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Do we need a core outcome set for childbirth perineal trauma research? A systematic review of outcome reporting in randomised trials evaluating the management of childbirth trauma.

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Running title:
Outcome reporting in childbirth trauma trials.

Abstract

Background: Selecting appropriate outcomes to reflect both beneficial and harmful effects is a critical step in designing childbirth trauma trials.

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Objective: To evaluate the outcomes and outcomes measures reported in randomised controlled trials evaluating interventions for childbirth trauma.

Search strategy: Randomised trials were identified by searching bibliographical databases including Cochrane Central Register of Controlled Trials (CENTRAL), Medline, and EMBASE.

Selection criteria: Randomised trials evaluating the efficacy and safety of different techniques in the management of perineal lacerations.

Data collection and analysis: Two researchers independently assessed studies for inclusion, evaluated methodological quality and extracted relevant data. The Spearman`s rho correlation and the multivariate linear regression analysis using the backward stepwise model were used for analysis.

Main results: Forty-eight randomised trials, reporting data from 20,308 women, were included. Seventeen different interventions were evaluated. Included trials reported 77 different outcomes and 50 different outcome measures. Commonly reported outcomes included pain (34 trials; 70%), wound healing (20 trials; 42%), and anorectal dysfunction (16 trials, 33%). In the multivariate analysis no relationship was demonstrated between outcome reporting quality with year of publication ($p = .31$), journal impact factor ($p = .49$), and methodological quality ($p = .13$).

Conclusions: Outcome reporting in childbirth trauma research is heterogeneous. Developing, disseminating, and implementing a core outcome set in future childbirth trauma research could help address these issues.

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Keywords: Childbirth trauma**;** core outcome sets**;** lacerations**;** outcome variation**;** and perineal trauma.

Tweetable abstract: Developing @coreoutcomes for childbirth trauma research could help to reduce #research waste.

Introduction

Perineal and vaginal trauma during labour and vaginal childbirth, commonly referred as childbirth trauma, affects millions of women worldwide.[1] Research and clinical practice has focused on the perineal muscles and the anal sphincter complex over the last three decades. However, childbirth trauma may involve different organs and compartments of the pelvic floor and the perineum including muscles, nerves, connective tissue, as well as bone trauma. Stretching, compression, and rupture may occur during vaginal birth and result in nerve, muscle, and connective tissue damage.

The incidence of perineal trauma, regardless of its severity, exceeds 91% in nulliparous women and 70% in multiparous women.[2] The clinical diagnosis of obstetric anal sphincter injury ranges between 1% and 11% of women who deliver vaginally.[3] [4] The reported incidence of levator ani muscle trauma varies widely, ranging between 13% and 26% in these women.[5-8] These variations may be secondary to population characteristics, assessment criteria, and diagnostic criteria. [1, 9] Short, medium, and long term morbidity associated with childbirth trauma can affect daily activities, psychological wellbeing, sexual function, and overall quality of life. [10]

To date, there is no consensus among healthcare professionals, researchers and patients, regarding the outcomes and outcome measures that should be collected and reported in trials evaluating interventions for the management of childbirth trauma. Variation in outcome

reporting, outcome reporting measures, and poor reporting results in significant difficulties in undertaking secondary research, including pair-wise meta-analysis, network meta-analysis, and individual patient data meta-analysis. [11]

Although the variation in outcome reporting has been previously investigated and confirmed in several areas relevant to obstetrics and gynaecology no evaluation has been undertaken in childbirth trauma research.[11-15]

Therefore, we evaluated outcome and outcome measure reporting across published randomised controlled trials evaluating interventions for childbirth trauma. In addition, we investigated associations between outcome reporting quality with other factors including year of publication, journal impact factor, and methodological quality.

Methods

This study is part of a wider project of CHORUS, an International Collaboration for Harmonising Outcomes, Research and Standards in Urogynaecology and Women's Health.

