

Bilaga till rapport

Analsfinkterskador vid förlossning -
en systematisk översikt och utvärdering av
medicinska, hälsoekonomiska, sociala och
etiska aspekter, rapport nr 249/2016

Appendix 1 Included studies/Bilaga 1 Tabellverk, beskrivning av ingående studier

Author Year Reference Country	Study design	Population Setting	Intervention Control Adherence Loss to follow-up	Outcome results	Study quality Comments
<i>Perineal massage, oils hyaluronidase, warm compresses</i>					
Albers et al 2005 [1] USA	RCT 3 arm study	1 211 women Age: Mean (SD): 24.9 (5.3), 24.5 (5.2), 24.5 (5.1) years Hispanic 46–49% Nullipara 38.2–42.3% Episiotomy in the 3 study arms 1 (0.3%), 7 (1.7%), 2 (0.5%) 2% women had operative deliveries Midwifery care, University of New Mexico during 2001–2004	3 arm study (1:1:1), warm compresses, perineal massage and hands-off perineum Adherence (self-reported): 94– 95% Loss to follow-up directly after birth 0	ITT = All randomised patients were included in the analysis Warm compresses (404): 1 st degree: 97 (24.4%) 2 nd degree: 70 (17.3%) 3 rd degree: 3 (0.7%) 4 th degree: 0% Massage with lubricant (403): 1 st degree: (91) 22.2% 2 nd degree: 73 (18.1%) 3 rd degree: 4 (1.0%) 4 th degree: 1 (0.3%) Hands-off (404): 1 st degree: 80 (22.0%) 2 nd degree: 74 (18.3%) 3 rd degree: 2 (0.5%) 4 th degree: 4 (1.0%) Predictors intact genital tract: Compresses vs hands-off crude RR 1.04 (95% CI 0.81–1.35) Massage vs hands-off crude RR 1.05 (0.81–1.35). All stratified analysis NS	Medium
Dahlen et al 2007 [2] Australia	RCT	771 nulliparous women, ages mean and (SD) 27.0 (5.5) and 27.2 (4.9) years, Asian approximately 32% both groups	Perineal warm pack during late second stage of labor (n=360) vs standard care (n=357) Adherence warm pack 302/360	Primary outcome measures: Requirement for perianal suturing and maternal comfort Suturing required 283/360 (78.6%) and 284/357 (79.9%) OR 1.0 (95% CI 0.69–1.47)	Medium– high

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		Forceps 11 (3.1%) and 9 (2.5%), vacuum 32 (8.9%) and 39 (10.9%) 2 maternity hospitals in Australia, 1997–2004	Loss to follow-up 0	3 rd and 4 th degree laceration: 15 (4.2%) and 31 (8.7%) OR 2.16 (1.15–4.10) Episiotomy: 39 (4.2%) and 31 (8.7%)	
Harlev et al 2013 [3] Israel	RCT	164 nulliparous and multiparous women Wax: Age 26.2±5.3 years Episiotomy 7.3% Rich-oil: Age 26.3±5.1 years Episiotomy 15.9% Soroka University Medical center, 2008–2009	Wax group (n=82) vs rich-oil group (n=82) during delivery Loss to follow-up 0	Perineal tear grade Wax: 1 st degree: 58.3% 2 nd degree: 38.9% 3 rd degree: 2.8% Rich-oil: 1 st degree: 62.5% 2 nd degree: 34.4% 3 rd degree: 3.1% All comparisons NS	Medium
Araújo et al 2008 [4] Brazil	RCT	76 nulliparous women, age mean and SD 21.6±3.8, control, age 20.5±3.9 Excluded if episiotomy Amparo philanthropic hospital, Sao Paolo, 1990–1992	Use of liquid petroleum jelly on the perineum during the expulsive period of labor without any massage of the perineum (n=38) vs control (no jelly) n=38 Loss to follow-up 0	Experimental Intact: 36.8% Trauma: 63.2% 1 st degree: 66.7%, 2 nd degree: 33.3% Control Intact: 38.2% Trauma: 61.8% 1 st degree: 72.3%, 2 nd degree: 27.7% NS	Medium
Bodner-Adler et al 2002 [5] Austria	Observational	531 primiparous women Perineal massage: Age 30.0 (25.9–32.6) years Operative vaginal: 8.2% Episiotomy: None 69.4%	Perineal massage group asked to perform perineal massage 3–4 times a week for 5–10 minutes starting 6 weeks before estimated due date and	Main outcome measure: Perineal tears Perineal massage (n=121): 1 st degree: 14.1% 2 nd degree: 17.4% 3 rd degree: 2.5%	Medium No adherence data

