AOGS
Acta Obstetricia et Gynecologica Scandinavica

AOGS ORIGINAL RESEARCH ARTICLE

The effect of maneuvers for shoulder delivery on perineal trauma: a randomized controlled trial

ANNA J.M. AABAKKE[1,2], HANNE WILLER[1] & LONE KREBS[1]

[1]Department of Obstetrics and Gynecology, University of Copenhagen, Holbæk Hospital, Holbæk, and [2]Department of Obstetrics and Gynecology, Herlev University Hospital, Herlev, Denmark

Key words
Anal canal/injuries, delivery, delivery of the shoulders, labour stage, perineal trauma, perineum, shoulder delivery, vaginal delivery

Correspondence
Anna J.M. Aabakke, Department of Obstetrics and Gynecology, Holbæk Hospital, Smedelundsgade 60, 4300 Holbæk, Denmark.
E-mail: aabakke@gmail.com

Conflict of interest
The authors have stated explicitly that there are no conflicts of interests in connection with this article.

Please cite this article as: Aabakke AJM, Willer H, Krebs L. The effect of maneuvers for shoulder delivery on perineal trauma: a randomized controlled trial. Acta Obstet Gynecol Scand 2016; 95:1070–1077.

Received: 14 January 2016
Accepted: 19 April 2016

DOI: 10.1111/aogs.12914

Abstract

Introduction. Approximately 85% of vaginal deliveries are accompanied by perineal trauma. The objective of this trial was to compare the incidence of perineal trauma after primary delivery of either the anterior or posterior shoulder during vaginal delivery. *Material and methods.* This was a randomized single-blinded trial comparing primary delivery of either the anterior or posterior shoulder in women having their first vaginal delivery. Primary outcome was any perineal trauma. Results were analyzed according to the intention-to-treat principle and supplemented with a per-protocol and as-treated analysis. *Results.* Between June 2013 and March 2015, 650 women were randomized, and 543 (posterior, $n = 281$; anterior, $n = 262$) were included in the final intention-to-treat analysis. Most group characteristics were similar. The frequency of any perineal trauma did not differ between the two groups (posterior: 91.5%, anterior: 90.5%; odds ratio 1.130, 95% confidence interval 0.628 2.032, $p = 0.684$). The results did not change after adjustment for basic characteristics with significant group differences ($a_1$odds ratio 1.174, 95% confidence interval 0.632 2.179, $p = 0.612$) or predefined risk factors ($a_2$odds ratio 1.139, 95% confidence interval 0.599 2.166, $p = 0.691$). The rate of perineal trauma also did not differ between the groups in a "per-protocol" and "as-treated" analysis. *Conclusions.* There was no difference in the degree of perineal trauma after primary delivery of either the anterior or posterior shoulder. Consequently both maneuvers for shoulder delivery can be used at vaginal delivery, but further trials are warranted before certain methods can be recommended.

Abbreviations: AT, as-treated; ITT, intention-to-treat; OASIS, obstetric anal sphincter injuries; OR, odds ratio; PP, per-protocol.

Introduction

Approximately 85% of vaginal deliveries are accompanied by perineal trauma (1,2). Genital tract trauma is associated with both short- and long-term morbidity that is related to the degree of trauma (1,3–5). Hence, studies of preventive measures are of interest.

Several perineal management techniques used during delivery have been studied. Trials have primarily evaluated their effect on third- and fourth-degree perineal tears that include the anal sphincter complex, so-called obstetric anal sphincter injuries (OASIS). A Cochrane review concluded that warm compresses and perineal massage seem to reduce the risk of OASIS (4). The introduction of an interventional perineal protection program also seems to reduce the incidence of OASIS (6–8).

Key Message

This study showed that the incidence and severity of perineal trauma do not differ after primary delivery of either the anterior or posterior shoulder at vaginal delivery. Consequently both maneuvers for shoulder delivery can be used at vaginal delivery.

