Title page:

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Obstetric Anal Sphincter injuries (OASIS) in multiparous women with the use of epidural anaesthesia - A retrospective cohort study
Inge PUTRI1,3, Koen SIMONS1,2, Jonathan NETTLE3, Anthony WOODWARD3
1Joan Kirner Women’s and Children’s Hospital,
176 Furlong Road, St Albans VIC 3021, Australia,
Contact number: 03 8345 1616
2University of Melbourne,
347-22, 207-221 Bouverie Street, Parkville VIC 3052, Australia,
Contact number: 03 9035 7927
3Royal Women’s Hospital,
Corner Grattan Street & Flemington Road, Parkville VIC 3052, Australia,
Contact number: 03 8345 2000

Acknowledgements
Ms Lynne Rigg, Senior Project Officer, Quality and Safety, The Royal Women’s Hospital,
Melbourne, Victoria, Australia

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Obstetric Anal Sphincter injuries (OASIS) in multiparous women with the use of epidural anaesthesia - A retrospective cohort study

Short running Title: Epidural and OASIS in multiparous women (39 characters)

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Figure count: 1
Abstract

Background: The use of epidural as a form of analgesia is increasingly common in labour, but this has shown to have been associated with increased rates of instrumental delivery, and prolonged second stage, resulting in increased rates of OASIS (Obstetric Anal Sphincter Injury).

Aims: This study aimed to investigate the impact of epidural anaesthesia in multiparous women undergoing vaginal deliveries on OASIS and secondary maternal outcomes.

Materials and methods: A retrospective cohort study of multiparous women with singleton pregnancies delivering at term ≥37 weeks and the use of epidural analgesia in labour at a
tertiary hospital was undertaken between the period 2012-2018. Maternal outcomes were collated and dichotomised according to the presence of epidural use. Multiparous women with no prior history of a vaginal birth and non-cephalic presentation during labour were excluded.

**Results:** There were 14,124 multiparous women that met the inclusion criteria, spontaneous labour is associated with an increased risk of OASIS aOR1.46, P=0.012. The overall rate of epidural use was 17%. Women with epidural use had significantly lower chances of sustaining OASIS in normal vaginal births and instrumental vaginal births. (1% vs 1.8%, aOR 0.49, P=0.004). Epidural is associated with increased rates of prolonged second stage (8.5% vs 3.8%, P<0.05), instrumental delivery (26.1% vs 4%, P<0.05), episiotomy use (23.8% vs 10.2%, P<0.05).

**Conclusion:** The use of epidural analgesia in multiparous women is associated with a reduction in anal sphincter injuries.

**MeSH keywords:** epidural, OASIS, multiparous, labour, risk factors
Introduction

The use of epidurals is increasingly common in labour, with 30 in 100 women using an epidural during their labour process.\textsuperscript{1,2} Effective neuraxial analgesia is associated with a prolonged second stage of labour and an increased rate of instrumental vaginal delivery, resulting in an increased rate of Obstetric anal sphincter injuries (OASIS).\textsuperscript{3,4,5} There are a number of additional risk factors for OASIS including Asian ethnicity, primiparity, previous history of third and fourth-degree tears, induction of labour, prolonged second stage of labour, instrumental delivery, fetal macrosomia and persistent occipito-posterior position at time of delivery.\textsuperscript{3,7} The risk of OASIS at first time delivery is 5.7\% in nulliparous women compared to 1.5\% for parous women with no prior history.\textsuperscript{8}

OASIS is the result of perineal tissues getting distended beyond their elastic limit in the second stage, secondary to the effect of propulsive forces over tissue resistance. Causative factors contributing to OASIS in the nulliparous and multiparous patient population are different.\textsuperscript{2} While the association between regional anaesthesia and severe perineal trauma is well established in primiparous women secondary to prolonged second stage and instrumental deliveries, the relationship may be different in multiparous women. A retrospective cohort study of 61,308 nulliparous and multiparous women concluded that the positive association between the use of an epidural and sphincter injuries disappeared when parity was controlled for.\textsuperscript{9} Rates of instrumental delivery are much lower in multiparas regardless of whether regional analgesia is employed and they therefore have a much smaller effect upon the overall rate of severe perineal trauma in this group.\textsuperscript{9} Precipitate deliveries are more common in multiparous women, resulting in a different mechanism of severe perineal trauma compared to nulliparous women. The use of an epidural slows the birth process and rapid distension of tissues, reducing the uncontrolled urge to push at the point of delivery and may therefore reduce rates of severe perineal trauma in multiparas.\textsuperscript{8,9}
In light of this existing data we postulated that the use of an epidural is protective for severe perineal injuries in multiparous women, which is an important risk-reduction tool for OASIS given the physical and emotional burden faced by these women. These women may suffer significant psychosocial and physical difficulties such as perineal pain, faecal incontinence and dyspareunia. In some instances, this includes birth trauma and associated challenges encountered in future pregnancy planning, it may also negatively impact their sense of identity and subsequent ability to bond with their newborns.\textsuperscript{7,11,12}

