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Title:

Obstetric anal sphincter injury rates among primiparous women with different modes of vaginal delivery

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Authors:

Amanda J Ampt^a Jillian A Patterson^a Christine L Roberts^a Jane B Ford^a

^a Clinical and Population Perinatal Health Research, The Kolling Institute, Northern Clinical School, University of Sydney, New South Wales, Australia.

Corresponding author: Amanda Ampt amanda.ampt@sydney.edu.au Clinical and Population Perinatal Health Research, Bldg 52, Kolling Institute, Royal North Shore Hospital, St Leonards, NSW 2065, Australia Phone +61 2 9462 9814 Fax +61 2 9906 6742

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Synopsis (25 words)

Non-instrumental births without episiotomy, and forceps with episiotomy, were the only birth modes where the risk of OASI increased significantly over time.

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ABSTRACT

Objective: To determine whether OASI rates are increasing at equal rates among different vaginal birth modes.

Methods: Using New South Wales (NSW) linked population data, the overall yearly OASI rates were determined among the 261,008 primiparous vertex singleton term births which occurred from 2001-2011. OASI rates among non-instrumental, forceps and vacuum births with and without episiotomy were also determined. Multivariable logistic regression was used to ascertain the adjusted odds ratios (aORs) for each birth category by year. The trends of the aORs over time for each birth category were compared.

Results: The overall OASI rate was 4.1% in 2001 and 5.9% in 2011. The highest OASI rates were among forceps births without episiotomy (12.2% in 2001, 14.8% in 2011), and lowest for non-instrumental births without episiotomy (2.6% in 2001, 4.4% in 2011). After adjustment for known risk factors, the only birth categories to show significant increases with OASI over the study period were non-instrumental without episiotomy and forceps with episiotomy (linear trend p<0.01).

Conclusion: Overall OASI rates have continued to increase. Known risk factors do not fully explain the increase for non-instrumental births without episiotomy and forceps with episiotomy. Changes in clinical management and/or reporting may be contributing.

INTRODUCTION

Obstetric anal sphincter injuries (OASIs) (third or fourth degree tears) are a complication of vaginal births which can have profound short and long term consequences for women. Of concern, increasing OASI rates have been reported in population-based studies both from Australia [1] and internationally [2, 3]. In order to identify possible reasons for increasing OASI incidence, attention has turned to examining changes in the rates of known risk factors over time. With the marked increase in caesarean sections internationally [4], the current population of women experiencing a vaginal birth may have different characteristics to women who previously birthed vaginally, and as a result may have a different risk profile for OASI occurrence. For example, among vaginal births in Australia the relative percentage of Asian women has increased by 35% from 2001 to 2009, and the relative percentage of instrumental births by 16.0% [1]. Changes in risk factors may also be a reflection of changes within the birthing population in general.

Despite changes in the prevalence of known maternal risk factors and clinical practices, they are not the sole drivers of increasing OASI rates [1, 2]. Attempts to produce a risk scoring system for OASI have been problematic with prediction remaining elusive [1, 5]. Although prediction modelling takes into account changing rates of risk factors, it assumes a constant association of risk over time between each risk factor and OASI. However, with possible changes in clinical practice, staff experience and expertise, and/or a change in population characteristics, the strength of individual risk factors may have changed over time. In addition, increases in reported OASIs may be a consequence of improved clinical detection and reporting.

Examination of OASI trends over time within risk factor strata may help to detect if there are women whose risk is increasing disproportionately compared to others in different strata. To date, such studies have not adequately taken into account confounding factors [6] or have been undertaken in populations with unusually low OASI rates [7]. With shifts in the proportion of instrumental births at a population level [8, 9], it is plausible that the strength of risk for OASI may be changing among different birth modes.

This population-based study using routinely collected linked data aims to determine if the overall trend for OASI is continuing to rise, and if OASI risk for different modes of birth with and without episiotomy are constant over time.