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		Midline 16.5% Mediolateral 10.9% No massage: Age 27.2 (23.8–30.3) years Operative vaginal: 4.6% Episiotomy: None 73.0% Midline 16.1% Mediolateral 10.9% University hospital Vienna and Semmelweis Women's hospital	a parity-matched control group	No perineal massage (n=410): 1 st degree: 15.6% 2 nd degree: 17.1% 3 rd degree: 5.4% Trend Towards a reduction of 3 rd degree tears in the perineal massage group, (p=0.19)	
Mei-dan et al 2008 [6] Israel	RCT	234 nulliparous women Massage (n=99): Age mean and SD 27.6±3.5 years Control (n=104): 25.4±3.8 years Soroka University Medical center	Antenatal perineal massage, 10 minutes perineal massage daily from the 34 th week until delivery. Considerable number both groups loss to follow-up	Massage group Intact perineum: 31 (29.8%) Episiotomy: 23 (20%) 1 st degree: 44 (73.3%) 2 nd degree: 16 (26.7%) 3 rd /4 th degree: 0 Control group Intact perineum: 40 (40%) Episiotomy: 20 (18.9%) 1 st degree: 45 (78.9%) 2 nd degree: 11 (19.3%) 3 rd /4 th degree: 1 (1.8 %) p-values Intact perineum: 0.12 Episiotomy: 0.83 1 st degree: 0.39 2 nd degree: 0.39 3 rd /4 th degree: 0.39	Medium
Labrecque et al	RCT	Pregnant women with (n=493) and without	A 10-minute perineal massage daily from 34 th or 35 th week of	Main outcome measure: Intact perineum	Medium

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1999 [7] Canada		(n=1 034) previous vaginal birth. Mean ages in groups 28–31 years. Vacuum extraction 11.4 and 11.5%, forceps 13.5% both groups. 5 hospitals in Quebec	pregnancy until delivery vs control no massage. Adherence 85% or lower Loss to follow-up 1, 3, 1, and 0	Nulliparous 24.3% (100/411) and controls 15.1% (63/417). ARR 9.2% (95% CI 3.8–14.6%) Among multiparous 34.9% (82/235) and 32.4% (78/241). ARR 2.5% (95% CI –6% to 11.0%) Episiotomy 27 and 30.9% 3.4 th degree (without episiotomy) 10 (2.4%) and 12 (2.9%) NS. With episiotomy 33 (8%) and 35 (8.4%)	
Colacioppo et al 2011 [8] Brazil	RCT	160 primiparous women. Age 22.5±4.5 years, range 18–38 years Episiotomy Experimental: 3 Control: 8 Midwife-led Amparo Maternal Birth Centre São Paulo	Injection of hyaluronidase in perineum vs placebo injection Loss to follow-up 1 and 2	Main outcome measure "perineal outcome" Experimental group (n=80): Intact: 34.2% 1 st degree: 56.0% 2 nd degree: 38.0% 3 rd degree: 0% Loss to follow-up: 1 Control group (n=80): Intact: 32.5% 1 st degree: 15.6% 2 nd degree: 17.1% 3 rd degree: 7.4% (n=4) 3 rd degree tear difference NS	
Scarabotto et al 2008 [9] Brazil	RCT	139 primipara, approximately 50%, 15–20 years, 50% non-white Midwife-led Amparo Maternal Birth Centre São Paulo	Hyaloronidase Injection (n=71) vs control (no injection, n=68) Loss to follow-up 0	Intact perineum 60% and 23.5%, RR 0.52 (95% CI 0.48–0.55), 2 nd degree laceration/episiotomy 14.3% and 19.2% NS	Medium
Positions, stirrups					
Corton et al 2012	RCT	214 nulliparous women.	Stirrups (n=106) vs no stirrups (n=108)	Perineal lacerations No stirrups (n=108):	Medium

