

## Executive summary

### Conclusions

- ▶ More injuries to the anal sphincter can be detected and treated if an ultrasound examination is added to the routine visual and manual examinations currently performed on women immediately postnatally. Fewer women would therefore develop faecal incontinence and reductions to their quality of life.
- ▶ Fewer injuries to the anal sphincter are recorded when delivery ward staff are trained to promote slow delivery, to manually protect the perineal region with different handholds, and to use episiotomies when they are necessary. It is not possible to resolve which of these components are important.
- ▶ An episiotomy can prevent anal sphincter injuries when a woman, who is giving birth for the first time, requires vacuum extraction. However, the procedure itself causes a perineal injury. Even warm compresses applied to the perineum during the pushing stage of childbirth can provide some protection against anal sphincter injury.
- ▶ More research is needed to establish which examination methods can be routinely used directly postnatally to ensure that anal sphincter injuries do not go undetected. Rectal palpation after childbirth has not been assessed as a diagnostic method. Examination methods need to be simple as well as both accurate and sensitive. Unreliable methods for measuring outcomes and unclear diagnostic criteria make the existing research results difficult to assess.

### Background

Childbirth is usually free of complication for both mother and child, although minor tears in the mother's perineum are not unusual. This report focuses on the most severe form of perineal injuries: anal sphincter

tears. Such injuries are most often detected during a clinical exam. How the exam is carried out differs between clinics, as well as between examiners. Approximately 3.5% of women who deliver vaginally in Sweden are diagnosed with anal sphincter injuries that, if left untreated, could lead to the woman losing control of her bowels and lead to suffering. Risk factors associated with anal sphincter injuries include first time delivery, assisted vaginal delivery with vacuum or forceps, delivering a large baby, delivering a baby that presents abnormally (i.e. if the top of the baby's head does not descend into the birth canal first), or if the mother has been circumcised.

The Swedish agency for health technology assessment and assessment of social services (SBU) was tasked by the Swedish Government to audit and assess the available information regarding methods that reduce complications and injuries to women giving birth.

### Aims

The aims of this systematic assessment were to investigate:

1. whether ultrasound or rectal palpation could improve the diagnostic accuracy for anal sphincter injuries;
2. whether there are methods that can reduce the risk of anal sphincter injuries during vaginal delivery.

### Results

#### Diagnostics

- There is moderately strong scientific evidence that supplementing the standard clinical postnatal examination with an ultrasound examination will detect anal sphincter injuries in another 9% (95% CI, 4 to 14) of women, effectively at least doubling the number of anal sphincter injuries identified.
- There is moderately strong scientific evidence that fewer women will develop severe anal incontinence

3 to 12 months after giving birth, if the standard clinical postnatal examination is supplemented with an ultrasound examination. One woman would be spared developing severe anal incontinence within twelve months of delivery for each 29 women examined with a supplemental ultrasound.

- There is moderately strong scientific evidence that vaginal ultrasound examinations performed a long time after delivery can detect anal sphincter injuries with a sensitivity of approximately 46% and a specificity of approximately 85%.
- There is insufficient scientific evidence to establish the diagnostic accuracy of perineal ultrasound or rectal palpation for the detection of anal sphincter injuries.

### **Interventions for reducing the risk of injuring the anal sphincter**

- There is limited scientific evidence that moist warm compresses applied to the perineum during the pushing stages of delivery can reduce the frequency of anal sphincter injuries by 2.1% (95% CI, -1.2 to -3.6) resulting in a relative risk of 0.48 (95% CI, 0.28 to 0.84).
- There is limited scientific evidence that the hands-off method for protecting the perineum, where the birthing assistant places their hands on the infant's head and not on the perineum when assisting a delivery, prevents anal sphincter injuries by 2% (95% CI, -3 to 0) than the hands-on method where the birthing assistant places their hands on the infant's head as well as on the perineum when assisting a delivery. The associated odds ratio is 0.35 (95% CI, 0.13 to 0.96).
- There is strong scientific evidence that an episiotomy prior to instrument assisted deliveries, particularly when a vacuum extractor is used, will reduce the risk of anal sphincter injuries by about 7% (95% CI, -8 to -7) resulting in an odds ratio of 0.16 (95% CI, 0.14 to 0.19).
- There is limited scientific evidence that programs aimed at training staff to promote a slow pace for delivery, to manually protect the perineum using different handholds, and to perform episiotomies when they are necessary can reduce the risk of anal sphincter injury by 2 to 3%, which corresponds to reducing the risk by 50%.
- There is insufficient scientific evidence to draw any conclusions about the effectiveness of the other

interventions studied: injections of the enzyme hyaluronidase into the perineal region, oils, wax, vaginal massage during pregnancy or delivery, Epi-No (balloon for stretching the perineum), fundal pressure belts, delayed pushing, pelvic floor training before or during pregnancy, perineal protection devices designed to evenly distribute the stresses over the entire region, the Ritgen manoeuvre, leg supports during labour, or assorted birthing positions.