Leading textbooks recommend primary delivery of the anterior shoulder (9,10). However, if shoulder dystocia occurs, a recommended maneuver includes primary delivery of the posterior arm or shoulder (11,12). A computer-simulated trial found that primary delivery of the posterior arm during shoulder dystocia caused an 80% reduction in the delivery force (13). Primary delivery of the posterior shoulder could therefore be of advantage during uncomplicated deliveries, but, to the knowledge of the authors, various maneuvers for delivery of the shoulders have never previously been evaluated.

The objective of this randomized controlled trial was to determine the incidence and degree of perineal trauma after primary delivery of the anterior compared with primary delivery of the posterior shoulder during vaginal delivery in women having their first vaginal delivery.

Material and methods

This was a single-center, prospective, single-blinded, randomized controlled trial. It was undertaken at the University of Copenhagen, Holbæk Hospital, which is a Danish community hospital with an obstetric unit with 1600 deliveries annually.

Eligible participants were nulliparous women and women with a previous cesarean delivery having their first vaginal delivery in whom a vaginal delivery of a fetus in the cephalic presentation was planned. Participants had to be able to provide informed oral and written consent. Exclusion criteria were multiparity with a previous vaginal delivery, multiple pregnancy, cesarean delivery, delivery before 35 weeks of gestation, and breech presentation. Participants received no financial compensation.

Randomization was computer-generated, with a 1:1 allocation to primary delivery of the anterior or posterior shoulder by a third party not otherwise involved in the trial. The allocation was concealed in 650 identical, opaque, sequentially numbered sealed envelopes. The allocation list was stored electronically by a third party not otherwise involved in the trial.

Eligible women received an invitation to participate and the written trial information by mail together with the invitation to the first midwife consultation. Oral information was given by the consulting midwife during the first midwife consultation (14–15 weeks of gestation). Written consent was given any time during pregnancy, and all included women gave written informed consent. Recruited women were randomized after confirmation of consent upon arrival at the delivery ward, and a random allocation envelope was drawn. The randomization envelope was opened by the midwife when the patient entered the second stage of labor and was destroyed thereafter. The allocation was only shown to the midwife and the assistant, and if necessary the obstetrician. The trial intervention took place during vaginal delivery after the delivery of the head. Participants were randomized to one of two groups, primary delivery of the anterior shoulder or primary delivery of the posterior shoulder as illustrated in Figure 1 and in the Supporting Information (Videos S1 and S2). The participants could deliver in the position they preferred, and if spontaneous delivery of the shoulders occurred, this was to be respected regardless of randomization. The method of perineal support during the delivery of the head was not standardized. Episiotomy could be used primarily on fetal indication and more liberally in the case of vacuum delivery in accordance with local guidelines. In the event of vacuum-assisted delivery, which according to guidelines was to be performed by physicians, the midwife delivered the shoulders.

Primary outcome was any perineal trauma requiring suturing. Secondary outcomes were perineal injury subtypes, postpartum bleeding in milliliters evaluated 2 h after birth, umbilical artery pH, Apgar scores at 5 min,

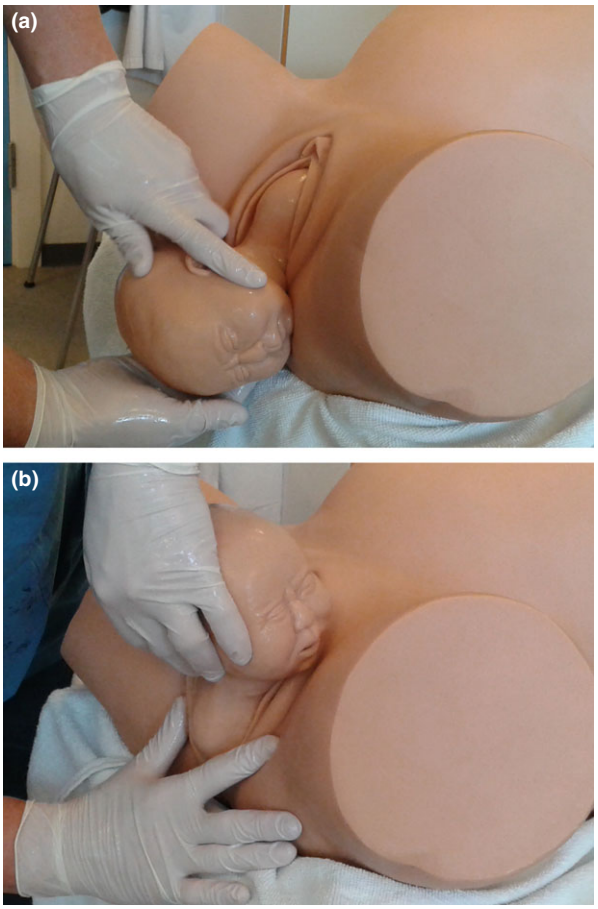

Figure 1. Primary delivery of the (a) anterior shoulder and (b) posterior shoulder.

