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Obstetric anal sphincter injuries before and after the introduction of the Episcissors-60: A multi-centre time series analysis

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ABSTRACT

Objective: To investigate the impact of the Episcissors-60 on obstetric anal sphincter injury (OASI) rates.
Study design: Observational multi-centre time series analysis at four maternity units in the North-East of England. The main outcome measures were obstetric anal sphincter injury rates and delivery blood loss.
Results: Data were analysed for women who had a vaginal birth of a singleton pregnancy before (11,192) and after (8064) the introduction of the Episcissors-60. There were 2115 episiotomies before and 1498 after the introduction of the Episcissors-60, of which 1311 (87.5%) were undertaken with the Episcissors-60, 114 (7.6%) with other scissors and the scissors used were not stated in 73 (4.8%) women. There was no significant association between the introduction of Episcissors-60 and the performance of an episiotomy ($\chi^2 = 0.006$, $p = 0.94$). Episiotomy was associated with a significant reduction in OASI rates (1.9% Vs 2.8%, odds ratio = 0.67 [0.51 – 0.86]; $p = 0.001$). There was no significant association between the introduction of the Episcissors-60 and the occurrence of OASIs in all women ($\chi^2 = 0.6$, $p = 0.46$) or in women who had an episiotomy ($\chi^2 = 0.20$, $p = 0.71$). In women who had an episiotomy, the mean estimated delivery blood loss was 550.3 ± 8.2 ml before and 598.8 ± 10.9 ml after the introduction of the Episcissors-60 ($p < 0.001$).
Conclusion: Introduction of the Episcissors-60 was not associated with a change in OASI or episiotomy rates but may be associated with a small increase in delivery blood loss.
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Introduction

An increase in obstetric anal sphincter injury (OASI) rates has been reported in several countries [1–6]. OASI is associated with pain, fecal incontinence and altered sexual function [7,8]. Evidence for the protective effect of episiotomy is conflicting [9–11] and restricted use is recommended [8]. The angle of the episiotomy has been shown to be important [12,13] and the National Institute for Health and Care Excellence (NICE) recommends an angle of 45–60° from the midline [14]. However, clinicians are unable to correctly estimate angles and lengths required to perform safe mediolateral episiotomies [15–17].

The Episcissors-60 are episiotomy scissors designed to achieve a mediolateral cut at 60° to the midline [18]. The Episcissors-60 is one of 6 innovations in the UK National Health Service (NHS) Innovation and Technology Tariff 2017–2019, a scheme designed to incentivise the adoption of transformational innovation [19]. Evidence that the Episcissors-60 reduces OASI rates is limited. In a simulated setting, the mean angle of the episiotomy cut using the Episcissors-60 was 60° compared to 45° with the Mayo scissors [20]. Episcissors-60 episiotomies were angled more laterally and were longer [20–23]. In a time series analysis, introduction of the Episcissors-60 was not associated with a significant change in episiotomy or OASI rates [24]. Mohiudin et al. reported another time series analysis across two hospitals following introduction of the Episcissors-60 plus clinician education, antenatal perineal massage and manual perineal protection [25]. At one hospital, there was an increase in episiotomy rates and a decrease in OASI

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rates. At the second hospital, there was a reduction in OASI rates in women who had an episiotomy for spontaneous or operative deliveries [25]. A recent systematic review concluded that introduction of Episcissors-60, when combined with other preventative measures, can reduce Obstetric Anal Sphincter Injuries by up to 50% and reported an increase in episiotomy rates [26]. Another systematic review and meta-analysis [27] found a possible reduction in OASI. An increase in episiotomy rate was not observed.

Introduction of the Episcissors-60 in association with other interventions may result in an increase in episiotomy rates and a reduction in OASI rates. It is uncertain whether introduction of the Episcissors-60 alone, would result in a change in OASI rates. There is no agreement on the most appropriate number of episiotomies needed to prevent one OASI. The objective of this study was to examine the impact of adoption of the Episcissors-60 in isolation, on OASI rates.

Patients and methods

This study was funded by the North East & North Cumbria Academic Health Sciences Network (NE & NC AHSN). All nine maternity units within the NE & NC AHSN were invited to participate in this study in May 2017. A project end date (30/06/2018) and a latest start date (31/01/2018) were agreed to allow a minimum of 4 months 'after' period plus a 1 month 'wash-out' period. The 'wash-out' period allowed time for all existing episiotomy scissors to be replaced with the Episcissors-60 scissors. Data from this period are not included in the analysis. Participating units could introduce the Episcissors-60 as local conditions permitted within these limits. Individual units provided training relating to use of the Episcissors-60 but no other interventions to prevent OASIs were introduced. In particular, there were no changes in the techniques used in the diagnosis or management of OASI during the periods covered by the study. Anonymised data were obtained from existing maternity databases. There was a parallel implementation study to examine the barriers and facilitators to the adoption of this innovation