**Materials and Methods**

A retrospective cohort study of all multiparous women with neuraxial labour analgesia having vaginal deliveries at a tertiary hospital during the years 2012-2018 was performed. Patient demographics and maternal outcomes were collected as standard of care. Obstetric data are recorded by medical and midwifery staff utilising the GE Healthcare Centricity Perinatal data system (GE Healthcare, Fairfield, CT, USA) during labour, delivery and discharge from hospital. Data were subsequently collated in database form by the Clinical Practice Improvement Unit. An electronic medical records search of patient demographics and medical data was performed using this system for the 6 calendar years 2012-2018. The inclusion criteria for the study group were all multiparous women with live singleton pregnancies at term $\geq 37$ weeks, cephalic presentation who had spontaneous vaginal births or instrumental vaginal births with epidural anaesthesia at a tertiary hospital in 2012-2018. The control population was selected from all multiparous women with singleton pregnancies at term $\geq 37$ weeks who had spontaneous vaginal births or instrumental vaginal births without epidural anaesthesia in 2012-2018. Multiparous women with no prior history of a vaginal birth, non-cephalic presentation during labour, preterm delivery and multiple pregnancies were excluded from the study.

The aim was to outline maternal demographics and to assess the rates of OASIS in this population including other contributing risk factors in multiparous women after spontaneous and assisted vaginal births with use of epidural anaesthesia. Ethics approval was obtained from the RWH Research Committee and RWH Human Research Ethics Committee with approval number AQA 19/06.

Demographic data collected included baseline maternal characteristics such as age, body mass index (BMI), parity and ethnicity. Obstetrical outcomes which included spontaneous or
induced labour, gestational age of fetus, birth weight of fetus, presence of episiotomy, mode of vaginal delivery (spontaneous and instrumental), lengths of second stage, previous OASIS tear and fetal position at time of delivery were also collected. The definition of prolonged second stage is defined as greater than or equal to 60 minutes without epidural and greater than or equal to 120 minutes with epidural.

The primary outcome of the study was to investigate the incidence of OASIS in different groups of women with and without neuraxial analgesia in labour. Comparison was performed using matched controls between the 2 comparison groups controlling for different categorical variables as mentioned. The secondary outcomes include length of second stage, mode of birth (spontaneous vs instrumental birth), presence of episiotomy and postpartum haemorrhage (PPH) ≥ 1L.

Statistical analysis
Summary statistics were calculated for the epidural and no epidural groups: mean (standard deviation) for continuous variables and count (percentage) for categorical variables. Association between risk factors and epidural use were tested using Fisher’s exact test or chi-square tests for categorical variables and two-sample t-tests for continuous variables. Logistic regression was used to model the association between epidural use and tear, adjusting for the following confounders, age, BMI, parity, spontaneous labour, induced labour, gestational age, birthweight (kg), prolonged second stage, instrumental delivery, episiotomy and precipitous birth. All tests are two-sided. A P-value of ≤0.05 was deemed to indicate statistical significance. Confidence intervals on the absolute risk differences were obtained by bootstrapping the procedure of fitting a logistic regression model and estimating the counterfactual probabilities of OASIS had none of our patients received epidural, and subtracting this from the estimated counterfactual probabilities had all of our patients received epidural. Statistical analysis of data was done with R statistical software, version 3.6.3.

Results
A total of 14 124 women fulfilled the inclusion criteria and data. Due to the retrospective nature of this study, 534 women had incomplete information and hence were excluded from the study, resulting in 13 590 patients being used for analysis, see figure 1. Information about
previous OASIS, fetal position at birth and racial ethnicities was inconsistently noted and hence these domains were not compared for statistical analysis.