and neonatal birth trauma including brachial plexus injury and fractures of the clavicle and humerus.

Perineal traumas were classified according to international standards (14,15). Anterior trauma comprised lacerations of the labia that required suturing. Posterior subtypes comprised lacerations of the vagina and/or perineum that required suturing: first-degree tears, where only the skin or mucosa was involved; second-degree tears, in which skin and perineal muscle were involved with the anal sphincter intact; third-degree tears involving the anal sphincter complex; and fourth-degree tears involving the anal sphincter complex as well as the anal epithelium. Posterior trauma also included episiotomy because it is a trauma to the perineum, although iatrogenic. OASIS comprised third- and fourth-degree tears.

After delivery of the placenta, a blinded midwife or an obstetrician not otherwise involved in the delivery assessed the perineum and graded the perineal tears. Secondary outcomes and information about which shoulder was delivered first were registered by the midwife responsible for the delivery.

Registered third- and fourth-degree tears were validated through manual assessment of patient records. Additionally, in order not to underestimate the level of higher degree tears, which we assumed would be diagnosed after trial assessment during repair, data on all third- and fourth-degree tears in our study population registered in the hospital register during the trial period were retrieved after the end of the trial. These data were validated against patient records and incorporated into the final data set.

Assessors of the primary outcome and the primary investigator were blinded to the randomization.

All midwives were trained in the two interventions by the primary investigator (HW) to secure uniform use of the techniques. Training sessions included an introductory video of the two methods and practical training on a birthing phantom (MODEL-med Sophie and her Mum Full Birth Obstetric Trainer, Carnegie, Australia). All midwives were also trained in evaluation and classification of perineal tears using an e-learning program to secure uniform training (GynZone ApS, Aarhus, Denmark). Attendance at a training session accredited midwives to deliver participants included in the trial.

Data were recorded on clinical registration forms and entered into an SPSS database (SPSS Inc, Chicago, IL, USA) by the primary investigator. After completion of the trial, data were cleaned and consecutively locked before the allocation was broken.

Before patient enrollment, the trial was approved by the regional ethics committee for Region Zealand (reg. no. SJ 310; approved 23 September 2012), and it was registered with ClinicalTrials.gov (reg. no. NCT01937546). We followed the CONSORT recommendations for reporting randomized, controlled, clinical trials involving nonpharmacologic treatment (16,17). Further details of the study methods and design have been published previously (18).

An audit at a Danish university hospital of all their primary vaginal deliveries from 2003 to 2011 (n = 15 587) found that 86% sustained a perineal tear (2). The sample size calculation for the primary outcome was based on the assumption that the rate of perineal tears using the traditional method of delivering the anterior shoulder first was 85% and that a minimal relevant difference in the proportions of perineal tears between the two intervention groups would be 10%. To obtain 80% power and a significance level of 0.05, we estimated that 250 women would have to be included in each intervention arm. In Denmark, 18% of primiparous women had an emergency cesarean delivery in 2011 (19). Because of this risk of emergency cesarean delivery and the risk of drop-outs, 650 women were included in the trial. To ensure that one intervention did not cause markedly more perineal trauma, interim analyses were performed by a data monitor not otherwise involved in the trial after the first year and consecutively thereafter every 6 months as previously described (18).