MATERIALS AND METHODS

The study population consisted of all primiparous women who had a vaginal singleton vertex birth at 37-41 weeks (term) gestation between 2001 and 2011 in New South Wales (NSW), Australia (n=261,008). NSW is the most populous state in Australia, and with over 95,000 births occurring in 2011 contributes to approximately one third of all Australian births [9]. Data for this study were obtained from the NSW Ministry of Health and consisted of two previously validated population data collections; the NSW Perinatal Data Collection (PDC, birth data), and the NSW Admitted Patients Data Collection (APDC, hospital data). The former is a legislated surveillance system of all births in NSW \geq 20 weeks gestation or \geq 400grams birthweight, and contains maternal, demographic, medical and obstetric information

including labour, birth and infant condition details. Data are recorded by the attending midwife or doctor. The APDC is a census of all discharges from public and private hospitals and day procedure centres, with administrative and demographic data as well as information regarding diagnoses and procedures coded according to the International Classification of Diseases, Australian Modification (ICD-10-AM) and the Australian Classification of Health Interventions (ACHI). These datasets were longitudinally linked using probabilistic methods by the Centre for Health Record Linkage, with de-identified records provided to researchers.

Obstetric anal sphincter injury (OASI) was identified from the hospital data by one or more of the following: ICD-10-AM diagnosis codes for third or fourth degree perineal laceration during delivery (O70.2 or O70.3), or the Australian Classification of Health Interventions procedure code for suture of third or fourth degree tear (16573-00). This combination has been reported as the most reliable method for ascertainment of OASI occurrence in NSW population health data [10]. Recognised risk factor data (maternal age, Asian country of birth, public/private care, hypertension, induction/augmentation, epidural, episiotomy, gestation, type of birth, birthweight and infant sex) were obtained from either one or both data collections based on accuracy of reporting [11].

The distribution of maternal and birth characteristics among non-instrumental, forceps and vacuum births were summarised using descriptive analysis. As OASI risk has previously been demonstrated to differ by birth mode with or without episiotomy [1, 3], births were classified into one of six categories: non-instrumental with and without episiotomy, forceps with and without episiotomy, and vacuum with and without episiotomy. Overall yearly OASI rates were determined, as well as yearly OASI rates for each birth category. Trend was examined by the Cochran-Armitage test (with p<0.05 representing a significant change).

Multivariable logistic regression was then undertaken to determine the association with OASI for each birth category at each year when maternal and birth characteristics were taken into account. Year of birth was combined with the birth category to create a new variable, with 'non-instrumental without episiotomy occurring in 2001' used as the comparator group. Risk factors with univariate p values<0.25 for association with OASI, and a priori plausible interactions with p values <0.05, were initially entered into the model, and progressively removed until all p values were <0.05 and any p value for interaction <0.01. Model build assessment was undertaken by log likelihood ratio tests. Removed covariates were assessed for confounding (changes in coefficients of >10%). The adjusted odds ratios (aOR) for each birth category for 2001 were then compared with the aORs for 2011 using the test for homogeneity of odds ratio as described by Altman and Bland [12]. Changes in association for OASI over time were then assessed for each birth category by determining the log-linear trend of the aORs.

All analyses were undertaken in SAS 9.3. Ethics approval was obtained from the NSW Population and Health Service Research Ethics Committee (PHSREC) prior to commencement of the present study. Informed consent was not required per the research protocol as researchers were provided with de-identified records as approved by the NSW PHSREC.

RESULTS

Between 2001 and 2011 there were 261,008 primiparous vertex singleton term vaginal births, of which 71.0% (n=185,179) were non-instrumental, 10.3% (n=26,919) forceps and 18.7% (n=48,910) vacuum. The distribution of maternal and birth characteristics among the three birth modes is presented in Table 1.

Overall, 5% of births resulted in an OASI (n=13,134). A pattern of increasing OASI incidence over time was seen, from 4.1% in 2001 to 5.9% in 2011. OASI rates among non-instrumental births with and without episiotomy, and among forceps births with episiotomy, significantly increased over time (p<0.01). In contrast, OASI rates among forceps without episiotomy showed a non-significant increasing trend, while no increases were evident for vacuum births (Figure 1).