This study was registered with the Core Outcome Measures in Effectiveness Trials Initiative Register (COMET) Initiative, registration number 981, and with the International Prospective Register of Systematic Reviews (PROSPERO), CRD42017077375. Our study was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[16]

Randomised controlled trials were identified by searching: (1) Cochrane Central Register of Controlled Trials (CENTRAL), (2) Latin American and Caribbean Health Sciences Literature (LILACS), (3) MEDLINE, (4) EMBASE, (5) PsycINFO, and (6) Scopus, from the inception of the database to September 2017. Our search strategy included the MeSH headings

childbirth trauma, obstetric anal sphincter injuries, obstetric trauma, perineal lacerations, perineal tears, perineal trauma, and vaginal tears. The reference lists of included studies were examined to identify additional randomised controlled trials. The search strategy is presented in Figure 1.

Eligibility criteria were predetermined. Randomised controlled trials related to perineal trauma, regardless of its degree, were considered eligible for inclusion in our study. Systematic reviews, non-randomised studies, retrospective studies, and case reports were excluded. Studies published in English were included. Two researchers (VP and CD) independently screened the retrieved titles and abstracts of electronically. Potentially eligible for studies were retrieved in full text to assess its eligibility. Any discrepancies between the researchers were resolved by review of a third senior researchers (SKD) and consensus of all authors.

Three researchers (CD, AE and VP) independently assessed the methodological quality of included randomised trials using the Jadad criteria.[17] Each included randomised trial was assessed for randomisation, blinding, withdrawals, and dropouts. An arbitrary decision was made to classify included randomised trials as high quality when they were assessed as achieving a score greater than four points on the JADAD criteria.

Outcome reporting quality was assessed, using the Management of Otitis Media with Effusion in Cleft Palate (MOMENT) criteria.[18] The MOMENT criteria assess the presence of a primary outcome (1 point); if the primary outcome was clearly defined for reproducible measures (1 point); if the secondary outcomes were clearly stated (1 point); if the secondary outcomes were clearly defined for reproducible measures (1 point); if the authors explain the choice of outcome (1 point); and if the methods that were used were appropriate to enhance quality of measures (1 point). A decision was made to classify included randomised trials as high quality when they were assessed as achieving a score greater than four points on the MOMENT criteria.

To evaluate the impact of various confounders that might significantly either contribute or reflect outcome quality we extracted information that was related to the journal`s type (general, specialty or subspecialty journal, based on scimago.org indication, impact factor based on InCites, Journal Citation Reports (Web of Science, Clarivate Analytics, Thomson Reuters), participants, interventions and pharmaceutical funding. Funding status was identified in the article text including commercial funding or the donation of equipment, which had facilitated the trial.

Non-parametric correlation coefficients (Spearman`s rho) were used to explore the univariate association between continuous factors. The chi-square, Fisher`s exact and non-parametric Mann-Whitney tests were used to compare outcome reporting quality between groups according to the type of journal (general vs specialist), funding source (commercial or other), year of publication, and impact factor in the year of publication. All tests were two-tailed. Statistical significance was set at 0.05 and analyses were conducted using SPSS statistical software (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp).

A multivariate linear regression analysis using the backward stepwise model was undertaken to assess relationship between quality of outcome reporting and journal type, impact factor during the year of publication, year of publication, and methodological quality as independent variables and outcome reporting as the dependent variable.

Results

Forty-eight randomised controlled trials, reporting data from 20,308 women, were included (Table S1).[19-66] Seventeen interventions were evaluated including different techniques (17 trials; 35%), different suture materials (6 trials; 13%), and biofeedback (3 studies; 6%). The majority of trials (71%) were published in general obstetrics and gynaecology journals. Four

trials (8%) declared commercial funding. Methodological quality (median = 5, rand 2 – 5) and outcome reporting quality (median = 4, range 1 – 6) varied across included trials.