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[10] USA		Age mean and SD 22±5 years Stirrups Episiotomy:7 (7) Forceps: 5 (5) No stirrups Episiotomy: 5 (5) Forceps: 5 (5) Labor and delivery units Parkland hospital Dallas	Loss to follow-up 0	None: 26 (24.0%) 1 st degree: 33 (31.0%) 2 nd degree: 44 (41.0%) 3 rd degree: 4 (4.0%) 4 th degree: 1 (1%) Loss to follow-up: 0 Stirrups (n=106): None: 22.0% 1 st degree: 29.0% 2 nd degree: 44% 3 rd degree: 6.0% 4 th degree: 0 (0%) Loss to follow-up: 0 No lacerations 26 (24%) and 23 (22%) p=0.8	
Stewart et al 1983 [11] UK	RCT	189 women Glasgow Royal Maternity Hospital	Birth chair (n=99, 36 nullipara) vs conventional (n=90, 40 nullipara) dorsal position vs “no difference in age, weight, gestational age, parity, social class”. 5 excluded from birth chair group	Mean duration of second stage: primigravidas 81 vs 94 minutes, NS. Multigravidas 18 vs 26 minutes, NS. Forceps. Primigravidas 9 and 11, multigravidas 1 and 1. Perineal damage. None: primigravidas 11 and 2 p<0.01, multigravidas 7 and 13 NS Third- and fourth degree tear. None Episiotomy. Primigravidas 12, 26 (p<0.01), multigravidas 7 and 13.	Medium Unbalanced withdrawal
Gardosi et al 1989 [12] UK	RCT Age mean and (SD) 24.5	151 women Ages upright mean and SD 24.5 (5.5) years, recumbent 24.6 (4.3) years	Active and upright (n=73) vs bed and recumbent (n=78) Adherence upright 74%,	Intact perineum 66 (90%) and 66 (85%) 3 rd degree tear 0 and 2 (3%) NS	Medium

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	(4.4) and 24.6 (4.3) years	Milton Keynes General Hospital	recumbent 81% Loss to follow-up 0	Episiotomy 22 (30%) and 30 (38%)	
Ragnar et al 2006 [13] Sweden	RCT	271 primiparous women Kneeling group: Age mean and SD 26.4±4.0 years Sitting group: Age 26.5±4.3 years Västerås County Hospital	Compare 2 upright delivery positions at the second stage of labor, kneeling (n=138) vs sitting (n=133) Loss to follow-up 0	Primary outcome: Duration of the second stage of labor, no significant difference Lacerations 69 (65%) and 72 (64%) Sphincter ruptures 3 (3%) and 6 (5%) NS	Medium
<i>Episiotomy, selective/routine</i>					
Belizan et al 1993 [14] Argentina	RCT	2 606 women; 1 555 nulliparous (778 in selective group and 777 in routine group) and 1 051 primiparous (520 in selective group and 531 in the routine group) Eligible if they were in uncomplicated labour at 37 to 42 weeks 8 city maternity hospitals in Argentina	Selective vs routine use of mediolateral episiotomy for women having first and second deliveries Loss to follow-up 0	Primary measure of outcome: Severe perineal trauma (3 rd degree and 4 rd degree lacerations) Rate of episiotomy: 30.1% vs 82.6% Selective group: Nulliparous 1.4%, primiparous 0.8%. Total: 1.2% Routine group: Nulliparous 1.8%, primiparous 0.9%. Total: 1.5% RR (95% CI): Nulliparous 0.79 (0.36–1.72), primiparous 0.78 (0.21–2.90). Total: 0.78 (0.40– 1.54)	Medium
Dannecker et al 2004 [15] Germany	RCT	109 primiparous women Restrictive policy age mean and SD 28.3±5.0 years	Restrictive policy (n=49) try to avoid an episiotomy even if a severe perineal trauma was judged to be imminent and only do it for fetal indications	Main outcome measures: Incidence of episiotomy, intact perineum, perianal tears Restrictive policy (n=49): Episiotomy 20 (41%)	Medium