All included women delivering vaginally were included in the final analysis. The analysis was primarily based on an intention-to-treat (ITT) principle. It was supplemented with a per-protocol (PP) analysis (of the women who received their random allocation) and an as-treated analysis (AT) (according to how the shoulders were delivered regardless of randomization). We additionally did a subanalysis of women in the ITT cohort with spontaneous delivery (excluding vacuum deliveries). Categorical variables including the primary outcome were analyzed with the chi-squared test or Fisher's exact test as appropriate, and the odds ratios (ORs) presented with 95% CIs. Adjusted ORs of the perineal subtypes were calculated using logistic regression controlling for (i) basic characteristics with significant differences between the two groups, and (ii) known predisposing factors including maternal age, epidural, stimulation with oxytocin, position at delivery, vacuum extraction, duration of the active second stage of labor, fetal birthweight, and occiput posterior presentation. Continuous variables were assessed for normal distribution with the Kolmogorov–Smirnov test. When normally distributed, they were analyzed with a t-test, and when not, with a Mann–Whitney test. Data analyses were performed using IBM SPSS Statistics 21 (SPSS Inc).

Results

From June 2013 to March 2015, 650 women were randomized. In the primary ITT analysis 543 women were

included, whereas 404 women were included in the PP analysis, and 486 in the AT analysis. The flow of participants is illustrated in Figure 2. Maternal, pregnancy, and delivery characteristics are shown in Table 1 for the ITT analysis and in the Supporting Information (Table S1) for the PP and AT analyses. Most characteristics were similar.

The primary and secondary outcomes of the ITT analysis are shown in Table 2, and those of the PP and AT analyses are shown in the Supporting Information (Tables S2 and S3). The PP and AT analyses were slightly underpowered due to the number of women included in the analyses. The frequency of any perineal trauma did not differ between the two groups in any of the analyses (ITT: OR 1.130, 95% CI 0.628 2.032, $p = 0.684$; PP: OR 1.488, 95% CI 0.752 2.943, $p = 0.251$; AT: OR 1.507, 95% CI 0.807 2.817, $p = 0.196$). Adjustment for the basic characteristics with significant differences between the groups did not change the results. Adjustment for the predefined risk factors also did not change the results. The frequency of any anterior trauma, any posterior trauma, and OASIS did not differ significantly between the two groups in any of the three analyses or after adjustment. The distribution of the type of primary perineal trauma did not differ between the groups in any of the three analyses (data not shown). There was no difference in postpartum bleeding,

