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Long-term risks of stress and urgency urinary incontinence after different vaginal delivery modes

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Condensation: In women under 50, forceps delivery is associated with increased long-term risk of stress incontinence compared to other vaginal delivery approaches.

Short version of title: Vaginal delivery and urinary leakage

AJOG at a glance:

A. There are no prior studies directly comparing different kinds of operative vaginal deliveries for risk of both stress and urgency urinary incontinence.

B. For women, aged less than 50, forceps delivery, but not vacuum, is associated with significant increased long-term risk of stress incontinence.

C. These data provide an additional rationale for vacuum over forceps, when considering long-term incontinence, and help decision-making between forceps and vacuum.

Abstract

Background: Although operative delivery increases the risk of immediate pelvic floor trauma, no previous studies have adequately compared directly the effects of different kinds of instrumental vaginal deliveries on stress urinary incontinence and/or urgency urinary incontinence.

Objective(s): To estimate and compare the impact of different kinds of vaginal deliveries, including spontaneous, vacuum and forceps, on stress and urgency urinary incontinence.

Study Design: All women aged 20 or older, living in one county in Norway, were invited to participate in two surveys addressing stress and urgency urinary incontinence using validated questions “Do you leak urine when you cough, sneeze, laugh, or lift something heavy?” and “Do you have involuntary loss of urine in connection with sudden and strong urge to void?” with response options “yes” or “no”. Incontinence data were linked to the Medical Birth Registry of Norway. For this study, we included only women who had history of vaginal birth(s). Case definitions for stress and urgency urinary incontinence≥ were “moderate to severe” based on Sandvik Severity Index (slight, moderate, severe). We adjusted analyses for age, parity, body mass index, and time since last delivery and addressed effect modification, including an age threshold of 50 years.

Results: The final analysis included 13,694 women of whom 12.7% reported stress urinary incontinence and 8.4% urgency urinary incontinence. Among women aged <50, there was a statistically significant difference in the risk of stress urinary incontinence for forceps delivery (OR 1.42, 95% CI 1.09-1.86, absolute difference 5.0%), but not for vacuum (OR 0.80, 95% CI 0.59-1.09) when compared to spontaneous vaginal delivery. Among women aged <50, forceps also had increased

risk for stress urinary incontinence (OR 1.76, 95% CI 1.20-2.60) when compared to vacuum. There was no association of stress or urgency urinary incontinence with mode of delivery in women aged ≥50.

Conclusion(s): For women aged <50, forceps delivery is associated with significant increased long-term risk of stress urinary incontinence compared to other vaginal deliveries.

Keywords: forceps, instrumental delivery, stress urinary incontinence, urgency urinary incontinence, urinary incontinence, vacuum, vaginal delivery, ventouse

Introduction

Urinary incontinence is a common condition among women, and associated with significant impact on quality of life, and huge societal costs.[1, 2] The International Continence Society and International Urogynecological Association define stress urinary incontinence (SUI) as the involuntary loss of urine on effort or physical exertion, or on sneezing or coughing, and urgency urinary incontinence (UUI) as involuntary loss of urine associated with a sudden and compelling desire to pass urine.[3] Both from the population perspective and from an individual perspective, SUI and UUI are the most burdensome and bothersome of all urinary symptoms in women.[4] Established risk factors for both major subtypes of urinary incontinence include age[2] and body mass index;[5] the prevalence and the associated costs of these conditions is therefore likely to increase with future demographic changes.

Vaginal delivery is associated with an almost twofold increase in the risk of developing SUI, compared with cesarean section, with a smaller effect on UUI.[6,7] This difference is greatest in younger women and diminishes progressively in older women.[6] There are, however, no prior studies directly comparing different kinds of operative vaginal deliveries (forceps and vacuum) for risk of both SUI and UUI. Earlier studies have either analyzed both major subtypes of incontinence as a single cluster, or failed to compare vacuum extraction to forceps delivery. Because SUI and UUI have different underlying pathologies,[2,8] combining them may have obscured important associations. We aimed to estimate and compare the effects of different kinds of vaginal deliveries on SUI and UUI, using a large prospective population-based study.