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		<p>Liberal policy age 28.6±4.5 years</p> <p>Vacuum 4 and 5</p> <p>University hospital setting Munich-Grosshadern, Germany</p>	<p>vs liberal policy (n=60) in addition to fetal indications use episiotomy when a tear is judged to be imminent</p> <p>Loss to follow-up 27 and 29</p>	<p>Intact perineum 14 (29%) Minor perineal trauma 19 (39%) 3rd degree tear 2 (4%) Anterior trauma 27 (55%)</p> <p>Liberal policy (n=60): Episiotomy 46 (77%) Intact perineum 6 (10%) Minor perineal trauma 8 (13%) 3rd degree tear 5 (8%) Anterior trauma 25 (42%)</p> <p>RR (95% CI): Episiotomy 0.47 (0.3–0.7); p=<0.001 Intact perineum 2.9 (1.2–6.9); p=0.023 Minor perineal trauma 2.9 (1.6–10.5); p=0,003 3rd degree tear 0.43 (0.1–2.1); p=0.46 Anterior trauma 1.1 (0.8–1.8); p=0.25</p>	
House et al 1986 [16] UK	RCT	<p>165 women, 98 primigravidae and 67 multigravidae, data on ages lacking</p> <p>Charing Cross Hospital London, UK</p>	<p>Restricted use vs liberal use of episiotomy</p> <p>Loss to follow-up 0</p>	<p>Restricted episiotomy (n=94): Primigravidae Intact or 1st degree tear: 16 (32%) 2nd degree: 18 (36%) 3rd degree: 0 Episiotomy 16 (32%):</p> <p>Multigravidae Intact or 1st degree tear: 24 (54%) 2nd degree: 19 (43%) 3rd degree: 0 Episiotomy: 1 (2%)</p> <p>Liberal episiotomy (n=71): Primigravidae Intact or 1st degree tear: 2 (4%) 2nd degree: 8 (17%)</p>	Medium

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				<p>3rd degree: 0 (2 forceps deliveries; extensions of episiotomies, 4%)</p> <p>Episiotomy: 38 (79%): Multigravidae Intact or 1st degree tear: 6 (26%) 2nd degree: 5 (22%) 3rd degree: 1 (4%)</p> <p>Episiotomy (p-values): Primigravidae Intact or 1st degree tear: p<0.001 2nd degree: p<0.05 3rd degree: –</p> <p>Episiotomy p<0.001: Multigravidae Intact or 1st degree tear: p<0.05 2nd degree: – 3rd degree: – Episiotomy: p<0.001 Third degree tear NS between interventions</p>	
Räisänen et al 2014 [17] Finland	Observational matched cohort study	303 750 singleton vaginal births from the Finnish Medical Birth Register 2004–2011. Matched pairs n=63 925, based on baseline risk for OASIS	Matched pair analysis of risk of OASIS with episiotomy	Reduced risk of OASIS with episiotomy 12.5% and 31.6% in first and subsequent vaginal births	High
Revicky et al 2010 [18] UK	Observational retrospective cross-sectional study	10 314 deliveries Norfolk and Norwich University Hospital delivery data	Risk factor analysis for anal sphincter tears with stepwise logistic regression	Anal sphincter lacerations 3.2%. Significant association with parity, birth weight, method of delivery, and shoulder dystocia. Delivery without mediolateral episiotomy increased risk OR 1.4 (95% CI 1.02-1.98)	High
<i>Mediolateral/lateral, episiotomy instrumental</i>					

