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Maternal and child health after assisted vaginal delivery: five-year follow up of a randomised controlled study comparing forceps and ventouse

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Objective To undertake a five year follow up of a cohort of women and children delivered by forceps or vacuum extractor in a randomised controlled study.

Design Follow up of a randomised controlled trial.

Setting District general hospital in the West Midlands.

Population Follow up questionnaires were sent to 306 of the 313 women originally recruited at the North Staffordshire Hospital to a randomised controlled study comparing forceps and vacuum extractor for assisted delivery. Two hundred and twenty-eight women responded (74·5%) and all were included in the study; forceps ($n = 115$) and vacuum extractor ($n = 113$).

Main outcome measures Bowel and urinary dysfunction, child vision assessment, and child development.

Results Maternal adverse symptoms at long term follow up were relatively common. Urinary incontinence of various severity was reported by 47%, bowel habit urgency was reported by 44% (98/225), and loss of bowel control 'sometimes' or 'frequently' by 20% of women (46/226). No significant differences between instruments were found in terms of either bowel or urinary dysfunction. Overall, 13% (20/158) of children were noted to have visual problems. There was no significant difference in visual function between the two groups: ventouse 11/86 (12·8%), compared with forceps 9/72 (12·5%); odds ratio 0·97, 95% CI 0·38–2·50. Of the 20 children with visual problems, a family history was known in 18, and 17/18 (94%) had a positive family history for visual problems. No significant differences in child development were found between the two groups.

Conclusions There is no evidence to suggest that at five years after delivery use of the ventouse or forceps has specific maternal or child benefits or side effects.

INTRODUCTION

On the basis of the finding that the vacuum extractor is less likely to injure the mother than forceps, it has been stated that it 'is the instrument of first choice for operative delivery'[1]. The data of our multicentre randomised controlled trial between forceps and vacuum extractor[2] and the subsequent meta-analysis[3], continue to support this claim.

Johanson *et al.*[4] undertook a longer term follow up of mothers from the North Staffordshire arm of the same original controlled trial ($n = 185$ at two years). At this time no significant differences were found between the two instruments in terms of perineal pain, dyspareunia or the sensation of prolapse. Three women in the forceps group said they had poor control of their bowels, one of whom had faecal incontinence. Obstetric trauma is regarded as the major aetiological factor in the development of anal incontinence in women[5]. The actual incidence is much higher than supposed as many women either are too embarrassed to volunteer their symptoms or tend to accept it as an expected consequence of childbirth. Sultan *et al.*[6] studied 43 consecutive women who had an instrumental delivery (26 forceps and 17 vacuum extraction, according to the operator's choice) with anal endosonography and neurophysiological tests. Eighty-one percent of forceps deliveries and 24% of vacuum deliveries were found to have sphincter defects. Defaecatory symptoms were present in 38% of women who were delivered by forceps and 12% who were delivered by vacuum.

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The differential effects of vacuum extraction and forceps on important neonatal and paediatric end-points remain to be studied. The studies carried out so far have concentrated on early assessment of the newborn infant. An increased likelihood of cephalhaematoma (odds ratio 2·7, 95% CI 1·71–4·25) and retinal haemorrhages (odds ratio 1·90, 95% CI 1·70–2·00) in the vacuum extractor group has been found consistently[3]. This, along with a trend towards lower Apgar scores in the vacuum extraction group, has suggested that more serious damage to the infant's head is at least a possibility. It was felt that these issues need to be studied further with longer term follow up of the neonates[2].

Only one of the 10 randomised controlled trials has included longer term follow up of the baby[7], and this was at one year only (n = 232). In that study strabismus was found in 8/115 babies born by vacuum extraction and in 6/117 babies whose mothers were delivered by forceps (odds ratio 1·38, 95% CI 0·46–4·12). No hearing problems were found in infants born by vacuum extraction, whereas hearing problems were found in three infants born via forceps.