Following exclusion of 8,485 records with missing data, 252,523 (96.8%) were available for multivariable analysis. After adjustment for maternal and birth characteristics, and using non-instrumental birth without episiotomy in 2001 as the comparator, the highest overall aORs for OASI were among forceps without episiotomy with aOR in 2001 of 6.31 (95% CI 4.57, 8.71) and aOR in 2011 of 7.95 (95% CI 5.82, 10.85). Non-instrumental births without episiotomy conferred the lowest overall association with OASI, with aOR in 2002 of 1.07 (95% CI 0.92, 1.25) and in 2011 aOR of 1.64 (95%CI 1.43, 1.89). Tests of linear trend for non-instrumental births without episiotomy (p<0.01) and forceps with episiotomy (p<0.01) demonstrated statistically significant increasing odds of OASI over time, while other

birth categories did not demonstrate significant trends. The only birth category with a significant difference in aORs between 2001 and 2011 was non-instrumental without episiotomy (p<0.01) (Figure 2).

DISCUSSION

This observational study has demonstrated that for women with non-instrumental births without episiotomy or forceps births with episiotomy, the risk of OASI has increased over time. In contrast, the risk did not significantly increase for women with non-instrumental births with episiotomy, forceps births without episiotomy, nor for vacuum births.

Comprising 58.5% of all vaginal births, non-instrumental births without episiotomy were the most common. Despite having the lowest overall association with OASI, they contributed most to the population burden of OASI. With both a significantly increased trend in aORs over time, as well as a significant difference in aORs across the study period, our results have highlighted that the adjusted risk of OASI has risen at a faster rate for non-instrumental births without episiotomy than for any of the other birth categories. This increase is of particular concern as this group is a main driver of increasing OASI rates overall. While there are known risk factors for OASI, there are still many circumstances whereby an adverse outcome such as this cannot be predicted. There are, however, reports of changes in clinical care for this group of women that are not collected in population data and have not been adjusted for. These include changes in perineal support techniques and waterbirths.

Anecdotal reports suggest that a 'hands poised' approach to assisting at birth has been adopted by clinicians, replacing the more traditional 'hands on' techniques. Using the newer approach, the perineum is no longer routinely supported, nor is flexion applied to the infant head at crowning. Instead, the hands are poised ready to apply gentle pressure in case of a rapid birth. International literature provides evidence for the occurrence of such changes in technique [13] and the Royal College of Midwives has adopted a recommendation that either 'hands on' or 'hands poised' can be used for spontaneous birth [14]. A Cochrane review of three randomised controlled trials (RCTs) comparing these two approaches reported that although there was no statistical difference in OASI rates between the 'hands off or poised' and 'hands on' group, there was substantial heterogeneity and that the effect could be in either direction [15]. Widespread education programs in Norway which have supported a return to a 'hands on' technique have resulted in decreased OASI rates [16]. Whether changes in techniques used at birth are associated with the increasing OASI rate for non-instrumental births without episiotomy is not known, but worthy of further research.

Similar to the 'hands poised' group, it is women having a non-instrumental birth without episiotomy who may have had a waterbirth. With waterbirths now an option for women having a normal low risk pregnancy [17, 18], we expect that the number of women birthing in water may have increased, however no local data are yet available. The few studies that have examined the association between OASI and waterbirth for primiparous women report an increased incidence of OASI among waterbirths women compared with non-water births, however differences did not

reach statistical significance [19, 20] which may have been a consequence of small numbers.

The other group to demonstrate significant increase in association with OASIS over time was forceps births with episiotomy. Among instrumental births, forceps deliveries have a greater association with OASI than vacuum. Their contribution to instrumental births has been slowly declining over the study period. In 2001 40.8% of instrumental births were by forceps, and 37.6% in 2011. Concern has been raised in the United States as to whether the forceps volume is now sufficient in some hospitals to provide adequate training and skill maintenance [21]. However another recent American study refuted any association between forceps volume and OASI incidence using data from one tertiary hospital (April 2008 - March 2012) [22]. In comparison with our study's findings of an OASI rate among forceps births of 11.6%, the authors reported a rate of 34.4%. It is thus highly questionable if their findings are generalizable to the Australian situation. Whether our finding of increased OASI risk among forceps births with episiotomy has been influenced by falling forceps volumes with the associated loss of training and skill maintenance opportunities in some Australian hospitals is not known. It is of note that our data showed a relatively stable association for this birth category with OASI after 2006, which may be a consequence of clinical detection and reporting.