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De Leeuw et al 2008 [19] The Netherlands	Observational	21 254 delivered with vacuum extraction and 7 487 women delivered with forceps. Data from the Dutch National Obstetric Database 1994–1995	Analysis of sphincter injury rates. Risk factors analysed with multivariate logistic regression	Main outcome measures. Sphincter injuries in relation to risk factors. Sphincter injury occurred in 3% of vacuum extractions and in 4.7% of forceps deliveries. Mediolateral episiotomy protected against sphincter damage with vacuum extraction (OR 0.11, 95% CI 0.09–0.13) and forceps delivery (OR 0.08, 95% CI 0.07–0.11). NNT 12 and 5 respectively	High
Murphy et al 2008 [20] Ireland	RCT	317 nulliparous women (11% >35 years of age) requiring operative vaginal delivery, 200 were randomised, 99 to routine episiotomy and 101 to restrictive use. Maternal age similar in groups, >35 years, 11% in both groups, vacuum delivery 24.2% and 23% 2 urban maternity units in England and Scotland	Women with indication for operative vaginal delivery, randomised to routine or restrictive use of episiotomy Loss to follow-up 7 and 8	Primary outcome measure: Rate of sphincter tears. Routine 8 (8.1%) and restrictive use 11 (10.9%), OR 0.72 (95% CI 0.28–1.87)	Medium
Education programs, finnish method					
Fretheim et al 2013 [21] Norway	Observational. Interrupted time-series analysis using segmented regression modelling. Data from Norwegian birth register	75 543 births during 2002–2008 Episiotomies 15–16% Monthly rupture rate 6–4% first years Obstetric departments at 5 Norwegian hospitals	Change in incidence of perianal tears and episiotomies before and after implementation of intervention program in 5 hospitals. Key component of the program hand on technique pressing the neonates head	Main outcome measures: Incidence of perianal tears and episiotomies. 2% absolute reduction in anal sphincter tears (RR about 50%) and a significant increase in episiotomies absolute 10% (95% CI 6–14%)	High
Stedenfeldt et al 2014	Observational	40 154 vaginal deliveries	To evaluate and compare risk profile of sustaining obstetric and sphincter injuries	Before intervention (n=21 123): Episiotomy 3 047 (14.4%)	High

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[22] Norway	Interventional cohort study with before and after comparison Data collected 3 years before intervention and 2 years 3 months – 3 years 6 months after intervention (4 hospitals in Norway)	Before intervention (n=21 123): Age 29.2 (5.0) After intervention (n=19 031): Age 29.2 (5.0) 4 Norwegian departments 2003–2009	(OASIS) after the OASIS rate was reduced from 4.6% to 2.0% following an interventional program Intervention: Theoretical and practical training, aimed at reintroducing the physicians and midwives to a traditional method of assisting delivery of the neonate during the final part of the second stage of delivery, providing adequate perineal support, and instruction on the use of episiotomy only upon indication. If performed, the cut should be with the incision point lateral to the midline	After intervention (n=19 031): Episiotomy 4 618 (24.3%) OR: Episiotomy CI 95% 1.91 (1.82–2.01) Adjusted OR (adjusted for age and parity): Episiotomy CI 95% 1.92 (1.82–2.02) OASIS: After the OASIS rate was reduced from 4.6% to 2.0% following an interventional program OASIS: Risk of sustaining OASIS decreased by 59% (OR 0.41; 95% CI 0.36–0.46) after the intervention The highest reduction of OASIS, (65%), was observed in group 0 (low risk) (OR 0.35; 95% CI 0.24–0.51), and a 57% (OR 0.43; 95% CI 0.35–0.52), 61% (OR 0.39; 95% CI 0.31–0.48), and 58% (OR 0.42; 95% CI 0.30–0.60) reduction in groups with 1, 2 and 3 risk factors, respectively. No change was observed in the group with 4 risk factors	
Hals et al 2010 [23] Norway	Observational. Interventional program observational cohort study	40 152 vaginal deliveries 2003–2009, 4 Norwegian obstetric departments. Nulliparity 37.7–42.4%, vacuum 6.9–13.8%, forceps 0.1–3.2%	Intervention program with focus on manual assistance during the final part of the second stage	Main outcome measure. Incidence of anal sphincter tears. From 4–5% to 1–2% during the study period in all hospitals, p<0.001, OR 0.43 (0.38–0.48). Non-instrumental births from 3 to 1% OR 0.42 (0.36–0.49). Instrumental from 16 to 7% OR 0.42 (0.35–0.50)	Medium
Laine et al 2008 [24] Norway	Observational. Interventional program observational cohort study,	12 369 vaginal deliveries 2002–2007. Nulliparity approximately 41% during whole study	Hands-on technique to slower down the delivery of the infants head and instruction to mother not to push	Time-series data analysed. Main outcome measure anal sphincter tears. From 4.03% (285/7 069) to 1.17% (42/3 577), p<0.001. Grade 4 sphincter tears during 2002–2004, 10–13 per year and only 1 during study period	Medium

