**Title:**

Levator ani Avulsion: a Systematic Evidence Review (LASER)

**Short title:** Levator ani avulsion

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**Tweetable abstract:** Levator avulsion incidence after caesarean, spontaneous, vacuum & forceps is 1%, 15%, 21% and 52% respectively

**Abstract:**

***Background:*** There is variation in the reported incidence of levator avulsion (LA).

***Objective:*** Explore incidence of LA by mode of birth, imaging modality, timing of diagnosis and laterality of avulsion.

***Search strategy:*** We searched MEDLINE, EMBASE, CINAHL, AMED and MIDIRS with no language restriction from inception to April 2019.

***Study eligibility criteria:*** A study was included if LA was assessed by an imaging modality after the first vaginal birth or if only delivered by caesarean section. Case series and reports were not included.

***Data collection and analysis:*** RevMan v5.3 was used for the meta-analyses and SW SAS and STATISTICA packages for type and timing of imaging analyses. .

***Results:*** We included 37 primary non-randomized studies from 17 countries and involving 5594 women. Incidence of LA was 1%, 15%, 21%, 38.5% and 52% following caesarean, spontaneous, vacuum, spatula and forceps births respectively, with no differences by imaging modality. OR of LA following spontaneous birth vs. caesarean was 10.69. While the OR for LA following vacuum and forceps compared to the spontaneous birth were 1.66 and 6.32 respectively. LA was more likely to occur on the right side following spontaneous birth ($p = 0.02$) and unilaterally vs. bilaterally following spontaneous ($P < .0001$) and vacuum-assisted births ($P = 0.0103$) only. Incidence was higher if assessment was performed in the first 4 weeks postpartum.

***Conclusions:*** Forceps significantly increases incidence and severity of LA. Ultrasound and MRI are comparable diagnostic tools but early postpartum imaging may lead to over diagnosis of LA.

**Keywords:** Assisted birth; Birth, Caesarean; Forceps; Hiatus; Labour; MRI; Operative; Parturition; Pelvic floor; Perineum; Prolapse; Transperineal; Ultrasound; Ventouse; Vacuum.

**Introduction:**

Gainey was probably the first to document a possible association between vaginal birth and levator ani muscle abnormalities in living women in 1943.[1] However, DeLancey and associates were the first to demonstrate this on MRI.[2] Levator ani trauma plays a key role in the pathophysiology of pelvic organ prolapse. Indeed, the associated urogenital hiatus ballooning leads to a 4-fold higher risk of pelvic organ prolapse development in women after obstetric levator avulsion (LA).[5] Furthermore, it is an important risk factor for cystocele recurrence after urogynaecological reconstructive surgery.[6–8]

Palpation of the site of insertion of the levator ani muscle[1] or assessing ballooning of the levator hiatus using pelvic organ prolapse quantification system parameters[15] have been suggested as methods of assessing the levator ani muscle, however, the diagnostic accuracy of these methods is dependent on the skill of the examiner and natural variation in anatomy can pose some limitations. Hence, diagnosis relies on imaging modalities mainly in the form of 3D/4D ultrasonography or MRI.[16–19]

There has been a variation in the description of levator ani muscle injuries depending on the diagnostic imaging modality. Using MRI, a muscle injury grading system ranging from 0, no injury, to 3, complete loss of the pubococcygeal portion, was proposed and based on the overall score for both sides, the trauma is classified into minor or major defects.[9] However, the term “levator avulsion”, was coined by Dietz and Lanzarone to describe the loss of continuity between the levator ani muscle and the pelvic sidewall.[10] This was further defined on tomographic ultrasound,[11] a method that is now internationally standardized.[12]

There is wide variation in the reported incidence of LA following the first childbirth, which could be due to several factors. The aim of this systematic review was to assess the current published literature with regards to the reported incidence of LA by mode of birth, imaging modality and the timing of diagnosis. Furthermore, we wanted to explore if there were any differences in LA laterality and mode of birth.

**Methods:**

***Eligibility criteria, information sources & search strategy:***

A protocol using widely recommended methods for systematic reviews of observational studies was developed and registered with PROSPERO (CRD42019120206) and the PRISMA statement and checklist were followed throughout the review preparation, conduct and reporting.

MEDLINE, EMBASE, CINAHL, AMED and Maternity and Infant Care (MIDIRS) databases were searched electronically from inception to April 2019. A combination of medical subject headings (MeSHs), encompassing different modes of birth and LA, keywords, and word variants using Boolean operators 'OR' and 'AND' to capture relevant text citations were used (search strategy: table S1). We included all study designs in our search, with the exception of case series and case reports, No language restrictions were applied, but the search was limited to human studies. A database of all citations' abstracts was compiled.