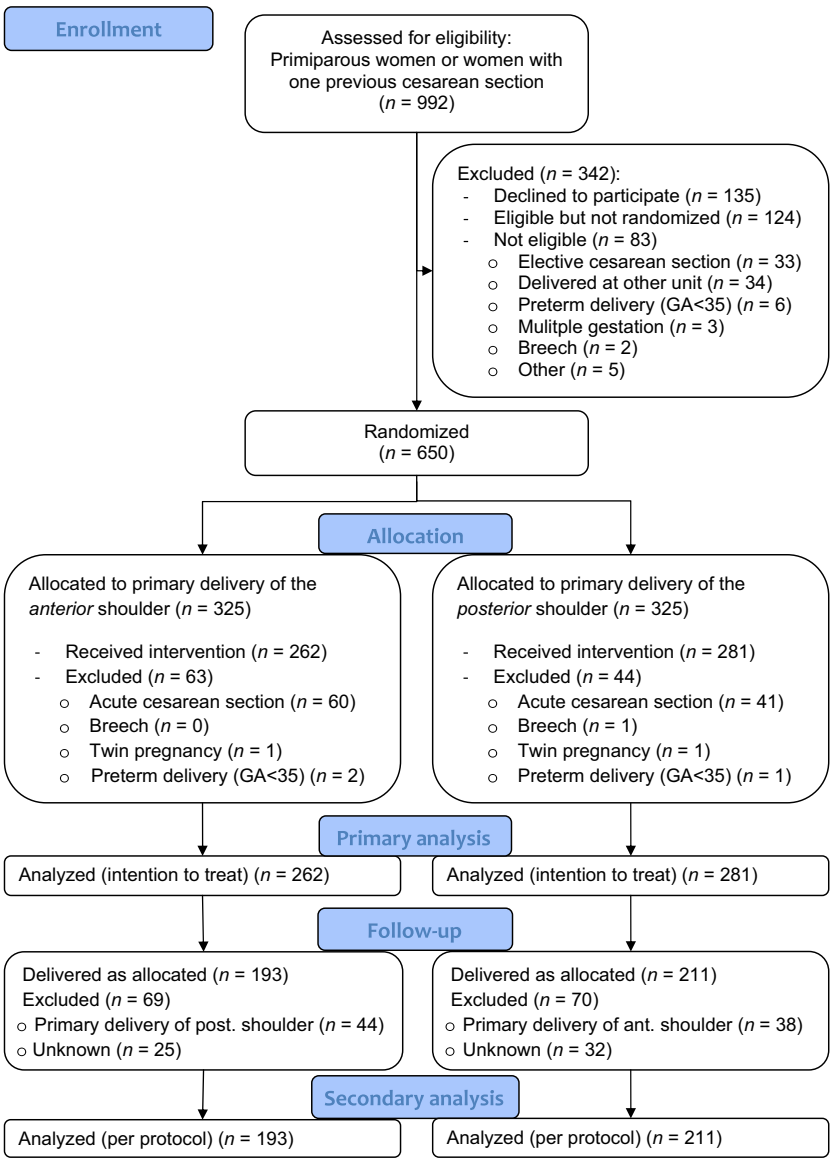

Figure 2. Study flow.

Table 1. Basic characteristics.

	Intention-to-treat		
	Posterior shoulder (n = 281)	Anterior shoulder (n = 262)	p
Maternal characteristics			
Age (years)	26.0 (23.0 30.0)	27.0 (23.0 30.0)	NS
Body mass index (kg/m^2)	24.0 (21.2 28.1)	23.6 (21.5 27.5)	NS
Smoking status (smoker)	38 (13.6%)	34 (13.1%)	NS
Parity			
Nullipara	275 (97.9%)	250 (95.4%)	NS
Previous cesarean section	6 (2.1%)	12 (4.6%)	
Pregnancy characteristics			
Gestational age (days)	281 (276 287)	280 (273 287)	NS
Delivery characteristics			
Induction	75 (26.7%)	66 (25.2%)	NS
Stimulation with oxytocin	117 (41.6%)	126 (48.1%)	NS
Epidural	61 (21.7%)	85 (32.4%)	0.005
Pudendal nerve block	11 (3.9%)	9 (3.4%)	NS
Vacuum extraction	49 (17.4%)	65 (24.8%)	0.035
Episiotomy	22 (7.8%)	33 (12.6%)	NS
Position at delivery			0.042
Semi-sitting	159 (57.8%)	158 (62.2%)	NS
Lithotomy	46 (16.7%)	52 (20.5%)	NS
Side lying	47 (17.1%)	24 (9.4%)	0.010
Hands and knees	8 (2.9%)	6 (2.4%)	NS
Standing	3 (1.1%)	1 (0.4%)	NS
Water birth	12 (4.4%)	9 (3.5%)	NS
Sitting on birthing stool/toilet	0 (0.0%)	4 (1.6%)	NS
Perineal support during delivery of the fetal head			
Hands-on technique[b]	252 (89.7%)	241 (92.0%)	NS
Warm compresses	168 (59.8%)	166 (63.4%)	NS
Ritgen maneuver[a]	28 (10.0%)	38 (14.5%)	NS
Hands-off technique	29 (10.3%)	21 (8.0%)	NS
Hand by cheek[c]	74 (26.3%)	57 (21.8%)	NS
Delivery of the body (n = 487)			
Head and body delivered in one contraction	91 (35.8%)	96 (41.2%)	NS
Head and body delivered in separate contractions	163 (64.2%)	137 (58.8%)	
Shoulder dystocia[d]	6 (2.1%)	5 (1.9%)	NS
Perineal support during delivery of the shoulders			
Hands-on technique[b]	163 (67.4%)	134 (62.0%)	NS
Warm compresses	60 (21.4%)	49 (18.7%)	NS
Hands-off technique	79 (32.6%)	82 (38.0%)	NS
Birthweight (g)	3470 ± 450	3424 ± 483	NS
Duration of the active second stage of labor (min)	39 (22 63)	42 (25 64)	NS
Type of cephalic presentation			
Occiput anterior	153 (90%)	235 (89.7%)	NS
Occiput posterior	15 (5.3%)	15 (5.7%)	
Other	13 (4.6%)	12 (4.6%)	

Data are expressed as mean ± SD, median (interquartile range), or count (%).