Statistical analysis

Descriptive and statistical analysis was performed using IBM SPSS Statistics 25 (IBM, White Plains, NY, USA). Patients' demographic characteristics are presented in terms of median standard deviation and range or percentage as appropriate. Two way relationships between categorical variables were analysed using chi-square analysis with log-linear analysis used to examine the relationship between three categorical variables. Differences between continuous variables were assessed using Student's *t*-test for independent measures and the Mann-Whitney test in the case of parity. Here because of very large sample size significance level was assessed using a Monte-Carlo method. Blood loss statistics were compared using a two-way factorial independent measures ANOVA. Statistical significance was considered with a p value of 0.05 or less.

Results

Six maternity units agreed to participate in the study. One of these units was excluded because of participation in the RCOG OASI care bundle project. Once data were available but prior to analysis, the data from one unit were rejected because of inconsistencies in the way the Episcissors-60 were introduced across the two sites that made up the maternity unit. Data were therefore analysed for 4 units: The Royal Victoria Infirmary, Newcastle (10 months 'after' period), Northumbria Healthcare Trust (8 months), South Tees NHS Trust (7 months) and City Hospital Sunderland NHS Trust (5 months). All units confirmed that there were no additional systematic interventions to reduce OASI rates in the period following the introduction of the Episcissors-60 and there were no changes in the way OASIs were identified, diagnosed or managed across the study periods. Data were available for 19,256 women following vaginal birth of a singleton pregnancy (11,192 before and 8064 after, Table 1). Data on whether or not an episiotomy was performed were missing for 151 women (5 operative vaginal and 146 spontaneous vaginal births) before and 225 women (2 operative vaginal and 223 spontaneous vaginal births) after the introduction of the Episcissors-60.

There was no significant association between the introduction of Episcissors-60 and the performance of an episiotomy ($\chi^2(1) = 0.006$, $p = 0.94$, Table 2). OASI rates were lower in women who had an episiotomy (1.9%) compared to those who did not (2.8%), odds ratio (OR) 0.67 [95% confidence interval (CI) 0.51 – 0.86]; $p = 0.001$; Table 3). Further analysis indicated this association was confined to the period before (1.8% Vs 2.9%; odds ratio 0.63 [0.44 – 0.88]; $p = 0.002$) and not after introduction of the Episcissors-60 (2.0% in women who had episiotomy Vs 2.7% in women who did not, odds ratio 0.76 [0.51–1.13]; $p = 0.10$). A three way log-linear analysis was performed including the effects of introduction of Episcissors-60, performance of an episiotomy and

Table 2
Number of women (%) who had an episiotomy before and after the introduction of the Episcissors-60 ($\chi^2(1) = 0.006$, $p = 0.94$). Data were missing on 151 women before and 225 women after the introduction of the Episcissors-60.

	Before	After	Totals
No episiotomy	8926 (80.8%)	6341 (80.9%)	15267
Episiotomy	2115 (19.2%)	1498 (19.1%)	3613
	11041	7839	

Table 1
Characteristics of women giving birth before and after the introduction of the Episcissors-60. SVD = Spontaneous vaginal deliveries.

	Period	Mean ± SD / Median (range)	*P*	Effect size *(Cohen's d)*
Age (years)	Before	29.0 ± 5.6	0.04	0.03
	After	29.2 ± 5.6		
Parity	Before	1.0 (0 – 10)	0.08	0.16
	After	1.0 (0 – 12)		
BMI	Before	26.4 ± 5.9	0.05	0.04
	After	26.6 ± 5.9		
Gestation (days)	Before	274.3 ± 27.7	< 0.001	0.06
	After	272.9 ± 15.6		
Birth weight (g)	Before	3352.6 ± 546.8	< 0.001	0.06
	After	3320.4 ± 574.8		
SVD (%)	Before	9493 (84.8%)	0.55	
	After	6865 (85.1%)		

Table 3
OASI rates in women with or without episiotomy. There is significant association between the performance of an episiotomy and occurrence of OASI $\chi^2(1) = 8.99$, $p = 0.001$ and this is confined to the period before the introduction of the Episcissors-60 ($\chi^2(1) = 7.71$, $p = 0.002$) but not after ($\chi^2(1) = 1.8$, $p = 0.10$). In nulliparous women having a spontaneous vaginal delivery (SVD), There is a significant association between the performance of an episiotomy and occurrence of an OASI ($\chi^2(1) = 16.47$, $p < 0.001$).