Materials and Methods

We used data from the ongoing Nord-Trøndelag Health (HUNT) Study. Every citizen of Nord-Trøndelag County in Norway aged 20 years or older was invited to participate in a series of questionnaires, interviews, clinical measurements and collection of biological samples (blood and urine). The questionnaires included questions on socioeconomic conditions, health related behaviors, symptoms, illnesses and diseases. The present analyses include data from HUNT2 (over the period 1995-97) and HUNT3 (2006-08). We obtained ethical approval from the Norwegian Regional Ethics Review Board (2016/804/REK nord). All women participating in the surveys gave explicit written consent for the use of the data. We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.[9]

Incontinence questions of the HUNT2 and HUNT3 survey started with an entry question whether the participant experienced involuntary loss of urine or not (Appendix 1). If the answer was “yes”, she was asked to answer more specific, validated questions:[10] “Do you leak urine when you cough, sneeze, laugh, or lift something heavy?” and “Do you have involuntary loss of urine in connection with sudden and strong urge to void?” with response options “yes” or “no”. Symptom severity was categorized as “slight”, “moderate”, or “severe” assessed using the Sandvik Severity Index[10] (Appendix 1). In the current study, we defined women reporting SUI (with or without UUI) and UUI (with or without SUI) with severity of “moderate” or “severe” as having the condition. Body mass index (kg/m^2) was calculated from direct measures of height and weight at the HUNT screening station at the time participants completed their surveys. We linked these HUNT2 and

HUNT3 information to data from the Medical Birth Registry of Norway,[11] which has registered information on all deliveries in Norway since 1967. Information on parity and years since last delivery were also obtained from the birth registry. If a woman had participated both HUNT2 and HUNT3, we used survey information from HUNT3 to maximize the time from the last delivery to assessment of UI. However, if a participant was excluded from our analyses in HUNT3 (due to a current pregnancy or being in the first postpartum year at the time of the survey), we used the available information from HUNT2.

Based on earlier literature,[6] we hypothesized that increases in both SUI and UUI associated with both forceps and vacuum deliveries would be greater in women younger than 50 vs. those 50 or older and tested the hypothesis with a test of interaction. Because we found significant interactions ($p<0.01$) consistent with all hypotheses (larger impact with both forceps and vacuum on both SUI and UUI in younger women), we present results separately for women aged less than 50 and 50 or more. We adjusted these analyses, presented separately for SUI and UUI, for pre-specified known risk factors: age,[2] body mass index (<25, 25-30; ≥30 kg/m^2),[5] parity[12] and years since last delivery.[12] We also performed a sensitivity analysis that included, along with age, parity, BMI and years since last delivery, adjustment for the weight of the each participant's heaviest baby.

To calculate the absolute risk increase of SUI with forceps delivery, we estimated the absolute risk of patient important/ bothersome SUI after spontaneous vaginal delivery using large population-based study:[13] 12.0% for SUI after spontaneous vaginal

delivery among women aged <50, and then used the odds ratio (OR) to calculate the absolute risk increase with forceps delivery.[14]

We also performed longitudinal analyses including women who delivered during follow-up (except if surveyed during the first post-partum year or during pregnancy at baseline or follow-up). Although out of all HUNT2 participants, 72% of women also participated in HUNT3, these analyses were underpowered, with no statistically significant effects of delivery mode on SUI or UUI detectable. Summary data of these analyses are available in Appendix 2. Finally, to estimate selection bias, we compared the baseline characteristics of responders and non-responders. The statistical software package SPSS 24.0 (SPSS Inc., Chicago, IL) was used for all data analyses.

Results

A total of 55,080 women participated either in HUNT2 or HUNT3 or both. Of these, 28,322 women were also included to the Medical Birth Registry of Norway and responded to the surveys. We excluded women who had ever given birth before 1967, had any cesarean delivery, had both vacuum and forceps deliveries or were nulliparous, pregnant or in the postpartum year at the time of survey. The final analyzable sample was 13,694 women (Figure 1). Moderate to severe SUI and UUI were reported by 1,745 (12.7%) and 1,157 (8.4%) women. Characteristics are summarized in Table 1, and grouped according to mode of delivery. In comparison of responders (n=13,694) and non-responders (n=2,834; Figure 1), we found that women who did not answer the UI questions were slightly younger and lower BMI, but without differences in parity, delivery mode and time since last delivery (Appendix 3).