There is the possibility that improved clinical detection may be contributing to the rise in OASI rates, as well as changes in clinicians' willingness to report adverse outcomes. The Royal College of Obstetricians and Gynaecologists (RCOG) recommended a more detailed classification system for perineal tears in 2001 [23] which stressed the importance of systematic examination for any woman with evidence of genital tract trauma. With adoption of the recommendations over time, increased awareness may have influenced the reporting of OASIs; however there is recent Australian evidence that OASIs are considerably under-diagnosed [24]. No longitudinal studies have been undertaken in Australia to determine if clinicians' diagnostic practices have changed. Our present study highlights that if increasing detection is the cause of apparent rises in OASI rates, it is not a driver of increases among vacuum births, which demonstrate no evidence of any increasing trend. Whether differential reporting has occurred, in which higher rates of third and fourth degree tears are reported among groups with known risk factors (such as instrumental births), is also not known, however re-analysis of a local validation study provides some reassurance this is not the case for perineal trauma in general [25]. Comparisons of sensitivities and positive predictive values (PPV) for perineal trauma among non-instrumental births with instrumental births were not statistically different (sensitivity 96.6 vs 97.9, PPV 96.0 vs 98.6 respectively).

Changing population demographics and risk characteristics among NSW birthing women may also be having an influence on OASI rates. With the long-term trend of decreasing vaginal births with a corresponding increase in caesarean sections [9], the current population of Australian women experiencing vaginal births may have different characteristics, and hence different risk profiles, to women in the past. In addition, the distribution of birth modes among vaginal births has also shifted with increases in instrumental deliveries. We have been able to adjust for many risk factors – however some remain unaccounted for, and may be unevenly represented among different birth categories and over time.

The strength of this study is underpinned by access to large validated population datasets, enabling examination of longitudinal trend for a fairly rare outcome. By examining the risk of OASI for year of birth within different birth categories and adjusting for known risk factors, we have been able to highlight birth categories in which unknown confounders may be operating. Targeting these birth categories for further research may be of value in helping to understand drivers behind increasing OASI rates. The study is limited by the population datasets' lack of detail regarding specific clinical practices.

In conclusion, overall OASI rates have continued to increase. Once known maternal and birth characteristics have been taken into account, non-instrumental births without episiotomy and forceps births with episiotomy are the only birth categories to show increasing risk of OASI. Unidentified risk factors that have been rising in these two groups may be related to clinical practice changes. Further research is needed within these two groups to help identify the drivers of increases with OASIs.

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CONFLICT OF INTEREST

The authors have no conflicts of interest.

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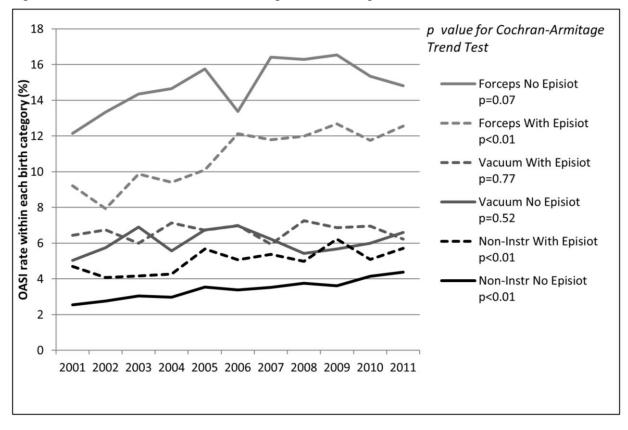
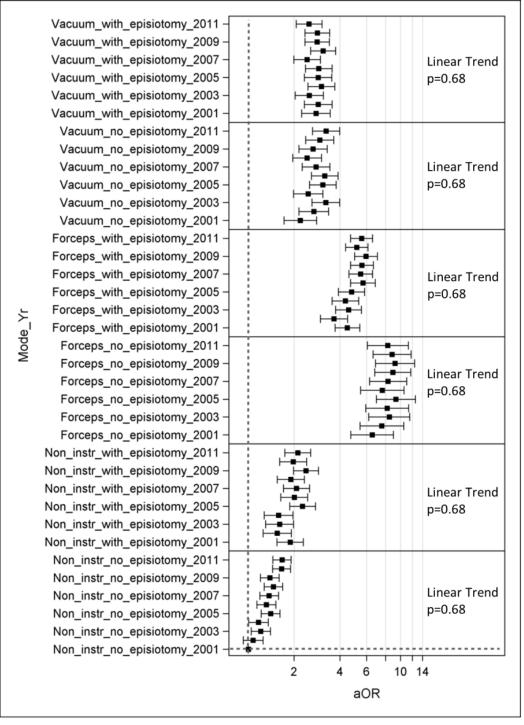