## **Discussion**

### **Diagnostics**

A thorough examination of the mother immediately after she has given birth is critical in the detection of tears in the genital region. The quality of postnatal examination methods varies, and some tears are missed. The scientific literature rarely describes exactly how immediate postnatal exams are performed. This report shows that endoanal or vaginal ultrasound examinations can uncover anal sphincter injuries in approximately 9% of women who were given standard postnatal exams immediately after giving birth vaginally. A similar proportion of anal sphincter injuries are detected when either vaginal or transperineal ultrasound is used to examine women well after they have given birth. Anal incontinence is significantly more common in women who are not examined with endoanal ultrasound, indicating that improved diagnostics could lead to less suffering. Endoanal ultrasound is an established objective and sensitive method that can be documented. Providing this diagnostic service, around the clock, at all of Sweden's 46 clinics would require a large investment in both equipment and training for health care staff. The development of more accessible routine methods for preventing birthing injuries could be an alternative solution.

### **Preventative methods**

This SBU report shows that there is scientific evidence indicating that the risks of sustaining an anal sphincter injury is lower when an episiotomy is performed prior to vacuum assisting a delivery for women giving birth for the first time who have a low to moderate risk of anal sphincter injury. Applying vacuum assistance is a risk factor, and the protective effect of an episiotomy is cancelled out when more than three additional risk factors exist, such as if the infant is big, if the pushing phase is long, or if the woman is advanced in age or has previously had an anal sphincter injury. To prevent an anal sphincter injury to one woman, episiotomies would need to be performed on approximately twelve women. An episiotomy can be considered a grade two injury to the perineum and

vaginal wall that is caused by health care providers. The injury from an episiotomy will require suturing so that all of the muscle attachments are reconstructed. What is more, women with anal sphincter injuries that are found and sutured correctly rarely develop any negative symptoms. The balance between risk and benefit for episiotomies is therefore not entirely straightforward, and depends heavily on the reliability of the diagnostic methods used to detect anal sphincter injuries. An episiotomy may be unavoidable if the baby needs to be delivered quickly. However, the routine use of episiotomies for vaginal births to protect the mother from anal sphincter injuries is not supported by the scientific evidence presented in this report, nor is it recommended by WHO.

Staff training initiatives conducted in countries neighbouring Sweden incorporated multiple components whose effectiveness were not independently assessed. It was suggested that manually protecting the perineal region was an important component despite this technique never having been studied independently in randomised controlled studies. The rate of episiotomies increased after these staff training initiatives. It was not clear whether this increase in episiotomies was specifically linked to vacuum assisted deliveries involving women who were giving birth for the first time. There is a risk that focusing on prevention could result in injuries being underreported, as staff will receive positive feedback when it is perceived that they have prevented tearing. The lack of objective diagnostics regarding anal sphincter tearing means the results should be interpreted with caution. It is believed that applying warm compresses to the perineal region can prevent anal sphincter injuries. However, it is not possible to determine if the warm compresses are responsible for the effect, or if it is due to the mechanical protection of the perineum the method affords.

## Ethics

During childbirth, there are two individuals with basically the same human dignity that must be given consideration, the mother and the infant. Occasionally a decision must be made to cause harm to one of the individuals to prevent harm to the other. For instance, by accelerating delivery with vacuum assistance, forceps or episiotomy when there is an imminent risk that the baby is not getting enough oxygen could inflict an injury on the mother that will result in a lifelong handicap. There is always an ethical dilemma, even when the decision is medically motivated; how big does the risk to the child need to be to motivate performing a procedure which will increase the mother's risks of being injured?

## Evidence gaps and future research

We have identified the following evidence gaps regarding the diagnostics for and prevention of anal sphincter injuries:

- In future studies, the examination methods used to detect birthing injuries should be carefully described, validated, and reproducible.
- Research is needed that evaluates diagnostic methods for the routine screening of anal sphincter injuries.
- There is insufficient research regarding how patient to caregiver ratios, team training, and education effect the rate of anal sphincter injuries.
- No studies have been identified that investigate pain relief issues associated with diagnostic procedures.
- More research is needed to establish the risks and benefits of performing episiotomies on women who are vacuum assisted while giving birth for the first time, especially with respect to long-term outcomes.

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SBU Assessments no 249, 2016

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