2305 out of 13 590 women used an epidural during their labour process, resulting in an epidural rate of 17% among multiparous women. Demographic and obstetric characteristics of the study groups are reported in Table 1. The groups were similar with respect to age, BMI, parity, gestational age and birth weight. Compared to induced and augmented labour, women who had spontaneous labour were less likely to request for an epidural (15.6% vs 76.1%, P < 0.001). 14 (0.6%) vs 200 (1.8%) multiparous women had an epidural during precipitous labour.

As shown in table 2, incidence of OASIS was stratified according to modes of vaginal birth, non-epidural use was correlated to increased rates of OASIS in the normal vaginal birth population (1.68% vs 0.43%, P < 0.001), as well as when compared to instrumental delivery, (1.68% vs 0.08%, P< 0.001). There were no patients in the epidural group that sustained an anal sphincter injury with a precipitous birth (6 vs 0), however this finding is not statistically significant. Having an epidural did not affect the rates of OASIS for women in the vacuum delivery group, but the rates of OASIS were higher for women in the forceps delivery group, 0.48% vs 0.04%, P<0.001.

With regard to secondary outcomes shown in table 2, epidural use was associated with a statistically significant increase in incidence of prolonged second stage (8.5% vs 3.8%, P < 0.001), instrumental birth (26.1% vs 4%, P < 0.001), and episiotomy use (23.8% vs 10.2%, P < 0.001). However, the rates of PPH ≥ 1L did not differ significantly between the 2 groups (4.3% vs 3.8%), P=0.286).

Using a logistic regression model to compare between the groups, use of epidural was correlated to an unadjusted OR of 0.53 (P < 0.005) of OASIS. As displayed in Table 3, when adjusted for confounding variables, the use of epidural is observed to be more strongly protective towards a reduction in OASIS, aOR 0.49 (P <0.05). The other statistically significant findings were related to parity, type of labour and fetal birth weight. The higher the parity, the less likely are the odds of a multiparous woman having OASIS [OR 0.44 (CI 0.33-0.58)], P < 0.05. A higher incidence of OASIS was found in women with higher fetal birthweight [OR 1.79 (CI 1.29- 2.49)], P < 0.05 and who had spontaneous labour compared
to induced labour, [OR 1.46 vs OR 0.58, P < 0.05]. On multivariate analysis, inclusion of precipitous birth did not change results.

According to table 4, the absolute risk for a multiparous woman sustaining an anal sphincter injury is low, (1% without an epidural vs 1.8% with an epidural), and the number needed to treat with an epidural is 100 women to prevent 1 tear.

Discussion
Epidural anaesthesia is the gold standard for effective pain relief during labour, and it results in greater maternal satisfaction when compared to alternative options. However, it is associated with specific risks related to the epidural itself, such as block failure, post epidural puncture headache, hypotension, temporary leg weakness, fever, as well as obstetric risks, such as prolonged second stage, instrumental deliveries. There are currently conflicting published data regarding the effect of epidural on OASIS.

The uptake of epidural in our population was lower at 17% compared to the published rates of about 30% in primiparous women. The lower rate of epidural uptake in multiparous labouring women is potentially due to the shorter average duration of labour. As a result, not only will this have an impact on their decision-making process, but it also limits the window of opportunity for effective insertion, especially in patients who had precipitous labour, hence the low epidural numbers observed in this group. Multiparous women who had induced and augmented labours were more likely to request an epidural due to the intensity of the contractions and longer duration of labour.

Incidence of OASIS was low in our population of multiparous women consistent with existing research. Our data suggest similar correlation with results published by MacDougall et al., in that OASIS was significantly lower in the epidural group than in the no epidural group (1.8% vs 1%). When this is stratified according to modes of birth, the correlation was seen to be strongest in the spontaneous vaginal birth group (1.68% vs 0.43%). With regard to secondary outcomes, there was a statistically significant increase in prolonged second stage, episiotomy, instrumental deliveries with epidural use, and a trend towards PPH ≥1L. The higher rates of OASIS with forceps delivery within the epidural group could be explained by the presence of prolonged second stage, and subsequent need for instrumental delivery.
After adjusting for confounding variables, epidural use reduced the risk of OASIS by half for multiparous women in our population. This is in concordance with a similar Australian population study by Turner et al, where epidural use was associated with a significant reduction in odds of OASIS.14 A similar cohort study by Jango et al in primiparous women also supported the protective effect of epidural as an adjusted variable on OASIS with a reduction of tears by 16%.15 This protective effect may be explained by controlled delivery of the fetal head at time of birth, perineal guarding, and prevention of sudden urge to push.9,10 The local anaesthetic used in the epidural dampens the motor and sensory system, and this may also explain the fact that there were no patients in the epidural group that sustained an anal sphincter injury with a precipitous birth compared to 6 in the non-epidural group.2