In women aged <50, when comparing forceps to spontaneous vaginal delivery, forceps delivery had a higher risk of SUI (OR 1.42, 95% CI 1.09-1.86) but not in women aged 50 or more (OR 0.96, 95% CI 0.67-1.37) (Figure 2). The absolute increase of was approximately 5.0% in bothersome SUI when comparing forceps delivery with spontaneous vaginal delivery in women aged <50. No difference was found between spontaneous vaginal delivery and vacuum in either among aged 50 or 50 or more (Figure 2). When comparing forceps to vacuum delivery, forceps had again a higher risk of SUI in women aged <50 (OR 1.76, 95% CI 1.20-2.60) but not in women aged 50 or more (Figure 2). When comparing forceps delivery to spontaneous vaginal delivery, forceps delivery had a near significant increased risk of UUI in women aged <50 (OR 1.39, 95% CI 0.98-1.97) but not in women aged 50 or more (Figure 3). In other analyses of UUI, there were no statistically significant differences between different modes of vaginal delivery (Figure 3). Finally, in sensitivity analyses with adjustment for the weight of the each participants heaviest baby, we found no material differences in the estimates (Appendix 4).

Comment

In this large, population-based study of women across a wide age range, forceps delivery was associated with a significantly increased long-term risk of SUI among women aged <50, but there was no longer a measurable impact for women aged 50 or more. For UUI there was a near significant impact on the risk of UUI with forceps among women aged <50.

The strengths of the current study include a study population representative of the

general population in numerous aspects, including income, age distribution, morbidity and mortality,[15] assessment of urinary incontinence symptoms with validated instruments, adjustment for major established risk factors of SUI and UUI, and linking of incontinence data to the Medical Birth Registry of Norway, which covers all births in Norway since 1967. Furthermore, our material was unaffected by the selection bias typical of clinic-based studies as a result of treatment-seeking. Finally, we not only estimated relative effects but also provided absolute estimates.

This study has some limitations. First, although this is the largest available study of the impact of different types of operative delivery on urinary incontinence subtypes, we did not have enough statistical power for longitudinal analyses. Second, women in this study were predominantly of European heritage, and results should be interpreted with caution for other ethnic groups. Third, we do not know how many of the women were incontinent before deliveries. Fourth, there may be confounding between the nature of the delivery and the choice of delivery method: clinicians may have chosen forceps for more obstructed labours, with greater cephalopelvic disproportion. Given the long time period over which eligible women for these analyses might have delivered (1967-2008), it can be questioned whether these results are generalizable to current obstetric practice. Certainly in Norway during these decades there were measurable shifts in practice, with more cesareans, more vacuum deliveries, and a rise and then fall in forceps deliveries.[16] It is unclear if the changes in frequency of use of the procedures are associated with different impacts on incontinence, however, we adjusted both for maternal age, and years since last delivery in multivariate analyses, which should have helped to control for differences due to changes in proportions of each kind of delivery over time. We considered carefully the choice of covariates in

multivariate analyses. Although associations in the literature between perineal trauma and urinary incontinence are inconsistent,[17-19] this may be one mediator or marker of the association of mode of birth and incontinence. We were not however, able to adjust for episiotomy or perineal trauma. Epidural may increase the use of forceps or vacuum,[20] but was not available in our data. Birthweight, and particularly weight of the heaviest baby delivered by a woman have been previously associated with risk of incontinence.[21-23] We did not find an association between birthweight and mode of delivery, but nevertheless tested the main model with and without inclusion of the weight of each participant's heaviest baby, finding no material difference. In common with almost all surveys of UI, the response rate for UI items was less than for questions about less stigmatizing conditions. In common with almost all surveys of UI, the response rate for UI items was less than for questions about less stigmatizing conditions. Approximately 17% of potentially eligible women did not answer the incontinence questions. We found that non-responders were slightly younger and thinner than responders, but found no differences in other characteristics. How this non-response might have impacted on estimates of association between mode of delivery and UI remains uncertain.

There are no randomized trials comparing the risk of SUI or UUI between spontaneous vaginal delivery, vacuum and forceps deliveries, or observational studies comparing the risk of SUI or UUI between vacuum and forceps deliveries. Norwegian EPINCONT study[24] also using HUNT2 data, results were given for any incontinence, whereas the current study defines cases based on moderate or severe stress cases and distinguishes SUI and UUI. The former study also compared vacuum deliveries to all other vaginal deliveries, that is, a combination of spontaneous vaginal deliveries and