We therefore agreed to study our cohort again at five years, looking at the following hypotheses:

1. That there is no difference between forceps and vacuum extractor in terms of maternal health.
2. That there is no difference between forceps and vacuum extractor in terms of the child's visual acuity.
3. That there is no difference between forceps and vacuum extractor in terms of the child's development.

METHODS

All 313 women who participated in the North Staffordshire arm of the Keele Multicentre Trial[2] between September 1989 and May 1990 were eligible to be contacted using the research register by the research midwife (J.C.) (original n = 313; this cohort comprised 52% of the total in the original study (n = 607)). Three computer information systems (the hospital clinical computer system; the hospital information support system and the child health computerised records system) were utilised and cross-referenced to obtain the required data on addresses and the child's name. The study was approved by the North Staffordshire Medical Ethics Committee.

The four specific areas for assessment in the questionnaires were maternal bowel habits/problems, maternal urinary habits/problems, child vision and child development. As there was no source of validated questions for this purpose, a four-part questionnaire was developed. Questions concerning bowel and urinary habits/problems were developed from consensus discussion and based on the types of questions used in clinical practice. Regarding the child's vision, the mother was simply asked in the questionnaire whether the child had been given an orthoptic eye test and where such a test had been carried out. Children who had not had an eye-test were invited to have one.

No validated questionnaire was available for maternal assessment of a child's progress in the age range of 4½ to 5½ years. The Oxford/NPEU questionnaire[8,9], designed for 7 year olds, was used as a guideline, as was the Griffiths Mental Development Scale. Additional questions were included, based on the clinical practice and experience of the paediatric investigator (E.H.).

The final questionnaire was drawn-up by one of the authors (J.C.) and underwent a pilot test among 15 unselected women locally, with resulting minor adjustments being made to help comprehension.

An information leaflet regarding the nature of the follow up study was sent to each woman. They were all invited to fill in a confidential questionnaire regarding their own health and the development of their child. At this time they were also invited to attend the Maternity Hospital for a more detailed physical assessment of anal structure and function, as described in previously[10]. A freepost envelope, addressed to the researcher, was included with each questionnaire. Repeat questionnaires were sent out two months later. This repeat questionnaire was accompanied by a letter which requested the return of the blank questionnaire if the mother did not wish to participate in the study. Finally, nonreturners were contacted, where possible, by telephone to check that the questionnaire had been received. To help with 'lost cases' the patient's general practitioner was contacted and the post office assisted by returning all undelivered mail. Data on visual tests already undertaken were obtained from the district computer.

A study of 313 women would have a power of nearly 90% to detect a difference of 15% in terms of defaecatory symptoms (10% to 25%). For the purposes of the analyses undertaken here, women in the forceps and ventouse groups continued to remain in the group to which they were initially allocated, regardless of the eventual actual mode of delivery.

Continuous data are expressed as mean (SD) and are compared using t tests. Frequency data are analysed

Table 1. Comparability of the two groups. Values are given as n (%) or mean [SD].

	Ventouse (n = 113)	Forceps (n = 115)	P
Primiparity	99 (88)	93 (81)	0·22
Age (years)	25·7 [5]	25·3 [5]	0·55
1st stage (min)	531 [259]	596 [318]	0·9
2nd stage (min)	81 [60]	77 [57]	0·61
Epidurals	21 (19)	32 (28)	0·16

using the StatXact Turbo package and are presented as odds ratios (95% confidence intervals), with exact *P* values being calculated when the frequencies are small.

RESULTS

The questionnaires, accompanied by an explanatory letter, were sent to 306 women at the beginning of December 1994. Of the 313 women in the original study, only seven were completely untraceable. There was an initial response rate of 53%. Repeat questionnaires were sent out in early February. The response rate increased to 73·8% (226/306). Among the nonresponders contacted by telephone only another two returned their questionnaires (74·5%; 228/306). Of the remainder, eleven returned blank forms, but seven did not return them even though they were contacted by telephone and did have the forms. The other 60 could not be contacted by telephone either because they had moved, changed name, or had their telephone disconnected.