***Study selection***

Studies were selected in a three-stage process. Firstly, two independent reviewers (LP & AV) screened titles and abstracts of potential articles identified by our search using RAYYAN software package[20] and the full selected articles were obtained. Secondly, two independent reviewers (LP & MK) assessed each of the selected articles against pre-designed inclusion/exclusion criteria. A study was included only if LA was assessed by an imaging modality and it reported data on LA in primiparous women following a first vaginal birth (spontaneous or operative) or those delivered only by caesarean section (CS). Case control studies, where recruitment was based on presence or absence of LA and studies not presenting LA by mode of birth were excluded from our review. Finally, reference lists of included articles were manually searched to identify relevant papers not captured by electronic searches.

***Data extraction & synthesis***

Data were extracted on study design, participants' characteristics, mode of birth, type(s) of imaging used, timing of imaging in relation to birth, laterality of avulsion and the diagnostic criteria used for diagnosis. LP & MK extracted data independently in duplicates. Extracted information was logged in an excel spreadsheet.

Any discrepancies in the study selection or extracted information were reviewed by VK, ZR & KI for a final decision.

RevMan v5.3 was used for the meta-analyses which were performed if data from two or more eligible studies were available.[21] The number of positive events and the total number of potential events were analysed and summarized with the resulting incidence rate and its 95% confidence interval (CI). Meta-analytical estimates of the overall incidence rate (point estimate and 95% CI) were obtained by fitting random-effects models because of the high likelihood of clinical and statistical heterogeneity; the inverse variance (IV) method with Log-transformation of the incidence rate was used. For these analyses the event mean and 95% CI were used to calculate the standard error of the mean using the calculator facility in RevMan. If the 95% CI was not provided in the study this was calculated based on Gaussian approximation. Binomial approximation (exact confidence limits calculation) was used for smaller n and smaller or greater p. For odds ratios (OR) comparisons, only the studies that reported on both of the compared modes of birth contributed to the analysis and these were calculated using the Cochran-Mantel-Haenszel approach. $I^2$ statistic was used as a measure of statistical heterogeneity, where the cut offs for low and high heterogeneity were considered to be <25% and >75% respectively.[22,23] The Gaussian approximation calculation of the standard error of the mean and the comparisons for the type of imaging modality, timing of imaging and laterality of LA were performed using SW SAS (SAS Institute Inc., Cary, NC, USA) and STATISTICA (StatSoft, Inc., Tulsa, OK, USA). A p value <0.05 was used as a cut-off for statistical significance.

***Assessment of risk of bias***

Data were extracted regarding study design, target population, participants' selection process, participants' characteristics and statistical methodology. Two independent reviewers (RK and KI) used the Joanna Briggs Institute Prevalence Critical Appraisal Tool (table S2) to assess the risk of bias and quality of included studies.[24] Quality assessment was then used to assess the methodological adequacies of the included studies and assist with interpretation of the systematic review findings and potential bias resultant from study heterogeneity.

## Results:

### *Study selection and study characteristics*

The literature search for this review was conducted on the 25th of April 2019 following *a priori* set strategy (table S1), which identified 363 citations, of these 57 full articles were selected for detailed review. Reference lists review of the selected articles did not identify any further articles for consideration. Of the 57 selected articles 20 did not meet our inclusion criteria and were hence excluded from further analysis (table S3). A total of 37 primary non-randomized studies from 17 countries and involving 5594 women were included in our systematic review (Table 1, Figure 1, table S4).[4,10,17,25–58] All studies were reported in English with the exception of one study, which was in Czech, and hence the authors undertook the translation.

### *Risk of bias of included studies*

None of the included studies fulfilled all 10 quality assessment criteria. Eight studies (20.5%) fulfilled 9 of the 10 criteria. A total of 21 (53.8%) and 7 (17.9%) studies satisfied 8 and 7 of the 10 criteria respectively. The remaining 3 studies (7.7%) fulfilled at least 5 out of the 10 assessment parameters (table S5). No studies were excluded from the systematic review for failure to fulfil the quality criteria. The risk of publication bias for pooled data was assessed by Funnel plots (figures S1-S5.

### *Synthesis of results*

<u>*Incidence of LA by mode of birth irrespective of imaging modality*</u>

For studies that have assessed LA at multiple postpartum time points, we used the last reported time point for this analysis.