forceps deliveries, and compared forceps deliveries to a combination of spontaneous vaginal deliveries and vacuum deliveries. This means that both control and comparison groups included one form of instrumental delivery; this was especially relevant as 46% of the instrumental deliveries were vacuum and 54% forceps. They did not show any difference in the risk of SUI when comparing spontaneous vaginal delivery and forceps (OR 0.8 95% CI 0.7-1.0). In a recent systematic review,[6] no difference was found in the long-term prevalence of SUI between vacuum delivery and spontaneous vaginal delivery (two studies[13,25], OR 1.10, 95% CI, 0.80-1.51), concurring with our current analysis. However, in the same systematic review (6), no difference was found in the risk of SUI between forceps and spontaneous vaginal delivery (three studies[13,26-27], OR: 1.16; 95% CI, 0.71-1.89; heterogeneity: p=0.06, I^2=65%). This pooled analysis is inconsistent with our results. However, here we include substantially more participants than there were in these three earlier studies combined.[13,26-27] Furthermore, there are methodological concerns regarding earlier work, including reliance on maternal recall of obstetric exposures, [26-27] which is known to be unreliable for classification of forceps and vacuum.[28] Many UI risk factors (BMI and comorbidities) associate with age.[29-30] Our results concur with previous studies reporting that the association of vaginal delivery on UI diminish in older age.[6] There is still probably an underlying association with mode of delivery in older age, but it is more difficult to detect because of competing causes of incontinence which, in this context, represent random error.

There remains wide practice variation in both the overall rates of operative delivery, and choice of method.[31] Forceps are less likely than vacuum to fail to achieve a vaginal birth.[31] However, with forceps facial injury is more likely,[31] and forceps

delivery is associated with an increased prevalence of pelvic organ prolapse, whereas vacuum delivery is not.[13, 31] In low- and middle-income countries less than 1% of institutional deliveries are operative deliveries with vacuum preferred over forceps.[32] In the United States between 2005 and 2013, approximately 5% of the deliveries were vacuum and 1% forceps deliveries.[33] In 2016, approximately 9% of deliveries were vacuum and 1.6% forceps deliveries in Norway.[16]

For informed decision-making between forceps and vacuum, we need accurate, unbiased estimates about their immediate and long-term consequences. These data provide an additional rationale for vacuum over forceps, at least when considering long-term incontinence. The estimates provided here are useful when counselling women about the risk and benefits of different delivery modes.

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413

Table legends

Table 1. Age distribution, prevalence of moderate to severe urinary incontinence and demographic characteristics among the 13 694 women included.

Figure legends

Figure 1. Study flow chart.

Figure 2. Age-stratified, less than 50 years vs. 50 years or more, impact of mode of vaginal delivery on SUI in the multivariate analyses.[a]

[a] Analyses adjusted for age, BMI, parity, and years since last delivery.

Figure 3. Age-stratified, less than 50 years vs. 50 years or more, impact of mode of vaginal delivery on UUI in the multivariate analyses.[a]

[a] Analyses adjusted for age, BMI, parity, and years since last delivery.

Supplementary Material

Appendix 1. Questions to assess urinary incontinence with response categorization.

Appendix 2. Longitudinal analyses

Appendix 3. Baseline characteristics for responders and non-responders to urinary incontinence questions.

Appendix 4. Sensitivity analyses including 13,686 women.

Table 1. Age distribution, demographic characteristics, and prevalence of moderate to severe stress and urgency urinary incontinence among the 13 694 included women.[a]

Characteristics	**SVD** (n=12 276) **Mean ± SD / N (%)**	**Vacuum** (n=713) **N (%) / Mean**	**Forceps** (n=705) **N (%) / Mean**
Age (y)[b]			
	Mean 47.2±10.52	Mean 43.5±9.90	Mean 46.7±10.01
<50 years	6896 (56.2)	520 (72.9)	437 (62.0)
≥50 years	5380 (43.8)	193 (27.1)	268 (38.0)
Years since last delivery[b]	18.30±10.58	13.32±9.42	16.47±15.89
Parity[b]	2.38±0.87	2.23±0.89	2.34±0.87
BMI			
<25	5348 (43.6)	298 (41.8)	304 (43.1)
25-29.9	4649 (37.9)	262 (36.7)	269 (38.2)
≥30	2279 (18.5)	153 (21.5)	132 (18.7)
Stress urinary incontinence[c]	1553 (12.7)	84 (11.8)	108 (15.3)
<50 years	780 (11.3)	51 (9.8)	72 (16.5)
≥50 years	773 (14.4)	33 (17.1)	36 (13.4)
Urgency urinary incontinence[c]	1026 (8.4)	60 (8.4)	71 (10.1)
<50 years	411 (6.0)	33 (6.3)	38 (8.7)