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	Fredriksstad, Norway			(18 months). Anal sphincter rupture and instrumental deliveries 16.26% (113/695) to 4.90 (19/388), $p < 0.001$. Episiotomies 13.9% (980/7 069) 2002–2004 and 21.1% (381/1801) last 9 months	
Leenskjoeld et al 2015 [25] Denmark	Observational intervention quality improvement cohort study	768 primipara and 1 175 multipara	Intervention lectures for all midwives and physicians with focus on communication, visualization of the perineum, support of perineum during last stages of pushing, and episiotomy at indication. Analysis of OASIS rate and episiotomies before and after study	OASIS decreased from 4.4% (45/1 025) to 1.7% (16/918) $p < 0.001$, RR 0.40, (0.23–0.70) Primipara: 7.2% (28/388) to 2.9% (11/380) $p = 0.006$, RR 0.40 (0.20–0.79) OASIS non-instrumental primipara: 6% (20/332) to 2.2% (7/316) RR 0.38 (0.16–0.86), multipara 2.0% (12/615) to 0.96 (5/523) RR 0.49 (0.17–1.38) OASIS instrumental deliveries nullipara: 14.3% (8/56) to 6.3 (4/64) RR 0.44 (0.14–1.40), multipara 22.7% (5/22) to 0/15 $p = 0.047$ Episiotomies increased from 4.4% to 7.1%. RR 1.65 (95% CI 1.14–0.239) for all deliveries	Medium
<i>Delayed vs immediate pushing</i>					
Fitzpatrick et al 2002 [26] Ireland	RCT	178 nulliparous with continuous epidural analgesia Immediate: Age 28 (18–38) years, instrumental 35/90, caesarean section 5/90, episiotomy 66/90, forceps 12/90 Delayed:	Immediate pushing (n=90) vs 1 hour delayed pushing (n=88) All patients underwent anal manometry Loss to follow-up 0	Immediate 3 rd degree tear: 10% 2 nd degree tear: 8% Dyspareunia: 20% Delayed 3 rd degree tear: 7% 2 nd degree tear: 9% Dyspareunia: 23% RR (95% CI) Episiotomy: 1.37 (0.68–2.74)	High

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		Age 30 (18–40) years, instrumental 39/88, caesarean section 3/88, episiotomy 61/88, forceps 11/88 Tertiary referral teaching hospital		3 rd degree tear: 1.56 (0.53–4.59) 2 nd degree tear: 0.86 (0.29–2.50) Dyspareunia: 0.83 (0.39–1.78)	
<i>Epi-No, belt, perineal protection device</i>					
Ruckhäberle et al 2009 [27] Germany	RCT	276 primiparous women Epi-No group Age 31.3±4.2 years Ventouse: 20 Forceps: 4 Control Age 31.3±4.4 years Ventouse: 22 Forceps: 4 4 university hospitals in Germany	With Epi-No vs without Epi- No Loss to follow-up 4	Vaginal deliveries With Epi-No (n=107): Intact perineum 40 (37.4%) Episiotomy 44 (41.1%) 1 st /2 nd degree 22 (20.6%) 3 rd /4 th degree 6 (5.6%) All others 40 (37.4%) Control (n=105): Intact perineum 27 (25.7%) Episiotomy 53 (50.5%) 1 st /2 nd degree 26 (24.8%) 3 rd /4 th degree 5 (4.8%) All others 27 (25.7%) p-value: Intact perineum 0.05 Episiotomy 0.11 1 st /2 nd degree 0.81 3 rd /4 th degree 0.51 All others 0.05	Medium
Acanfora et al 2013 [28]	RCT	80 pregnant women Ages and SD 30 (5.2) and 31 (4.2)	Abdominal belt inflated (n=40) at second stage of labor vs non inflated belt (n=40)	Several outcome measures	Medium

