation; (()): *p*25–75; NS: Non significant;
*Chi-squared test;
**Student's test;
***Paired simple Student's test

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In the second picture (once the infant has been delivered) (Figure 2), the average angle was 43.1°, with no differences in the studied groups. The average angle difference between both pictures was 10.9°. The angle difference was least of 0° (first angle acuter than second) in 28.1%, and this differences were less frequent in younger age and less experienced.

The average lengths of episiotomies drawn were 18.9 mm in Figure 1 and 14.5 mm in Figure 2. The length difference was 4.3 mm, and it was longer with experience of < 15 years. The average distance of the start of the episiotomy from the midline was 3.3 mm in picture 1 and 0.7 mm in Figure 2, with no difference in the starting point between groups studied.

Discussion

In daily practice, the accoucheur determines three factors when performing an episiotomy: The angle, the distance from the posterior fourchette to start cutting the perineum and the length of the episiotomy. There is also another constitutional factor to consider, the perineal body. This study confirmed that the individual interpretation of mediolateral episiotomy differed widely even among professionals of the same hospital (Figures 1 and 2). Both individual [4,5,12,16,17] and institutional [9,5,12,13,15] variability has been confirmed by previous studies. The most important factors that determine these differences, in our study, were the degree of experience and the age. When the experience is less than 15 years, the episiotomy angle in perineum with a crowning head is less acute, however there were no differences in resting perine. Younger professionals are more updated on the latest scientific evidence as well as the most recent clinical studies.

Tincello [4] and Wong [17] found that episiotomies were significantly longer, and at a greater angle with the perineal midline, when they were performed by physicians rather than by midwives. In our study, we report no differences between episiotomies performed by doctors or midwives. And in a study of episiotomy measurements, van Dillen et al. [15] reported the same result. In our study, only 28.1% of the accoucheurs drew episiotomies that met the requirements for MLE. Silf et al. [16], reported only 12.7% of incisions preformed on a training model complied with the defined technique of a mediolateral episiotomy in a group of midwives and trainee obstetricians.

There is emerging evidence that the angle of the episiotomy does indeed affect the risk of OASIS. Multiple studies about episiotomy technique support this evidence [4,6,9,14,15] indicating that narrow-angled episiotomies increase the risk of OASIS (especially in operative vaginal delivery [8]). Kalis et al. [9] made the important point that the angle of incision and the angle after repair were quite different. This was not a new observation, but quantification of the degree of difference was, by about 15°. It is an important consideration, especially when this difference brings the incision into the region of the sphincter. If the incision needs to be cut at 60° to achieve a 45° angle after delivery, then the lack of clarity may lead to an increase in injury if an incision is cut at 45°, resulting in a 25–30° post-repair angle falling within the region of the anal sphincter muscle. In our study, in 53% of episiotomies the angle of incision was less than 60°, and 28.1% of accoucheurs indicated an acuter episiotomy angle with a crowning head (angle difference <0°). Wong et al. [17] reported only 25% accoucheurs stated they would incise them at an angle of 60° degrees or more from the midline.

As for the episiotomy length, in our study, there were no differences between groups, however others [4,17] reported that midwives drew episiotomies that were shorter. The study showed a reduction of 23.28% (18.9–14.5 mm) between incision and scar, but there are no studies that confirm this reduction. Stedenfeldt et al. [7] demonstrated that the longest episiotomy scars were significantly associated with less risk of OASIS, However, Andrews et al. [10] did not find this association.

And about the distance from fourchette to incision, Stedenfeldt et al. [7] demonstrated that women with an episiotomy for which the incision point was lateral to the midline had less risk of OASIS than those women with an episiotomy with the incision point close to the midline. Empirically, our accoucheurs believe that there is a reduction in this distance (an average of 78.8%) between after episiotomy repair and with a crowning head, but there are no studies to confirm the behavior of this opinion. In Europe, for hospitals with a definition of mediolateral episiotomy, Kalis [12] found that 7% stated the beginning was located 1 or 2 cm from the midline, and other observational studies have shown that one-third of UK professionals began the episiotomy lateral at the midline [4]. Such a lateral origin of incision could be regarded as a true lateral episiotomy.

We acknowledge that using a pictorial representation of the perineum may not represent exactly what accoucheurs do in clinical practice. However, we therefore believe that our findings are representative of current practice [17].

Evidence suggests that correct execution of the episiotomy incision can have significant implications on the degree of perineal trauma. The individual interpretation of MLE differed widely among professionals of the same hospital and among different institutions, and so there is a need to standardize this practice, both to make the technique more homogeneous and to decide those specific situations where it is clearly clinically indicated, but also particularly in the context of future research into the risks and benefits of episiotomy with respect to major perineal trauma. Other authors [17] suggest that midwives and doctors should perform at least ten supervised episiotomies prior to independent practice, and that courses should be an adjunct and not a substitute for hands-on clinical training. We suggest that training can improve the visual accuracy of estimating the incision angle at crowning, and for this we have developed the application Episiotomy© (episiotomy.uspcaule.es), a program for devices Apple that enhances this training.

Acknowledgements

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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