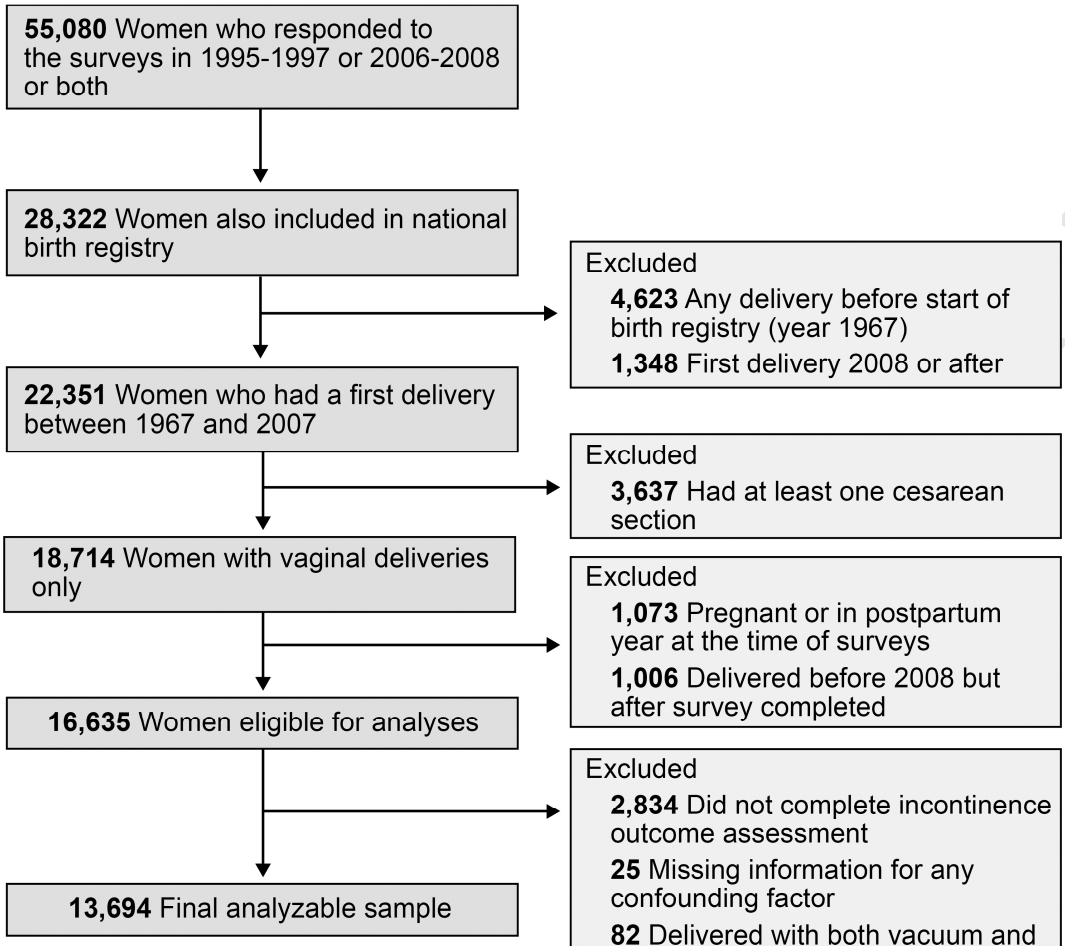
≥50 years	615 (11.4)	27 (14.0)	33 (12.3)