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Italy		San Guiseppe Hospital, Empoli, Italy	Loss to follow-up 4	Mild perineal lacerations 1 (2.5%) and 15 (37.5%), severe perineal lacerations 2 (5%) and 16 (40%) p<0.001 for both comparisons Vacuum extraction 4 (10%) and 12 (30%), p<0.01	
Lavesson et al 2014 [29] Sweden	RCT	1 148 women. Ages: median and range for intervention group 30.1 (18–47 years) and control group 29.8 (18–45 years). Primiparous 62 and 64%, episiotomies 5.1 and 4.6%, instrumental deliveries 10% and 9.9%	Perineal protection device (n=574) vs control (n=574) without device Loss to follow-up 6 and 8	Main outcome measure: Rate of perineal tears. No perineal tears 184 (34.9%) and 142 (26.6%), p=0.034. Numbers needed to treat to 12. Rate of anal sphincter rupture 19 (3.4%) in both groups	High
<i>Hands-on vs hands-off methods, perineal protection, Ritgen's vs standard</i>					
Jönsson et al 2008 [30] Sweden	RCT	1 623 nulliparous women. Ages 28 (1 642) and 28 (16–44 years). Episiotomy 13.7 and 16.9% Primary and tertiary level hospital Lund, Sweden during 1999–2001	Ritgen's maneuver (extracting the fetal head during delivery, 1 hand to pull the chin and 1 hand to control speed of delivery n=554) vs standard care (n=727). Adherence 79.6 % and 4.3 % Loss to follow-up 0	Main outcome measure: Rate of 3 rd and 4 th degree perianal ruptures 5.5% (38) vs 4.4% (32), RR 1.24 (95% CI 0.78–1.96). Operative deliveries excluded sphincter injuries 5.5% and 4.4%	Medium
Mayerhofer et al 2002 [31] Austria	RCT	1 161 women, similar ages in groups, mean 29 years University hospital of Vienna and Semmelweis women's hospital Vienna, Austria	Traditional hands-on vs innovative hands-poised method Loss to follow-up 45 and 40	Primary outcome measure: Risk of perineal tears 187/574 (32.5%) and 180/502 (35.8%). 3 rd degree tear: 16 (2.7%) and 5 (0.9%), p<0.05 Episiotomy: 103 (17.9%) and 51 (10.1%), p<0.01	Medium
<i>Training</i>					
Bo et al 2009 [32]	Observational cohort study	18 865 primiparous women Norwegian Mother and Child Cohort Study.	Pelvic floor muscle training before and during pregnancy	Risk of perineal lacerations, episiotomy, instrumental deliveries	Medium

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Norway		Obstetric outcomes from the Medical Birth Registry of Norway. Data from self-completed questionnaires at gestational weeks 17 and 30 analysed by logistic regression		3 rd or 4 th degree laceration, 7.2% and 6.3% for training less than once a week compared with at least 3 times a week respectively. Rates of episiotomy 29.1% compared with 24.9%, vacuum/forceps delivery 15 % vs 15%. After adjusting all OR included 1.0, NS	
Diagnosics, missed sphincter tears					
Corton et al 2013 [33] USA	Observational diagnostic study	114 primiparous women without clinically diagnosed anal sphincter lacerations at delivery Age mean and SD 21.4±4.3 years Midline episiotomy: With US sphincter defect 2/13 Without US sphincter effect 5/94 Forceps 0 and 0 Parkland Hospital, Dallas, USA	Endoanal ultrasonography within 72 hours of delivery	n=13 (12%) 3-D sphincter defects (interpretable data n=107) Women with sonographically detected sphincter defects had a significantly increased rate of 2 nd degree lacerations (54 vs 20%, p=0.008) Intra-observer 0.82 (CI 0.66–0.99) and inter-observer 0.72 (CI 0.54–0.92)	Medium
Valsky et al 2007 [34] Israel	Observational	139 primiparous women without clinically diagnosed anal sphincter lacerations at delivery (group I) and 13 primiparous women with recognized 3 rd degree sphincter tears (group II).	Group I (127/139) were examined prospectively 24–72 hours postpartum with a 3-D transperineal probe placed at the area of the fourchette and perineal body. Group II underwent surgical repair of 3 rd degree tear and followed	In group I occult sphincter tear was suspected in 10/127 cases which was confirmed at surgery. Thickening and scar was observed in the external sphincter in group II in 13 women at follow-up	Medium