NS, non-significant.

[a]The Ritgen maneuver was defined as one hand on the emerging occiput to control speed of delivery and keep flexion of the fetal head while with the other hand the fetal chin was reached behind the anus and lifted forward.

[b]Any perineal support method including compresses and massage. (There was no uniform method of perineal support recommended at the trial unit at the time of the trial and birth assistants had not been trained in any specific methods, as for example described in refs 6–8).

[c]The baby's hand is positioned by its cheek during delivery of the head.

[d]Shoulder dystocia defined as requiring at least internal rotation maneuvers.

Table 2. Primary and secondary outcomes.

Outcomes	Intention-to-Treat								
	Posterior shoulder (n = 281)	Anterior shoulder (n = 262)	p	OR (95% CI)	p	a_1OR^a (95% CI)	p	a_2OR^b (95% CI)	P
Type of perineal trauma									
Any perineal trauma	257 (91.5%)	237 (90.5%)		1.130 (0.628 2.032)	0.684	1.174 (0.632 2.179)	0.612	1.139 (0.599 2.166)	0.691
Any anterior trauma	119 (42.3%)	106 (40.5%)		1.081 (0.768 1.522)	0.655	0.996 (0.697 1.424)	0.983	0.992 (0.685 1.436)	0.966
Any posterior trauma	211 (75.1%)	190 (72.5%)		1.142 (0.779 1.675)	0.496	1.273 (0.847 1.913)	0.245	1.200 (0.781 1.843)	0.405
OASIS	13 (4.6%)	15 (5.7%)		0.799 (0.373 1.712)	0.563	0.839 (385 1.828)	0.659	0.800 (0.346 1.851)	0.602
Other outcomes									
Postpartum bleeding (ml)	300 (300–400)	300 (288–413)	0.801						
Apgar score	10 (10–10)	10 (10–10)	0.448						
Umbilical artery pH	7.22 ± 0.07	7.22 ± 0.07	0.637						
Neonatal birth trauma	1 (0.4%)	1 (0.4%)	NR						

Data are expressed as mean ± SD, median (interquartile range), or count (%). NR: Statistical analysis not relevant due to low number of cases.
OASIS, obstetric anal sphincter injuries; OR, odds ratios.
[a]a_1OR: OR adjusted for significant characteristic differences between the two groups (Table 1).
[b]a_2OR: OR adjusted for maternal age, epidural, stimulation with oxytocin, position at delivery, vacuum extraction, duration of the active second stage of labor, fetal birthweight, and occiput posterior presentation.

APGAR scores, or umbilical artery pH between the groups in any of the analyses. There were two cases of neonatal birth trauma, one in the anterior and one in the posterior shoulder group; both were nerve trauma. In the sub-analysis of women with spontaneous delivery (excluding vacuum deliveries) (n = 429) the results did not differ significantly in the primary or adjusted analyses (see Supporting Information Table S4).

Discussion

This randomized controlled trial showed no difference in the degree of perineal trauma caused by primary delivery of the anterior shoulder compared with the posterior shoulder at vaginal delivery.

Leading textbooks in obstetrics recommend primary delivery of the anterior shoulder (9,10). This trial indicates that primary delivery of the posterior shoulder can be used as an alternative method of delivering the shoulders.

In this trial, we found slightly higher rates of any perineal trauma than previously reported (1,2). The rate of perineal trauma is higher among primipara vs. multipara (1), and only primary vaginal deliveries were included in this study. Additionally, the power calculation was based on register data, with possible under-reporting of tears (2), and the systematic recording of data in this trial possibly increased the awareness of perineal trauma.

There was a nonsignificant reduction in the rate of OASIS of 2.4 2.6% in women with primarily delivery of the posterior compared with the anterior shoulder (PP and AT analyses, Supporting Information, Tables S2 and S3). The lack of significance could be due to a type II statistical error. A trial exploring a difference in the rate of OASIS between the two methods of shoulder delivery would require 3726 participants to have 80% power to detect a 2% difference in the rate of OASIS.