LA and caesarean section (CS)

A total of 23 studies involving 1207 women who were only delivered by cesarean section contributed data for this outcome.[4,10,17,25–29,31,32,35–37,39,43–47,52,54,56,57] All the studies reported no LAs with the exception of Araujo et al[46], Guedea et al[36] and Aydin et al[39] who reported LA incidences of 14%, 5% and 40% respectively. A meta-analysis of all 21 studies showed an overall incidence of 0.03 (0.00 – 0.05, $I^2$ 66%,). The incidence reported by Aydin et al[39] was deemed an outlier compared to the rest of the results and removal of this study from the analysis reduced $I^2$ from 66% to zero hence a decision was made to exclude this study from further analyses because of its effect on the degree of statistical heterogeneity. Meta-analysis of the remaining 22 studies, involving 1120 women, showed a pooled incidence of 0.01 (0.00-0.02, $I^2 = 0$) for LA in women delivered by CS only (Figure 2, figure S1).

LA and spontaneous first vaginal delivery

We identified 23 studies involving a total of 2152 women that assessed LA following the first spontaneous vaginal birth.[4,17,25,28,32,33,35–38,41,44,46–51,53–56,58] The pooled incidence of LA in these studies was 0.16 (0.13-0.19, $I^2$ = 73%; supplementary figures). The highest incidence of LA of 0.58 was reported by Araujo et al (2018)[46] which was much higher than the reported incidence by other studies. Excluding this study reduced the degree of heterogeneity, as measured by $I^2$, from 73% to 66%. Excluding this study from the analysis resulted in an overall LA incidence following SVD of 0.15 (0.12-0.18; Figure 2, figure S1).

LA and vacuum extraction in the first vaginal delivery

Thirteen studies including 796 women contributed to this analysis.[4,17,25,28,33–36,38,44,49,50,55] The pooled incidence for LA following vacuum extraction was 0.21 (0.16-0.27, $I^2$ = 68%; Figure 2, figure S1).

LA and forceps in the first vaginal delivery

A total of 469 women from 13 studies contributed to this analysis.[4,17,25,28,32–35,37,40,44,46,55] The overall incidence of LA following the first vaginal birth by forceps was 0.52 (0.44 – 0.61, I2 = 66%; Figure 2, figure S1).

There was only one study that reported on LA and the use of a spatula in the first vaginal delivery. In their study, Guedea et al reported that 5 of the 13 women delivered by spatula (38.5%) were diagnosed with LA postnatally.[36]

*Odds ratios (OR) of LA by mode of birth irrespective of imaging modality*

It was decided *a priori* that OR will be calculated for the following clinically meaningful comparisons; spontaneous vs. CS, vacuum vs. spontaneous, forceps vs. spontaneous and forceps vs. vacuum. For this analysis, only studies that have reported on the two compared modalities were included. A total of 12 studies involving 1570 women reported on LA following spontaneous and CS at first birth.[4,17,25,28,32,35–37,44,47,54,56] The calculated OR for having an LA following a spontaneous delivery compared to CS was 10.69 (5.44 – 21.0; $I^2$ = 0%) (Figure 3). The OR of an LA following vacuum compared to spontaneous delivery was 1.66 (0.99 – 2.79; $I^2$ = 62%). This was based on 12 studies reporting on a total of 1783 births (Figure

3).[4,17,25,28,33,35,36,38,44,49,50,55] While that following forceps vs. spontaneous delivery was 6.32 (4.56 – 8.76; $I^2 = 0\%$) (Figure 3) as assessed by 10 studies involving 1372 women.[17,25,28,32,33,35,37,44,54,55] For this analysis we did not include the study by Thibault-Gagnon et al[4] because removing this study from the analysis reduced the $I^2$ from 47% to 0% without much change in the OR (5.68 [3.49 – 9.22]; figures S2-S5). LA following Forceps compared to vacuum extraction at the first vaginal birth was reported by 9 studies and the pooled OR was 4.09 (2.87 - 5.84; $I^2$ 0%) (Figure 3).[4,17,25,28,33–35,44,55]

<u>*Incidence of LA by imaging modality:*</u>

Of the 37 included studies, 5 (13.5%) studies, involving 249 births, used MRI while the rest used on ultrasound for diagnosis.[27,29,31,55,58] For this analysis we did not include the studies by Aydin et al[39] and Araujo et al[46] because of their impact on statistical heterogeneity. The comparisons for the rates of LA following different modes of birth by imaging modality are presented in Table 2. None of these comparisons reached statistical significance.