Author Year Reference Country	Study design	Population Setting	Intervention Control Adherence Loss to follow-up	Outcome results	Study quality Comments
		Age mean 26.7 years (16-43)	for up to 4 months with ultrasound		
<i>Diagnosis of anal sphincter tears to prevent fecal incontinence</i>					
Faltin et al 2005 [35] Switzerland	RCT	752 primiparous women without a clinically evident anal sphincter tear Age mean SD 28.9±4.5 and 29.2±5.0 (control) years Forceps 92 (24.4) and 99 (26.3) Vacuum 60 (16.0) and 59 (15.7) Episiotomy 194 (51.6) and 195 (51.9) Follow-up 3 and 12 months Loss to follow-up 6 Department of Obstetrics and Gynecology, University Hospitals of Geneva, Switzerland 1999–2001	Endoanalt ultrasound and clinical examination vs clinical examination alone Loss to follow-up 2 and 1	Main outcome measure: fecal incontinence 3 months postpartum. Among women assessed by US 5.6% sphincter tear Fecal incontinence: Experimental (clinical examination and endosonography): 3 months postpartum n=364 Any incontinence: 33.0% Severe incontinence: 3.3% 1 year postpartum n=342 Any incontinence: 25.1% Severe incontinence: 3.2% Control (clinical examination only): 3 months postpartum n=355 Any incontinence: 32.1% Severe incontinence: 8.7% 1 year postpartum n=342 Any incontinence: 26.6% Severe incontinence: 6.7% RR 3 months postpartum; Any incontinence: 0.9 (–6.0–7.7); p=0.81 Severe incontinence: –5.4 (–8.9–2.0); p=0.002 1 year postpartum Any incontinence: –1.5 (–8.0–5.1); p=0.66 Severe incontinence: –3.5 (–6.8 to –0.3); p=0.03	High
<i>Vaginal vs anal ultrasound, transvaginal versus anal endosonography for detecting damage to the anal sphincter</i>					

Author Year Reference Country	Study design	Population Setting	Intervention Control Adherence Loss to follow-up	Outcome results	Study quality Comments
Frudinger et al 1997 [36] Austria	Observational diagnostic study	47 primiparous and 1 nulliparous Age: median 41.3 years (range, 24–77) 36/48 had a history of forceps-assisted delivery 36/48 complained of fecal incontinence Loss to follow-up 3	Accuracy of transvaginal endosonography for detecting damage to the anal sphincter. Reference method endoanal US	Internal sphincter defects revealed by transvaginal endosonography (n=45); Yes: True-positive: 8 True-negative: 1 No: True-positive: 10 True-negative: 26 Sensitivity = 48% Specificity = 96 % Positive predictive value: 88% Negative predictive value: 72% External sphincter defects revealed by transvaginal endosonography; Yes: True-positive: 10 True-negative: 3 No: True-positive: 11 True-negative: 21 Sensitivity = 48% Specificity = 88% Positive predictive value: 77% Negative predictive value: 66%	Medium
Roos et al 2011 [37] UK	Diagnostic study	161 women. Routine follow-up after OASIS 98 (61%), subsequent pregnancy following OASIS 52 (32%), postpartum bowel symptoms in 11 (7%)	Transperineal (TPU) and endovaginal ultrasound (EVU) in detection of anal sphincter defects in women with sphincter injuries and/or symptoms of fecal	EAU showed defect in 42 women (26%). 39 (93%) had an external and 23 (55%) had an internal anal sphincter defect. Sensitivity and specificity for detection of any defect was 48% (30–67%) and 85% (77–91%) and 64% (44–81%) and 85% (77–91%) for TPU respectively	High

Author Year Reference Country	Study design	Population Setting	Intervention Control Adherence Loss to follow-up	Outcome results	Study quality Comments
			incontinence. Endoanal ultrasound was used as reference standard		
<i>Digital examination vs perineal ultrasound</i>					
Shobeiri et al 2002 [38] USA	Diagnostic study	Women with 3 rd degree tear, n=26, mean age 22 years and 4 th degree tear, n=8, mean age 21 years, who underwent primary end–end sphincteroplasty. Primigravid 73 and 87%. Forceps delivery 73 and 62%	Ultrasound measurement of external anal sphincter muscle diameter and perineal length vs measurement by digital examination	Pearson´s correlation coefficient digital external sphincter examination – trans perineal ultrasound and digital perineal examination, trans perineal ultrasound 0.88 and 0.40 respectively	Medium

ARR = Absolute risk reduction; CI = Confidence interval; ITT = Intention to treat; n = Number; NS = Not significant; OR = Odds ratio; P = p-value; RCT = Randomised controlled trial; RR = Relative risk; SD = Standard deviation.

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