The incidence of epidural use in multiparous women undergoing spontaneous labour is lower than average at 15.6%. Interestingly, spontaneous labour rather than induced labour as an independent variable in our study was found to be associated with a higher incidence of OASIS [OR 1.46 (CI 1.09-1.95)], P < 0.05. This is in contrast to published population studies on the Australian Commission on Safety and Quality in Health Care (ACSQHC) data where labour induction or augmentation were identified as risk factors for severe perineal tears.7 With the majority (53%) of multiparous women having spontaneous labour, this finding is clinically relevant for clinicians in counselling women that epidural is available as an intervention to reduce the risk of OASIS in this group of patients.

The high number needed to treat (NNT) of 1:100 is attributed to a low incidence of OASIS in this population. Nonetheless, given the significant morbidity associated with OASIS, options that potentially reduce risk further should ideally be discussed with patients at risk.

There are a number of limitations with this study. This is a retrospective cohort study and there is potential for selection and information bias and there is a limitation on sample size. However, our study is strengthened by the large number of patients recruited and a heterogeneous multi-ethnic population. All data collected were collated at the Clinical Practice Improvement unit and underwent an auditing process. Data collected were dependent on data routinely collected by midwifery and medical staff during the intrapartum periods, hence there will be some missing or incorrect data entry due to the nature of this data collection. A number of potentially useful obstetrical data points were not looked at, such as
maternal ethnicity, previous OASIS, indications for epidural use in labour, other intrapartum variables such as seniority of accoucheur at birth, the presence of perineal guarding, maternal position and fetal presentation at time of delivery. At this tertiary hospital, women with a history of previous OASIS are offered an elective caesarean section accounting for a lower rate of previous OASIS within this population studied.

Irrespective of the limitations, this study provides a source of useful information that epidural analgesia is a safe and effective method for pain relief during labour and its use reduces the risk of OASIS in multiparous women by half without significant associated harms. Given the widely published data on the deleterious effect of OASIS on the wellbeing of women, it may be possible to further reduce the incidence of tears particularly for multiparous women undergoing spontaneous labour by counselling women about epidural use.2,7,10,11

Further research should aim to evaluate the maternal perception of epidural use in this population and the impact on acceptability of epidural as an analgesia in labour. More research to study the effect of epidural on different grades of OASIS would also provide useful information.

References


14. Turner J, Flatley C, Kumar S. Epidural use in labour is not associated with an increased risk of maternal or neonatal morbidity when the second stage is prolonged. Aust N Z J Obstet Gynaecol. 2020;60(3):336-343


The table below shows the descriptive data comparing epidural and no epidural use in terms of different categorical variables. The data is reported as whole numbers, percentages, and mean (standard deviation).

Table 1: Descriptive table comparing epidural and no epidural use according to different categorical variables. Data reported as whole numbers, percentages and mean (sd).

<table>
<thead>
<tr>
<th></th>
<th>No epidural</th>
<th>Epidural</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Labour</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous labour</td>
<td>n = 11285 (83%)</td>
<td>n = 2305 (17%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Augmented labour</td>
<td>n = 6774 (60.0%)</td>
<td>n = 359 (15.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Induced labour</td>
<td>n = 1155 (10.2%)</td>
<td>n = 479 (20.8%)</td>
<td></td>
</tr>
<tr>
<td>Precipitous labour</td>
<td>n = 2614 (23.2%)</td>
<td>n = 1275 (55.3%)</td>
<td></td>
</tr>
<tr>
<td>Age of mother</td>
<td>31.8 (4.8)</td>
<td>32.2 (4.9)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>24.8 (4.9)</td>
<td>25.7 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td>1.6 (1.1)</td>
<td>1.5 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Gestational age</td>
<td>39.3 (1.1)</td>
<td>39.1 (1.2)</td>
<td></td>
</tr>
<tr>
<td>Birthweight (in grams)</td>
<td>3474 (454.8)</td>
<td>3495 (483.0)</td>
<td></td>
</tr>
</tbody>
</table>