All	No OASI	OASI	Totals
No episiotomy	14845 (97.2%)	422 (2.8%)	15267
Episiotomy	3545 (98.1%)	68 (1.9%)	3613
Before			
No episiotomy	8669 (97.1%)	257 (2.9%)	8926
Episiotomy	2077 (98.2%)	38 (1.8%)	2115
After			
No episiotomy	6176 (97.4%)	165 (2.6%)	6341
Episiotomy	1468 (98.0%)	30 (2.0%)	1498
Nulliparous women with SVD			
No episiotomy	5098 (96.2%)	201 (3.8%)	5299
Episiotomy	921 (98.8%)	11 (1.2%)	932

occurrence of OASI. The final model fit was not significantly different to what was expected (Likelihood ratio $\chi^2 = 1.27$, $p = 0.74$) but the third order interaction (Episcissors-60 introduction x episiotomy x OASI) was not significant ($\chi^2 = 0.622$, $p = 0.43$) and neither was the two way interaction between Episcissors-60 introduction and OASI ($\chi^2 = 0.009$, $p = 0.92$). The two way interaction between performance of an episiotomy and OASI was significant ($\chi^2 = 9.72$, $p = 0.002$) indicating that the occurrence of an OASI is reduced by the performance of an episiotomy and this effect is not modified by the introduction of the Episcissors-60. The number of episiotomies needed to prevent one OASI was 109. In nulliparous women having a spontaneous vaginal birth, OASI rates were also lower in women who had an episiotomy (1.2%) compared to women who did not (3.8%), odds ratio 0.29 [0.16 - 0.54, $p < 0.001$; Table 3). Log-linear analysis was performed in this subgroup and the three way interaction is not significant – i.e. the introduction of Episcissors-60 does not influence the association between episiotomy and OASI. The number of episiotomies needed to prevent one OASI in nulliparous women with a spontaneous vaginal birth was 37.

There were 1425 episiotomies following the introduction of the Episcissors-60, of which 1311 (92%) were undertaken with the Episcissors-60 and 114 (8%) performed with other scissors. There was no significant association between the introduction of the Episcissors-60 and the occurrence of OASIs in all women ($\chi^2 = 0.6$, $p = 0.46$, Table 4), women who had an episiotomy ($\chi^2 = 0.20$, $p = 0.71$, Table 4) or women who had an episiotomy with the Episcissors-60 in the 'after' period (25/1311, 1.9% with Episcissors-60 compared to 2/114, 1.8% with other scissors; $\chi^2 = 0.013$, $p = 0.99$). The type of scissors used for episiotomy was not stated in 73 (4.8%) women, 3 (4.1%) of who had an OASI. In women who had an episiotomy, the mean delivery-to-discharge interval was 1.67 ± 0.04 days before and 1.58 ± 0.04 days after the introduction of the Episcissors-60 ($p = 0.14$). In these women, the mean estimated delivery blood loss was 550.3 ± 8.2 ml (n = 2057) before and 598.8 ± 10.9 ml (n = 1498) after the introduction of the Episcissors-60 ($p < 0.001$). There is a main effect of episiotomy on blood loss [$F(118,556) = 1649.2$, $p < 0.001$] and this is the major influence on the blood loss with mean without episiotomy being 337ml (95% CI 332–342) and the mean with episiotomy being 575ml (95% CI 564–585). Effect size for this difference r = 0.45. There is a main effect of before or after introduction of Episcissors-60 [$F(118,556) = 29.2$, $p < 0.001$] with the mean blood loss before being 440ml (95% CI 433–448) and after being 472ml (95% CI 463-480. The effect size for this difference is r = 0.03. There is also a significant interaction between the performance of an episiotomy and the introduction of Episcissors-60 on blood loss [$F(118,556) = 8.42$, $p = 0.004$] indicating that the introduction of Episcissors-60 affected blood loss in those who did or did not have an episiotomy differently. These results indicate that the difference in blood loss cannot be entirely explained by changes in the way blood loss was estimated over time.

Table 4
OASI rates before and after the introduction of the Episcissors-60. There is no significant association between the introduction of Episcissors-60 and OASIs in all women ($\chi^2(1) = 0.6$, $p = 0.46$) or women who had an episiotomy ($\chi^2(1) = 0.20$, $p = 0.71$).

All women	Before	After	Totals
No OASI	10763 (97.3%)	7649 (97.5%)	18412
OASI	295 (2.7%)	195 (2.5%)	490
	11058	7844	
Women with episiotomy			
No OASI	2077 (98.2%)	1468 (98.0%)	3435
OASI	38 (1.8%)	30 (2.0%)	68
	2115	1498	

Comment

We found that introduction of the Episcissors-60 was not associated with an increase in episiotomy rates. This suggests that apart from the use of a different scissors, there were no other changes in clinical practice and any observed differences are more likely to be attributable to the Episcissors-60. Introduction of the Episcissors-60 was not associated with a reduction in OASIs in all women, women who had an episiotomy or women who had an episiotomy with the Episcissors-60. Multiple factors contribute to OASIs including diameter of the presenting part (fetal presentation, position and attitude), rapidity of delivery, episiotomy (type, angle, timing and size), instrumental birth, maternal anatomy and skill of the accoucheur. It is therefore not surprising that modification of the angle of episiotomy alone did not have an impact on OASIs. Multi-modal interventions may be more successful but those that result in a significant increase in episiotomy rates need additional analysis.