The purpose of a randomized trial and an ITT analysis is to avoid bias. Nevertheless, we found statistically significant differences in some basic characteristics between the two groups. We controlled for these characteristics in the statistical analyses to reduce their influence. The increased rate of epidural use in the group randomized to primary delivery of the anterior shoulder is probably caused by chance. The randomization envelope was not opened until the second stage of labor, and all epidurals were administered before this stage. Additionally, the difference between the groups diminished in the PP analysis and disappeared in the AT analysis. More women randomized to primary delivery of the posterior shoulder delivered in a side-lying position. The side-lying position allows for good overview of the posterior perineum and was probably less discouraged in women randomized to the

posterior shoulder. More women randomized to primary delivery of the anterior shoulder delivered by vacuum extraction. This difference remained to a greater extent in the PP and AT analyses. In the ITT analysis, the difference was probably caused by chance. However, vacuum extraction is performed by the obstetrician rather than the midwife and often under stressful conditions. It might therefore lead to the use of the traditional method of primary delivery of the anterior shoulder.

Additional delivery characteristics varied between the two groups in the PP and AT analyses (Supporting Information, Table S1), and this was probably associated with the shoulder delivery technique used. There was a higher rate among the posterior shoulder group of the condition in which the baby's hand is positioned by its cheek. We assume that the condition is more often diagnosed when the posterior shoulder is delivered primarily and that the condition encouraged primary delivery of the posterior shoulder. There was a higher rate of episiotomy in the anterior shoulder group, as was the duration of the second stage of labor in the AT analysis. The two characteristics are associated with an increased use of episiotomy when the second stage of labor is prolonged. Also, it is a stressful situation that might lead to the use of the traditional method of shoulder delivery.

The literature on delivery techniques is limited, and previous studies have primarily focused on their effect on OASIS. Most studies have been observational, and maneuvers for shoulder delivery have never been evaluated. Hence, the strengths of this study are the randomized design, the intervention studied, and the outcome of any perineal trauma.

The validity of this trial could be affected by the fact that several midwives performed the interventions. But, because numerous birth assistants are the reality at most centers, this increases the external validity and generalizability of the results. Additionally, it might be interpreted as a limitation that this was a single-center trial, although it increases internal validity of the trial. The perineal tears were evaluated by several objective assessors, which could have affected the validity of the outcome assessment. We tried to overcome this by validating all cases of OASIS included in the final analysis. Vacuum extraction is a known risk factor for perineal injury and it can be postulated that the delivery of the head during vacuum delivery is a higher contributor to perineal tearing than the delivery of the shoulders. We included vacuum extractions to mimic a normal population of primiparous women and controlled for it in the analyses. Additionally, a sub-analysis excluding vacuum deliveries did not change the results of the study.

In conclusion, this study showed no difference in the degree of perineal trauma after primary delivery of the anterior compared with the posterior shoulder at vaginal delivery, indicating that both maneuvers can be used at vaginal delivery. Further trials about maneuvers for shoulder delivery are warranted before certain methods can be recommended.

Acknowledgments

The authors thank Karina Klode, MHS, for her advice on the statistical power calculation, Kevin Steger for his assistance with the trial website, Helene Willer Piironen for making the trial logo, Jacob Jørgen for data monitoring, and Anne Fabricious, Head Midwife, Department of Obstetrics and Gynecology, University of Copenhagen, Holbæk Hospital, for her assistance on the steering committee.

Funding

This work was supported with non-profit grants from the Danish Association of Midwives, the Region Zealand Health Sciences Research Fund, Axel Muusfeldt's Fund, Torben and Alice Frimodt's Fund, and Aase and Ejnar Danielsen's Fund.