Included trials reported 77 different outcomes and 50 different outcome measures. Outcomes were inconsistently reported across included randomised trials (Table S2). Commonly reported outcomes included pain (34 trials; 70%), wound healing (20 trials; 42%), and anorectal dysfunction (16 trials, 33%) (Table 1). Pain was evaluated using 2 different measurement instruments, including visual analogue scales (17 studies; 50%) and Pain McGill Questionnaire (3 studies; 9%) (Table S3). The majority of trials (85%) evaluated wound healing subjectively, with the exception of three trials which used the Redness, Oedema, Ecchymosis, Discharge, Approximation (REEDA) scale. Anorectal dysfunction was evaluated using 11 different measurement instruments including anorectal manometry rest pressure (9 studies; 56%), anorectal manometry squeeze measure (7 studies, 44%), and endoanal ultrasound for the detection of sphincter defects (5 studies; 31%). A minority of trials reported quality of life (4 trials; 8%) and patient satisfaction (7 trials; 15%), which were subjectively evaluated.

The median value of the methodological quality was 4 (range 2-5) and the median outcome reporting 4 (range 1-6). When we directly compared the differences between OASIS and non-OASIS studies we observed that non-OASIS studies had better methodological quality scores (4 (3-6) vs 3 (1—6) *p=.013*). There were no differences between the two groups in terms of methodological outcome (5 (2-5) vs 4 (2-5) *pp=.066*). The majority of articles – 34 (71%) were published in obstetrics and gynecology journals, whereas 5 studies (10%) were published in subspecialized journals in the field of urogynecology and pelvic floor disorders. Only 16 studies (33%) used validated questionnaires for the assessment of patient outcomes. Of the remaining studies, 22 (46%) used non-validated methods and 11 (23%) did not specify the methods of outcome assessment. Thirty-five studies (73%) enrolled more than 100 women and ten studies (21%) included more than 500 women. Only four studies (8%) received commercial funding.

To summarize our main findings, we tabulated the most frequently reported outcomes in Table 2, which demonstrates the significant discrepancies in terms of outcome reporting. Outcomes outlined in light grey color are specific to OASIS and are not expected to be reported among studies referring to perineal laceration of mild severity. Significant discrepancies were observed in terms of reported outcomes when comparing OASIS studies to studies evaluating mild degree lacerations. Specifically, studies on OASIS tended to underreport symptoms related to wound healing, pain and sexual dysfunction problems.

In the multivariate analysis no relationship was demonstrated between outcome reporting quality with year of publication ($p = 0.31$), journal impact factor ($p = 0.49$), and methodological quality ($p = 0.13$) (Table 3).

Discussion

Main findings

Randomised controlled trials evaluating interventions for childbirth trauma have reported many 77 different outcomes and 50 different outcome measures. Outcomes were inconsistently reported across included trials. Commonly reported outcomes included pain, wound healing, and anorectal dysfunction. Of 48 randomised trials, reporting data from 20,308 women, less than a fifth reported information on quality of life and patient satisfaction. Standardised definitions and validated measurement instruments were infrequently used. No relationship was demonstrated between outcome reporting quality with year of publication, journal impact factor, and methodological quality.

On a closer look into outcome measures, we noted that they were specifically described in only a few studies, thus, pointing towards potential reporting bias and flawed findings. Moreover, as previously mentioned, validated questionnaires were only reported to have been used in 33% of the studies included, thus, pointing the need for future studies in this field that will permit proper interpretation of outcomes. This observation contradicts the

actual MOMENT and JADAD scores of included studies which, at a first look, indicate appropriate study design and outcome reporting.

Taking into account our findings, one could assume that current research could be seriously misleading in the field of perineal trauma as selective reporting and potential publication bias prohibit proper interpretation of our findings; hence, future studies in the field should take into account outcomes and outcome measures that have been already reported in previous systematic reviews to investigate the reproducibility of established knowledge.