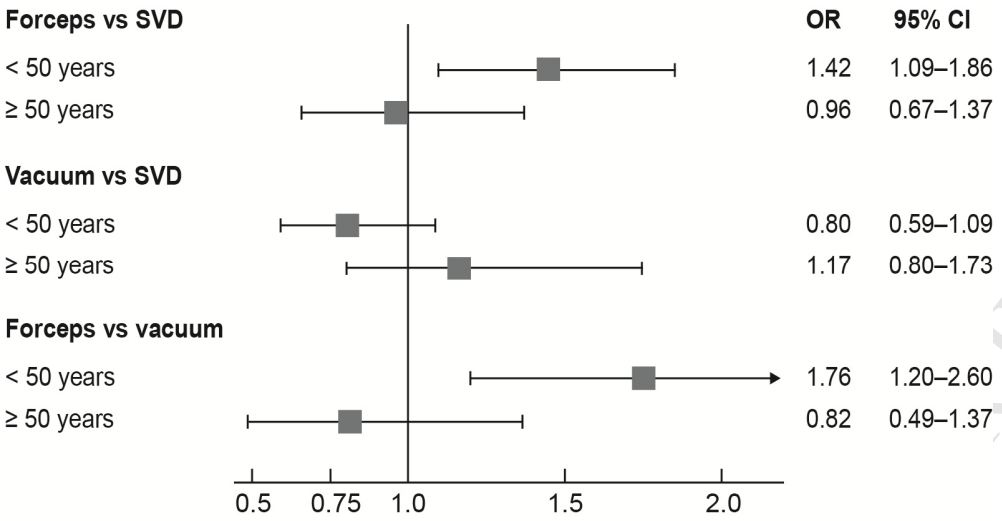
SVD, spontaneous vaginal delivery

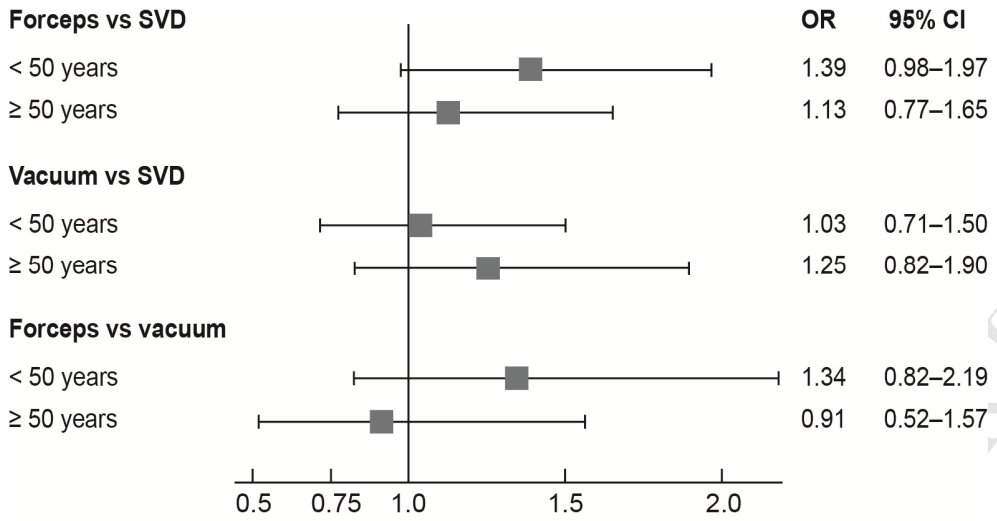
[a] Spontaneous vaginal delivery indicates a history of spontaneous vaginal deliveries only. Vacuum indicates a history of at least one vacuum delivery but no forceps deliveries. Forceps indicates a history of at least one forceps delivery but no vacuum deliveries.

[b] p-value less than 0.05 regarding between group differences.

[c] We defined women reporting stress urinary incontinence (with or without urgency urinary incontinence) and urgency urinary incontinence (with or without stress urinary incontinence) with severity of “moderate” or “severe” as having the condition.







Appendix 1. Questions to assess urinary incontinence with response categorization[a].

Symptom	**Defining question**	**Response categorization or scores**	
		Normal	Abnormal
Urinary leakage	Do you have involuntary loss of urine?	No	Yes
Stress urinary incontinence	Do you leak urine when you cough, sneeze, laugh, or lift something heavy?	No	Yes
Urgency urinary incontinence	Do you have involuntary loss of urine in connection with sudden and strong urge to void?	No	Yes
Frequency of leakage[a]	How often do you have involuntary loss of urine?"	1: Less than once a month 2: One or more times a month 3: One or more times a week 4: Every day and/or night	
Amount of leakage[a]	How much urine do you leak each time? (scale: 1, drops or little; 2, small amount or large amounts).	1: Drops or little	2: Small amount or large amount

[a] Sandvik Severity Index is obtained by multiplying the scores for questions "Amount of leakage" and "Frequency of leakage": 1-2 indicates slight incontinence; 3-4, moderate incontinence; 6-8, severe incontinence.[10]

Appendix 2. Longitudinal analyses

A total of 6,566 women participated in both surveys (HUNT2 and HUNT3). We performed longitudinal analyses looking for incidental cases of stress urinary incontinence (SUI) or urgency urinary incontinence (UUI) between HUNT2 (baseline) and HUNT3 (follow-up). To these analyses, we included only nulliparous women who were continent at the baseline (HUNT2) and who delivered before HUNT3 (except if they were surveyed during the first post-partum year or during pregnancy at either baseline or follow-up). Same pre-specified known risk factors were treated as confounders as in the cross-sectional analyses: age, body mass index (<25, 25-30; ≥30 kg/m^2), parity and years since last delivery. Parity and years since last delivery were obtained from Medical Birth Registry of Norway (MBR) {{4656 Anonymous;}}.

