The impact of an interventional program employing a hands-on technique to reduce the incidence of anal sphincter tears: An interrupted time-series re-analysis (study protocol)

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Background

Anal sphincter tears occur in a significant proportion of Norwegian women (3-5%) in relation to child birth, and the incidence has been rising over the last decades [1].

It is estimated that between one third and two thirds of women with anal sphincter tears suffer from persistent anal incontinence [2].

Norwegian health authorities implemented a national plan in 2006 to address this problem [3]. One element in this plan was to re-introduce a traditional hands-on technique where the birth attendant presses the neonate’s head during the final stage of delivery, to control the speed of crowning, while simultaneously supporting the woman’s perineum with the other hand. This technique was implemented as the key element of a multifaceted quality improvement intervention first in one hospital in 2005, followed by four hospitals in 2006 and early 2007. Other elements of the intervention were 1) to promote good communication between the delivery assistant and the woman, 2) the use of delivery positions that visualized the perineum during the final stage of delivery, 3) and episiotomy only on indication [4].

The intervention programme is described in more detail elsewhere [4]. Briefly, an experienced midwife from Finland (where the described hand-on technique is widely used) conducted the training during a period of 7 to 13 weeks at each hospital. All staff-members participated and were taught the hands-on technique, first on a pelvic model, then in the clinical setting where the instructor first held her hands on the delivery assistant’s hands, and finally with the midwife or doctor delivering themselves under the Finnish midwife’s supervision.

The use of hands-on techniques has been debated for decades, and some randomized controlled trials have been conducted to assess the effectiveness of such approaches – mostly with inconclusive findings [5-8]. A Cochrane-review is underway that addresses this issue [9].

Unfortunately a randomized controlled trial was not possible to conduct since the intervention was implemented before an evaluation was planned.

The team that developed and implemented the intervention programme reported a dramatic reduction in the incidence of anal sphincter tears following programme-
implementation both in the first hospital [10], and in the four hospitals that followed [4]. However, due to methodological limitations in the evaluation-design, convincing causal inferences could not be made. The main limitation was that the authors did not take the underlying down-going trend in incidence of anal sphincter tears in the intervention hospitals – or in Norway as a whole – into consideration in the analysis.

Rigorous evaluations are a prerequisite for evidence informed policies. It is extremely valuable information and good news for women in labor all over the world. If a relatively simple hands-on technique can reduce the incidence of anal sphincter tears by as much as 50%, as claimed by proponents of the technique [4]. However, the claim needs to be substantiated by solid data. Particularly when there is a risk of harm: In one randomized trial the authors reported a higher incidence of third-degree perineal sphincter tears among women treated with a “hands-on method” compared to women treated with a “hands-poised” approach (2.7% versus 0.9%; p<0.05) [7].

Our objective is to assess the impact of this hands-on technique with the use of an interrupted time-series approach, which is widely considered a reasonable alternative method for impact evaluation when randomized controlled trials are not possible to conduct [11].
Method

We will conduct two analyses on the incidence of anal sphincter tears:

1. An interrupted time-series analysis where we will estimate the change in incidence of anal sphincter tears before and after implementation of the intervention in five intervention-hospitals taking into account the trends in incidence of anal sphincter tears before and after implementation. The analysis will also take into account the launch in January 2006 of a national campaign to reduce the incidence of anal sphincter tears.

2. A comparison of trends in incidence of anal sphincter tears before and after the implementation of the technique in the five intervention-hospitals, and the incidence of anal sphincter tears in hospitals where the technique has not been actively implemented into routine practice. This analysis will take into account the launch in January 2006 of a national campaign to reduce the incidence of anal sphincter tears, as well as the implementation of local interventions in non-intervention hospitals.

The second analysis should in principle provide the most robust effect-estimate of the intervention. However, this analysis may underestimate the effect due to partial implementation of similar techniques in non-intervention hospitals. Consequently, the first analysis will be regarded as the primary one.

Our main data-source will be the Medical Birth Registry of Norway, from which we will receive monthly incidence data on anal sphincter tears (grade 3 and 4 injuries) and episiotomies for all hospitals from 2002 to 2008 (or 2009). We will also receive data on the number of births and the number of cesarean sections. This will enable us to calculate monthly rates of anal sphincter tears for all hospitals in Norway.

We have received information about when the programme was implemented (month and year) for each hospital from the implementers of the intervention. In our analyses we will include a 3-4 month transition-period (i.e. the “interruption” in an interrupted time-series analysis). Data from the transition period will not be utilized in our analyses.

In addition, we are surveying all facilities in Norway to collect information about local practices and changes in practices regarding hand-on techniques during delivery.
We will analyse trends in incidence for each hospital, and assess whether there are statistically significant (p<0.05) differences between intervention and non-intervention hospitals. We will also conduct a similar analysis on the use of episiotomy as a secondary outcome.

The statistical analyses will be conducted using repeated measurement techniques with each hospital as the unit of observation (repeated observations for each hospital). The analysis will be specified as follows:

- **Analysis 1 (only intervention hospitals)**
  The following segmented regression model will be specified: \( Y(t) = B0 + B1*Preslope + B2*Postslope + B3*intervention + B4*Focusslope + B5*Focus + e(t) \) where \( Y(t) \) is the outcome in timeperiod \( t \). Preslope is a continuous variable indicating time from the start of the study (coded as 0, 1, 2, 3 etc). Postslope is coded 0 up to and including the first point post intervention and coded sequentially from 1 thereafter. Intervention is coded 0 for pre-intervention time points and 1 for post-intervention time points. Focusslope is coded 0 up to and including the first point post Focus and coded sequentially from 1 thereafter. Focus is coded 0 for pre-focus time points and 1 for post-focus time points.

- **Analysis 2 (both intervention and non-intervention hospitals)**
  The following segmented regression model will be specified: \( Y(t) = B0 + B1*Preslope + B2*Postslope + B3*intervention + B4*Focusslope + B5*Focus + B6*Localslope + B7*local + e(t) \) where \( Y(t) \) is the outcome in timeperiod \( t \). Data from intervention hospitals will be coded in the same way as in Analysis 1 for the variables preslope, postslope, intervention, focus slope and focus. In addition localslope and local will be coded as 0 for intervention hospitals. Postslope and intervention is coded 0 for all observations from non-intervention hospitals. Preslope, focusslope and focus is coded in the same way for both intervention and non-intervention hospitals. For non-intervention hospitals where a local intervention has been implemented localslope is coded 0 up to and including the first point post local intervention and coded sequentially from 1 thereafter, and local is coded 0 for pre-local intervention time points and 1 for post-local intervention time points. For all other non-interventions hospitals localslope and local are coded 0.

In the two specified models, \( B1 \) estimates the slope of the pre-intervention data, \( B2 \) estimates the change in slope post-intervention for intervention hospitals and \( B3 \) estimates the change in level of outcome for intervention hospitals as the difference between the estimated first point post intervention and the extrapolated first point post intervention if the pre-intervention line was continued into the post-intervention phase. \( B4 \) estimates the change in slope as a consequence of the increased focus, \( B5 \) estimates the change in level of outcome as a consequence of increased focus, \( B6 \) estimates the change in slope as a consequence of locally implemented interventions, \( B7 \) estimates the change in level of outcome as a consequence of locally implemented interventions.
Our findings will be published in a peer-reviewed medical journal, preferably one with an open-access policy.
References