Strengths and limitations

The strength of this systematic review of outcome reporting, includes its prospective registration, comprehensive search strategy, methodological design, and statistical analysis. To our knowledge, this is the first systematic review to describe outcome reporting in randomised controlled trials evaluating interventions for childbirth trauma. In order to prevent bias the review methods including study selection, data collection, and data analysis were guided by the Cochrane Collaboration handbook and COMET initiative handbook. [67, 68]

Our evaluation has some limitations. Our systematic review included only randomised trials and so may have missed outcomes more frequently reported in observational studies including outcomes related to the medium- and long-term. Outcomes identified through systematic reviews of randomised trials largely reflect outcomes healthcare professionals and researchers have considered important to collect and measure, particularly where trials pre-date the recent emphasis on patient and public involvement in their design. Outcomes reported in historic trials may not hold the same relevance for other stakeholder groups, such as women with lived experience of childbirth trauma. The majority of trials were performed in high-income countries, the outcomes reported in these trials may not hold the same relevance to healthcare professionals, researchers, and patients living in low- and middle-income countries.

Interpretation

Randomised controlled trials evaluating interventions for childbirth trauma have neglected to report important outcomes including quality of life, sexual dysfunction, and dyspareunia consistently. Poor outcome selection, collection, and reporting limits the usefulness of research to inform clinical practice. Developing a core outcome set could help to address these issues. A consortium of over eighty journals support the Core Outcomes in Women's and Newborn Health (CROWN) initiative which promotes the development, dissemination, and implementation of core outcome sets across women's and newborn health.[69] Several core outcome sets are currently in development across a broad range of healthcare conditions including infertility, endometriosis, termination of pregnancy, twin-twin transfusion syndrome, pre-eclampsia, and neonatal medicine. [11, 70-73]

An international consortium of healthcare professionals, researchers, and patients, International Collaboration for Harmonizing Outcomes, Research and Standards in Urogynaecology and Women's Health (CHORUS), has been established to develop core outcome sets across Urogynaecology and Women`s Health.

There is limited guidance regarding the development of core outcome sets.[68] The COMET initiative suggests three broad stages: (1) identifying potential core outcomes; (2) determining core outcomes using robust consensus methods engaging key stakeholders; and (3) determining how core outcomes should be measured. This study has completed the first step in developing a core outcome set for childbirth trauma by developing an initial long list of potential core outcomes. Further research is required to further develop the long list of potential core outcomes to ensure its holds relevance to women with childbirth trauma and healthcare professionals, researchers, and patients living in low- and middle-income

countries.[74] The development of the core outcome set for childbirth trauma will be informed by the methods used by recently completed core outcome sets including preterm birth.

Pending the development of a core outcome set for childbirth trauma we would recommend the collection and reporting of pain, would healing, quality of life, and sexual dysfunction. In addition, when considering the management of third and fourth degree tears we would recommend collecting and reporting faecal and flatus incontinence, endoanal ultrasound abnormality, and manometry abnormalities.

Conclusion

Outcome reporting in childbirth trauma research is heterogeneous. Developing, disseminating, and implementing a core outcome set in future childbirth trauma research could help to increase its reach and relevance to clinical practice.

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Conflicts of interest

The authors report no competing interests. Completed disclosure of interest forms are available to view online as supporting information.

Author contributions

VP, CD, AE and SKD had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: JMD, SKD Acquisition of data: CD, AE Analysis and interpretation of data: JMD VP Drafting of the manuscript: JMD, VP, SKD

Critical revision of the manuscript for important intellectual content: SKD Statistical analysis: VP

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Figure Legend

Figure 1. PRISMA Flow Diagram

Table 1. Perineal repair trials: outcome and outcome measures reported

Domain	RCTs	Outcomes	Outcome measures
Pain	34	9	8
Wound healing	20	13	4
Anorectal dysfunction	16	4	5
Sexual dysfunction	14	2	1
Analgesia requirement	11	5	1
Suture related morbidity	11	3	0
Anorectal manometry abnormality	11	8	8
Anal ultrasound abnormality	7	2	2
Patient's satisfaction scale	7	5	2
Evaluation of suture material and handling	6	8	2
Depressive/stress morbidity	5	6	5
Impact on quality of life	4	3	3
Pudendal nerve terminal motor latency abnormality	3	8	7
Urinary incontinence	2	1	2