<u>*Laterality of LA by mode of birth:*</u>

The assessment as to whether a unilateral LA was on the right or the left side was assessed by 3[32,41,49], 2[34,49] and 3[32,34,40] studies following spontaneous, vacuum and forceps deliveries respectively. While the assessment regarding the LA being unilateral or bilateral was reported by 5 studies following spontaneous[32,49,50,56] , 4 studies following vacuum[28,34,49,50] and 4 studies after forceps[28,32,34,40]. The rate of right LA following spontaneous was higher compared to left LA and this difference reached statistical significance (p = 0.0202). Furthermore, the rate of unilateral LA was significantly higher than bilateral LA following spontaneous ($p < 0.0001$) and vacuum ($p = 0.0103$) deliveries. All the other comparisons relating to laterality of avulsion and mode of birth did not reach statistical significance (Table 2).

<u>*Incidence of LA depending on timing of imaging after birth:*</u>

Similar to the incidence of LA by imaging modality we did not include the Aydin et al[39] and Araujo et al[46] studies because of their effect on statistical heterogeneity. A total of 8,[31,35,37,45,48,54,56,57] 6,[17,27,32–34,58] 8,[4,10,25,26,42,44,48,53] 9[29,30,36,37,40,49–51,55] and 6[28,38,41,43,47,59] studies reported performing their imaging modality to assess LA at 0 – 1, > 1 – 3, > 3 – 6, > 6 – 12 and > 12 months post birth respectively. Two of the included studies reported LA avulsion rates at two time points each.[32,48] Using LA rate at > 12 months as the reference standard there was a trend to higher reported LA rates at 0 – 1 month for all birth modalities. However, this reached statistical significance for the SVD only ($p < .0001$). There was also a statistically significant difference in the reported LA rate after spontaneous and forceps deliveries at > 3 - 6 months ($p = 0.0190$) and > 6 – 12 ($p = 0.0014$) months when compared to reported LA for the same mode of birth at > 12 months respectively (Table 2 and Figure 4).

## Discussion

### *Main findings*

We calculated the pooled incidence of LA following CS, spontaneous, vacuum extraction and forceps assisted births to be 1%, 15%, 21% and 52% respectively. The OR of having an LA following the spontaneous delivery compared to CS was 11. The risk of having a LA if a vacuum was used to assist the first vaginal birth was not significantly different from a spontaneous birth while the OR of LA if a forceps is used to assist the first birth was 6 compared to spontaneous delivery. LA was more likely to occur on the right hand side following a spontaneous birth ($p = 0.0202$). Furthermore, unilateral compared to bilateral LA was significantly more likely to occur following spontaneous and vacuum-assisted births ($p < 0.0001$ and $p = 0.0103$ respectively). We did not identify statistically significant differences in the pooled incidence of LA following different modes of birth by imaging modality. Finally, there was a trend to higher reported LA rates when assessment was performed in the first 4 weeks postnatal compared to later dates, However, this reached statistical significance for spontaneous delivery only ($p < .0001$).

***Strengths and limitations***

The main strength of our systematic review lies in the methodology we followed. Our search strategy and study selection criteria were set *a priori*. Furthermore, decisions about study inclusion and data extraction were all done in duplicates by two independent reviewers. However, we appreciate that there are some limitations to our review that might have introduced bias into our findings. There was evidence of moderate to high degree of heterogeneity between studies in some of our analyses. This might be a reflection of variation in obstetric practices between the studies, but also could be due to difference in the degree of expertise between practitioners diagnosing the LA. Second, some of the studies included in our review were small observational studies and some fulfilled only half of the quality assessment criteria and hence, at high risk of bias. Nevertheless, we did not exclude any studies based on their quality assessment because we wanted our review to be comprehensive and present a realistic view of the current state of evidence.

***Interpretation***

Our results concur with previous studies showing good agreement between MRI and 3D/4D transperineal ultrasound has been previously reported by several groups.[60–62]. Although MRI has a superior spatial resolution and fluid sensitive sequences allowing for exploration of oedema, ultrasound assessment is more feasible, acceptable and cost effective. Indeed, only 14% of studies, providing 249 of a total of 5594 (4%) patients included in our review, were performed using MR.