A possible increase in episiotomy rate was recognised as a potential adverse consequence of the adoption of the Episcissors-60. In addition, soon after the scissors were introduced, there was formal (through structured interviews; Farnworth et al. unpublished observation) and informal feedback that clinicians were observing increased blood loss from the perineum. We therefore requested data on delivery blood loss. These data confirm a significant increase in blood loss in women who had an episiotomy after the introduction of the Episcissors-60. The majority of blood loss at delivery is from the placental bed and it is recognised that clinicians underestimate blood loss. Although the excess blood loss (about 50 ml) might be small, clinicians in one centres modified practice to facilitate rapid repair of Episcissors-60 episiotomies and minimise the anticipated increase in blood loss. Other interventions like the application of pressure to bleeding perineal vessels would limit blood loss but leave clinicians with a concern about the potential for haemorrhage. We therefore believe that the statistically significant increase in blood loss may be a clinically important finding. There are several reasons why the Episcissors-60 may be associated with increased perineal blood loss. Firstly, episiotomies made with the Episcissors-60 are longer than those made with the Braun-Stadler scissors (47 mm compared to 40 mm) [23] and would therefore be expected to result in greater blood loss. Secondly, blunt dissection of tissue is associated with lower blood loss compared to sharp dissection [28]. The Episcissors-60 are recognised to be sharper than other episiotomy scissors. Finally, the surgical anatomy of the perineum means that longer and more

lateral episiotomies are more likely to disrupt branches of the internal pudendal vessels. The vascular anatomy can contribute to 'alarming haemorrhage from obstetrical or surgical wounds of the vulva and vagina and the possibility of massive hematomas' [29]. The recommendation that episiotomies should be made at an angle of 45-60° from the midline when the perineum is distended [14], and the subsequent design of the Episcissors-60 with a 60° cutting angle does not appear to take full account of the surgical anatomy of the perineum and the need to protect major blood vessels. In addition, the observation that Episcissors-60 episiotomies are longer [23] is not necessarily beneficial and surgical objectives should be achieved with as little tissue injury as possible.

Strengths and limitations

The multi-centre design and large sample size make the findings more generalizable and are the main strengths of this study. The effect sizes of the differences in demographic characteristics before and after the introduction of the Episcissors-60 are very small and do not impact the analysis of the primary or secondary outcomes. The Episcissors-60 was introduced without additional interventions to reduce OASI rates and this approach allowed us to examine their impact in isolation. The data on blood loss at delivery have biologically plausible explanations and analysis was prompted by clinical observations, making the findings clinically important. A time series analysis is a robust method of assessing the impact of an intervention and is more feasible than a randomised trial which would have been the ideal study design. The use of routinely collected data is a limitation because of concerns about data quality. The data from one maternity unit were rejected for this reason but missing data persisted even in centres with acceptable data quality. The absence of randomisation and blinding means that the data may be subject to bias, although it would be impossible to blind clinicians to the use of readily distinguishable scissors.

Interpretation (in the light of other evidence)

Our data confirms previous findings that episiotomy is associated with a significant reduction in OASI rates. However, we found that introduction of the Episcissors-60 was not associated with a reduction in OASI rates, in contrast to previous studies [24–27]. These earlier studies introduced the Episcissors-60 in addition to other interventions to reduce OASIs and reported a possible increases in episiotomy rates. The reduction in OASIs rates previously reported was not adjusted for confounding factors especially episiotomy. It is recognised that episiotomy may reduce the risk of OASIs [9] and this is confirmed by our study. We therefore believe that our data reflect the true impact of the Episcissors-60. However, given the findings of previous studies and the high priority assigned to the prevention of OASI, a randomised trial is warranted.

Conclusion

The Episcissors-60 is not associated with a reduction in OASI rates and may be associated with an increase in perineal blood loss.

Contribution to authorship

PA, AF and SCR conceived the study, obtained funding, contributed to data collection & analysis and wrote the paper. AK, DE, VR, AU and VR contributed to funding application, introduced the Episcissors-60 in their units, collected the data and wrote the paper. EL collected the data in one unit, cleaned up the data, contributed to data analysis and wrote the paper. JR analysed the data and wrote the paper.

Declaration of Competing Interest

None declared.

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