A total of 391 women were nulliparous at the baseline. Four women had SUI at the baseline and were excluded from longitudinal SUI analyses; three had UUI and were excluded from longitudinal UUI analyses.

In total, 387 women were included to the longitudinal SUI analyses and 388 women to the longitudinal UUI analyses. At the follow-up, 48 (12.4%) of the women had moderate to severe SUI and 16 (4.1%) had moderate to severe UUI. Of those with SUI at the follow-up, 38 women had spontaneous vaginal deliveries (SVD), 7 vacuum and 3 forceps deliveries. Of those with UUI at the follow-up, 13 women had SVD, 2 vacuum and 1 forceps deliveries. Statistical power for these longitudinal analyses was too small for reliable, precise estimates (see table below).

Outcome	Comparison[a]	OR	95% CI
SUI	Vacuum delivery vs SVD	2.08	0.84-5.11
	Forceps delivery vs SVD	1.16	0.33-4.08
UUI	Vacuum delivery vs SVD	1.53	0.33-7.08
	Forceps delivery vs SVD	1.11	0.14-8.89

SVD, spontaneous vaginal delivery; SUI, stress urinary incontinence; UUI, urgency urinary incontinence

[a]Spontaneous vaginal delivery indicates a history of spontaneous vaginal deliveries only. Vacuum indicates a history of at least one vacuum delivery but no forceps deliveries. Forceps indicates a history of at least one forceps delivery but no vacuum deliveries.

Appendix 3. Baseline characteristics for responders and non-responders to urinary incontinence questions.

Characteristics	**Responders** (n=13,694)	**Non-responders (n=**2,834)
	Mean ± SD / N (%)	**Mean ± SD / N (%)**
Age (y)[a]	Mean 46.97±10.49	Mean 43.73±10.26
<50 years	7,853 (57.3)	1476 (71.2)
≥50 years	5,841 (42.7)	598 (28.8)
Years since last delivery	17.95±10.53	15.45±10.29
Parity	2.37±0.87	2.46±0.92
BMI[a]		
<25	5,950 (43.4)	975 (47.6))
25-29.9	5,180 (37.8)	711 (34.7)
≥30	2,564 (18.7)	363 (17.7)
Delivery mode[b]		
SVD	12,276 (89.2)	2,527 (89.9)
Vacuum	713 (5.2)	146 (5.2)
Forceps	705 (5.0)	141 (5.0)

SVD, spontaneous vaginal delivery

[a]Information on age and BMI was available for 63.6% and 71.6% respectively.

[b]20 women delivered both vacuum and forceps in non-responders group and are excluded.

Appendix 4. Sensitivity analyses[a] including 13,686 women.[b]

Outcome		Comparison	OR	95% CI
<50	SUI	Forceps vs vacuum	1.76	1.19-2.60
		Vacuum vs SVD	0.81	0.60-1.10
		Forceps vs SVD	1.43	1.09-1.87
		All assisted vs SVD	1.09	0.88-1.34
	UUI	Forceps vs vacuum	1.34	0.82-2.18
		Vacuum vs SVD	1.05	0.72-1.53
		Forceps vs SVD	1.40	0.99-2.00
		All assisted vs SVD	1.22	0.93-1.59
≥50	SUI	Forceps vs vacuum	0.83	0.49-1.37
		Vacuum vs SVD	1.15	0.78-1.70
		Forceps vs SVD	0.95	0.66-1.37
		All assisted vs SVD	1.04	0.79-1.36
	UUI	Forceps vs vacuum	0.91	0.52-1.57
		Vacuum vs SVD	1.25	0.82-1.91
		Forceps vs SVD	1.13	0.77-1.65
		All assisted vs SVD	1.18	0.88-1.58

[a] Analyses adjusted for age, BMI, parity, years since last delivery, and weight of the each participants heaviest baby.

[b] Correct birthweight information was missing from eight women.