Primary outcomes

<table>
<thead>
<tr>
<th></th>
<th>No epidural</th>
<th>Epidural</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OASIS</td>
<td>200 (1.8%)</td>
<td>22 (1%)</td>
<td>0.004</td>
</tr>
<tr>
<td>- Forceps delivery</td>
<td>5 (0.04%)</td>
<td>11 (0.48%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Vacuum delivery</td>
<td>5 (0.04%)</td>
<td>1 (0.04%)</td>
<td></td>
</tr>
<tr>
<td>- Spontaneous NVB</td>
<td>190 (1.68%)</td>
<td>10 (0.43%)</td>
<td></td>
</tr>
<tr>
<td>- Precipitous birth</td>
<td>6 (0.05%)</td>
<td>0 (0%)</td>
<td>0.568</td>
</tr>
</tbody>
</table>

Secondary outcomes

<table>
<thead>
<tr>
<th></th>
<th>No epidural</th>
<th>Epidural</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged 2nd stage</td>
<td>432</td>
<td>197</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Table 2: Descriptive table showing absolute incidence of variables when comparing epidural and non-epidural use according to different categorical variables. Prolonged second stage is defined as ≥ or equal to 60 mins without epidural and ≥ or equal to 120 minutes with epidural

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value 1</th>
<th>Value 2</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of delivery (instrumental vs normal vaginal birth)</td>
<td>453 (4.0%)</td>
<td>601 (26.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Episiotomy performed</td>
<td>1150 (10.2%)</td>
<td>548 (23.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PPH ≥ 1 L</td>
<td>427 (3.8%)</td>
<td>98 (4.3%)</td>
<td>0.286</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.02 (0.99-1.05)</td>
<td>0.234</td>
</tr>
<tr>
<td>BMI</td>
<td>1.01 (0.98-1.04)</td>
<td>0.682</td>
</tr>
<tr>
<td>Parity</td>
<td>0.44 (0.33-0.58)</td>
<td>0.001</td>
</tr>
<tr>
<td>Spontaneous labour</td>
<td>1.46 (1.09-1.95)</td>
<td>0.012</td>
</tr>
<tr>
<td>Induced labour</td>
<td>0.58 (0.40-0.85)</td>
<td>0.005</td>
</tr>
<tr>
<td>Gestational age</td>
<td>1.12 (0.98-1.29)</td>
<td>0.105</td>
</tr>
<tr>
<td>Birthweight (kg)</td>
<td>1.79 (1.29-2.49)</td>
<td>0.001</td>
</tr>
<tr>
<td>Prolonged 2nd stage</td>
<td>1.33 (0.78-2.27)</td>
<td>0.299</td>
</tr>
<tr>
<td>Instrumental delivery</td>
<td>1.32 (0.76-2.29)</td>
<td>0.327</td>
</tr>
<tr>
<td>Episiotomy</td>
<td>1.31 (0.88-1.94)</td>
<td>0.187</td>
</tr>
<tr>
<td>Precipitous birth</td>
<td>1.82 (0.79-4.16)</td>
<td>0.158</td>
</tr>
</tbody>
</table>
Table 3: Unadjusted and adjusted effect size estimates on OASIS tear using logistic regression. OR = Odds Ratio.

<table>
<thead>
<tr>
<th></th>
<th>Estimated risk</th>
<th>Standard error</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural</td>
<td>0.0089</td>
<td>0.0020</td>
<td>0.0051 - 0.0127</td>
</tr>
<tr>
<td>No epidural</td>
<td>0.0181</td>
<td>0.0013</td>
<td>0.0154 - 0.0207</td>
</tr>
<tr>
<td>Absolute risk difference</td>
<td>-0.0092</td>
<td>0.0024</td>
<td>-0.0138 - -0.0045</td>
</tr>
</tbody>
</table>

Table 4: Absolute risks between groups averaging over the observed distribution of covariates.
Figure 1: Flow chart of population study

14124 women
- 476 unknown BMI
- 2 unknown age
- 8 unknown birth weight
- 54 unknown second stage length

534 women
13590 patients used for analysis

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