Table 2. Reported outcomes by study (outcomes reported by ≥ 5 studies included only)

			Outcomes															
	Study	Sample size (N)	Anal USS abnormality	Anal manometry abnormality	Anal incontinence	Defecatory difficulties	Flatus incontinence	Faecal urgency	Dyspareunia	Time of resumed intercourse	Perineal pain	Need for analgesia postnatally	Need to remove sutures	Need for Resuturing	Wound dehiscence	Wound healing	Wound infection	Wound gapping
OASIS studies	Fynes M & al.	40		x	x													
	Tjandra J & al.	23	x	x	x	x											x	
	Gamble J. & al.	103																
	Ghahramani L. & al.	27			x													
	Williams A. & al.	112			x													
	Nordenstam J. & al.	165		x	x													
	Oakley S. & al.	54		x	x	x												
	Sultan A. & al.	44	x	x	x		x	x										
	Farrell S. & al.	150	x	x	x	x	x	x			x							
	Garcia V. & al.	41	x	x	x		x											
	Eogan M. & al.	147	x	x	x			x	x		x							
	Peirce C. & al.	120		x	x													

	Mahony R.& al.	105	x	x	x	x	x	x	x			x						x	
	Fernando J.& al.	32			x	x	x	x	x			x							
	Rydningen M.& al.	58			x	x													
	Rygh A. &al.	128	x	x	x														
Mild lacerations studies	Oboro V.& al.	823							x	x	x	x	x	x	x	x		x
	Upton A.& al.	391							x	x	x							
	Spencer J. & al.	737							x	x	x		x		x			
	Morano S.& al.	214							x		x		x	x				
	Duggal N.& al.	147													x			
	Franchi M.& al.	61									x							
	Zafar S.& al.	110									x							
	Sadaf-Un-Nisa & al.	100									x							
	Yildizhan R. & al.	200									x							
	Kettle C. & al.	1542				x			x		x	x	x		x			x
	Valenzuela P. & al.	445									x							
	Fleming V. & al.	1314									x					x		
	Alvarenga M. & al.	54									x					x		
	Colacioppo P. & al.	96									x							
	Berlit S. & al.	100									x							
	Leroux N. & al.	192							x	x	x	x						
	Aslam R. & al.	138									x							
	Lundquist M. & al.	80								x	x				x			x

Akil A. & al.	95									x								
Ismail K. & al.	3681								x	x	x	x					x	
Dudley L. & al.	34							x		x					x	x		
Fyneface - Ogan S. & al.	482									x								
Kindberg S. & al.	400									x			x		x			x
Greenberg S. & al.	1361									x	x	x		x				
Selo-Ojeme D. & al.	260							x		x	x	x		x				
Mota R. & al.	100									x				x			x	
Dencker A. & al.	1139									x				x			x	x
Gordon B. & al.	1780							x		x		x	x		x			
Grant A. & al.	793							x	x				x					
Mahomed K. & al.	1574							x	x	x	x				x			
Grant A.& al.	414									x								
Feigenberg T.& al.	102									x								
Total	20308	7	11	15	7	5	5	14	8	34	7	8	5	9	7	6	5	

Grey columns depict outcomes specific to OASIS which are not expected to be present among non-OASIS studies

Table 3. Outcome reporting. Univariable and multivariable correlation				
	Univariable		Multivariable	
Factor	Spearman`s rho	p-value	Beta	p-value
Study quality	.377	.008	0.330	.129
Journal IF	.105	.526	-0.074	.489
Year of publication	.389	.006	0.044	.313
Study size	-.426	.002	0.001	.146
Journal type	-	-	-0.381	.467
Type of tear *	-	-	0.176	.781
Commercial funding	-	-	0.209	.774
Validated questionnaire	-	-	1.212	.035