Figure 1 – Crude rates of OASI among different vaginal births

Figure 2 – Association of birth category and year with OASI (adjusted for maternal and birth characteristics)



Reference=non-instrumental birth without episiotomy 2001 p value for linear tests of trend of the coefficients Adjusted for age, country of birth, public/private care, diabetes, hypertension, Induction/augmentation, epidural, gestation, birthweight, and significant interactions where p<0.01

		Non-instrumental n=185,179 (col%)	Forceps n=26,919 (col%)	Vacuum n=48,910 (col%)
Age (years)	<25	64,643 (34.9)	4,768 (17.7)	9,679 (19.8)
	25-34	104,248 (56.3)	18,018 (66.9)	32,376 (66.2)
	≥35	16,288 (8.8)	4,133 (15.4)	6,855 (14.0)
Country of birth	Asian	25,935 (14.0)	4,704 (17.5)	8,769 (17.9)
Public/private care	Public	133,521 (72.1)	14,489 (53.8)	27,081 (55.4)
Hypertension		13,591 (7.3)	2,781 (10.3)	4,662 (9.5)
Diabetes		7,032 (3.8)	1,264 (4.7)	2,256 (4.6)
Induction/augmentation		110,815 (59.8)	22,449 (83.4)	38,741 (79.2)
Epidural		45,187 (24.4)	22,520 (83.7)	29,681 (60.7)
Episiotomy		32,546 (17.6)	22,383 (83.2)	25,836 (52.8)
Gestation (weeks)	37	10,786 (5.8)	1039 (3.9)	2270 (4.6)
	38	25,763 (13.9)	3,047 (11.3)	6,008 (12.3)
	39	47,364 (25.6)	6,009 (22.3)	11,711 (23.9)
	40	64,277 (34.7)	10,265 (38.1)	17,793 (36.4)
	41	36,989 (20.0)	6,559 (24.4)	11,128 (22.8)
Birthweight (kg)	<3.0	36,808 (19.9)	3,336 (12.4)	7,873 (16.1)
	3.0- <3.5	79,805 (43.1)	10,379 (38.6)	20,307 (41.5)
	3.5- <4.0	54,714 (30.0)	9,788 (36.4)	16,165 (33.1)
	≥4.0	13,807 (7.5)	3,409 (12.7)	4,548 (9.3)
Infant sex	Male	90146 (48.7)	14532 (54.0)	260.1 (53.2)
Year of birth	2001	16,867 (9.1)	2,534 (9.4)	3,680 (7.5)
	2002	16,612 (9.0)	2,266 (8.4)	3,960 (8.1)
	2003	16,728 (9.0)	2,173 (8.1)	3,980 (8.1)
	2004	16,443 (8.9)	2,066 (7.7)	4,028 (8.2)
	2005	16,528 (8.9)	2,059 (7.7)	4,354 (8.9)
	2006	16,703 (9.0)	2,136 (7.9)	4,296 (8.8)
	2007	17,020 (9.2)	2,494 (9.3)	4,779 (9.8)
	2008	16,860 (9.1)	2,670 (9.9)	4,755 (9.7)
	2009	17,048 (9.2)	2,590 (9.6)	5,117 (10.5)
	2010	17,138 (9.3)	2,980 (11.1)	5,063 (10.4)
	2011	17,232 (9.3)	2,951 (11.0)	4,898 (10.0)
OASIs		6,875 (3.7)	3132 (11.6)	3127 (6.4)

Table 1 – Mode of birth and maternal/birth characteristics