References

1. Albers L, Garcia J, Renfrew M, McCandlish R, Elbourne D. Distribution of genital tract trauma in childbirth and related postnatal pain. Birth. 1999;26:11–7.
2. Kindberg S. Hvor stor risiko er der for at få en bristning. [What is the risk of a perineal tear - results from a Danish audit at a University Hospital.] (in Danish). Available online at: http://www.gynzone.dk/kvinde-liv/faq-om-underliv (accessed July 1, 2015).
3. Radestad I, Olsson A, Nissen E, Rubertsson C. Tears in the vagina, perineum, sphincter ani, and rectum and first sexual intercourse after childbirth: a nationwide follow-up. Birth. 2008;35:98–106.
4. Aasheim V, Nilsen AB, Lukasse M, Reinar LM. Perineal techniques during the second stage of labour for reducing perineal trauma. Cochrane Database Syst Rev. 2011;12: CD006672.
5. Williams A, Herron-Marx S, Carolyn H. The prevalence of enduring postnatal perineal morbidity and its relationship to perineal trauma. Midwifery. 2007;23:392–403.
6. Laine K, Pirhonen T, Rolland R, Pirhonen J. Decreasing the incidence of anal sphincter tears during delivery. Obstet Gynecol. 2008;111:1053–7.
7. Laine K, Skjeldestad FE, Sandvik L, Staff AC. Incidence of obstetric anal sphincter injuries after training to protect the perineum: cohort study. BMJ Open. 2012;2. pii: e001649.
8. Hals E, Oian P, Pirhonen T, Gissler M, Hjelle S, Nilsen EB, et al. A multicenter interventional program to reduce

the incidence of anal sphincter tears. Obstet Gynecol. 2010;116:901–8.
9. Downe S. The transition and the second stage of labour: physiology and the role of the midwife. In: Fraser D, Cooper MA, Myles MF (eds). Myles textbook for midwives, 15th edn. Edinburgh, NY: Churchill Livingstone, 2009. pp. 509–30.
10. Normal labor and delivery. In: Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY (eds). Williams obstetrics, 23rd edn. New York, NY: McGraw-Hill, 2009. pp. 374–409.
11. Sokol RJ, Blackwell SC. ACOG practice bulletin: shoulder dystocia. Number 40, November 2002. (Replaces practice pattern number 7, October 1997). Int J Gynaecol Obstet. 2003;80:87–92.
12. Royal College of Obstetricians and Gynaecologists. Shoulder Dystocia. Green-top Guideline No. 42. Available online at: http://www.rcog.org.uk/files/rcog-corp/GTG42_25112013.pdf (accessed July 22, 2015).
13. Grimm MJ, Costello RE, Gonik B. Effect of clinician-applied maneuvers on brachial plexus stretch during a shoulder dystocia event: investigation using a computer simulation model. Am J Obstet Gynecol. 2010;203:339–5.
14. Kettle C, Tohill S. Perineal care. Clin Evid. (Online) 2011;2011. pii: 1401.
15. Royal College of Obstetricians and Gynaecologists. The Management of Third- and Fourth-Degree Perineal Tears. Green-top Guideline No. 29. Available online at: http://www.rcog.org.uk/files/rcog-corp/GTG2911022011.pdf (accessed January 14, 2014).
16. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869.
17. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008;148:295–309.
18. Willer H, Aabakke AJ, Krebs L. The effect of primary delivery of the anterior compared with the posterior shoulder on perineal trauma: a study protocol for a randomized controlled trial. Trials. 2014;15:291.
19. Statens Serum Institut. Dataformidling: Sygehusfødsler og komplikationer. [Data communication: Hospital births and complications.] (in Danish). Available online at: http://www.ssi.dk/Sundhedsdataogit/Dataformidling/Sundhedsdata/Fodsler/Sygehusfodsler.aspx (accessed December 18, 2013).

Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Basic characteristics (per-protocol and as-treated analyses).
Table S2. Primary and secondary outcomes (per-protocol analysis).
Table S3. Primary and secondary outcomes (as-treated analysis).
Table S4. Primary and secondary perineal outcomes [subgroup of women in the intention-to-treat cohort with spontaneous delivery (excluding vacuum deliveries)].
Video S1. Primary delivery of the anterior shoulder. (Author and videographer: Hanne Willer; 1:04 minutes; 1.5 MB.)
Video S2. Primary delivery of the posterior shoulder. (Author and videographer: Hanne Willer; 0:58 minutes; 1.2 MB.)