Friedman and associates published a meta-analysis exploring mode of birth and the associated risk of LA.[65] Their review included 20 studies that met their inclusion criteria with 12 of these contributing to their calculation of the ORs of LA following forceps and vacuum compared to normal vaginal delivery. These were 6.94 (4.93–9.78) and 1.31 (1.00–1.72) respectively, both similar to our findings. In our review we only included studies that have reported on the first vaginal birth and ensured that this is clearly presented in our data to avoid extrapolation of our findings to any assisted vaginal birth. The use of an obstetric forceps has been identified as an independent intrapartum risk factor for levator ani injury.[44] Our review corroborates existing evidence of the significantly higher association of LA with forceps compared to other birth modes. Moreover, we also demonstrated a higher risk of bilateral lesions with forceps compared to spontaneous and vacuum-assisted births. Hence, forceps does not only seem to increase the risk of injury but also its severity.

When comparing rates of reported right and left LA in cases of unilateral avulsion, the incidence of avulsion on the right hand side was higher than the left for all modes of vaginal birth. However, this difference reached statistical significance following spontaneous deliveries only ($p < .0001$). It is plausible that this could be secondary to the direction of fetal head rotation if in a right occipito-posterior position. Alternatively, it could be the sigmoid colon protecting the left levator ani, or otherwise, displacing the head and increasing tension on the right levator ani muscle. It is unlikely though that this difference could be attributed to the laterality of an episiotomy, as mediolateral episiotomy was suggested not to be associated with the occurrence of LA.[66] Indeed, the reason(s) for this difference is beyond the scope of our systematic review, however it is an observation that warrants further exploration probably via finite element models.[67,68]

There is paucity of research with regard to the optimal timing for the assessment of the pelvic floor postnatally. In our study, the incidence of LA was higher when imaging was performed in the first month compared to later time points. However, this difference was only significant for spontaneous births. It has been suggested that early imaging can result in over diagnosis because of soft tissue changes and haematomas that would undergo a natural process of remodelling or resolution 6 - 12 weeks postnatal.[48,69] Our systematic review has demonstrated that, the calculated LA incidence was still significantly higher at > 3 – 6 and at > 6 – 12 months, compared to > 12 months post birth following spontaneous and forceps deliveries respectively. Although only speculative, it is possible that recovery and remodelling of the pelvic floor takes longer following a forceps-assisted compared to a spontaneous birth.

**Conclusion**

Transperineal ultrasound should be considered the mainstay modality for the diagnosis of LA for its comparable efficacy, better availability and lower cost compared to other imaging modalities. However, early postpartum imaging is better avoided because of the risk of over diagnosis. Although the numbers included in the analysis of imaging timing were relatively small, it seems reasonable to defer a final diagnosis till after 6 months postnatal. This duration might need to be extended to more than 12 months following a forceps assisted birth.

There is no doubt that forceps is associated with a higher incidence and severity of LA compared to spontaneous birth. However, given that instruments are used to assist a vaginal birth only when indicated, we believe that comparing forceps to spontaneous birth is not clinically meaningful. What is more relevant is the comparison between forceps and vacuum-assisted births. The debate amongst obstetricians and gynaecologists regarding the use of forceps in current obstetrics given its negative impact on the pelvic floor at the short and long term is on going. However, based on our findings, for every 3 vacuum-assisted births performed instead of a forceps, one less woman will have an LA (NNT = 3). Therefore, irrespective of professionals' opinions and views, it is important that women are made aware of the magnitude of this impact so that they can make an informed choice about their care if their vaginal birth is to be assisted. Arguably, the same principle could be applied to vaginal birth and CS, nevertheless, the latter is a major surgical intervention that has associated short and long-term implications and complications and these should be included in any counselling about mode of birth.

Finally, although the clinical relevance of the side of avulsion is doubtful, it might shed some light on the pathogenesis of LA, which has the potential to aid in considering interventions and manoeuvres to mitigate the risk of such trauma.

**Disclosure of interests:** The authors have no interests relevant to this work to disclose.

**Authors' contributions**

**ZR:** Protocol development, advice on literature search, study selection, data extraction, data management, manuscript writing.

**LP:** Study selection, data extraction, data management, manuscript editing.

**MK:** Study selection, data extraction, data management, manuscript editing.

**AV:** Study selection, data extraction, data management, manuscript editing.

**VK:** Protocol development, study selection, data extraction, manuscript editing.

**RK:** Study quality assessment, Data analysis and presentation, manuscript writing.

**KMI:** Conceived the idea, Protocol development, advice on literature search, study selection and quality assessment, data analysis, manuscript writing.

**Details of ethics approval:** In view of the nature of the study, ethics approval was not required.

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**Tables and figures**

**Tables**

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**Figures**

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- Figure 3: Comparison of risk of levator avulsion between different modes of birth.
- Figure 4: Incidence of levator avulsion depending on timing of imaging after birth.

**Supplementary material**