Sixty-nine percent of the children (158/228) had orthoptic tests. Of the remainder, 48 declined the offer of a test, 10 were out of the area and were unable to attend, and in 12 it was not possible to trace the results of tests said by the mother to have already been undertaken.

The comparability of the respondents in the forceps and ventouse groups reflects the original random allocation of the women to the two groups[2] (Table 1). The numbers within the cohort from North Staffordshire Maternity Hospital with significant maternal injuries (either third degree perineal tears or upper vaginal tear extensions) were 6/113 (5%) in the ventouse group and 12/115 (10%) in the forceps group (odds ratio 0·48, 95% CI 0·17–1·33). The same number of women in each group had subsequently had another child: 48/113 (42·9%) in the ventouse group and 48/115 (41·7%) in the forceps group.

The results of the questions on maternal bowel and urinary morbidity are shown in Tables 2 and 3. Adverse symptoms at long term follow up were relatively common. Urinary incontinence of varying severity was

Table 2. Bowel habits. Values are given as *n* (%).

	Ventouse	Forceps	Statistical significance*	OR (95% CI)
Bowels opened				
< 3 times per week	14 (13·1)	9 (8·5)	$\chi^2 = 0·03$;	
> 12 times per week	4 (3·7)	0	$P = 0·86$	
	$n = 107$	$n = 106$		
Straining				
Frequently	13 (11·5)	9 (8·0)	$\chi^2 = 2·38$;	
Sometimes	56 (49·6)	78 (69·0)	$P = 0·12$	
	$n = 113$	$n = 113$		
Use of laxatives				
Frequently	3 (2·7)	4 (3·6)	$\chi^2 = 0·01$;	
Sometimes	22 (19·5)	19 (17·0)	$P = 0·92$	
	$n = 113$	$n = 112$		
Rectal bleeding				
Yes (ever)	31 (27·4)	37 (32·7)		0·79 (0·44–1·39)
	$n = 112$	$n = 113$		
Loss of bowel control				
Frequently	1 (0·9)	1 (0·9)	$\chi^2 = 3·43$;	
Sometimes	28 (25·0)	16 (14·3)	$P = 0·06$	
	$n = 113$	$n = 113$		
1 = wind	9 (31·0)	7 (41·2)	$\chi^2 = 10·85$;	
2 = diarrhoea	8 (27·6)	2 (11·8)	$P = 0·18$	
3 = normal stool	1 (3·4)	0		
4 = hard stool	5 (17·2)	1 (5·9)		
1 + 2	2 (6·9)	3 (17·6)		
1 + 3	1 (3·4)	3 17·6)		
1 + 4	2 (6·9)	1 (5·9)		
2 + 4	1 (3·4)	0		
	$n = 29$	$n = 17$		
Urgency				
Frequently	10 (8·9)	11 (9·7)		
Sometimes	41 (36·6)	36 (31·9)		1·20 (0·70–2·00)
	$n = 112$	$n = 113$		

*Trend test.

Table 3. Urinary habits. Values are given as *n* (%).

	Ventouse	Forceps	Statistical significance*	OR (95% CI)
Frequency (day)				
>7 times	31 (27·7)	31 (27·2)		1·03 (0·57–1·84)
	n = 112	*n* = 114		
Frequency (night)				
0	59 (52·2)	54 (47·0)	$\chi^2 = 1·028$;	
≥2	6 (5·3)	14 (12·2)	$P = 0·31$	
	n = 113	*n* = 115		
Stress incontinence				
Frequently	8 (7·1)	12 (10·4)	$\chi^2 = 0·02$;	
Sometimes	46 (41·1)	41 (35·7)	$P = 0·89$	
	n = 112	*n* =115		
Urgency				
Frequently	4 (3·5)	6 (5·2)	$\chi^2 = 0·38$;	
Sometimes	30 (26·5)	32 (27·8)	$P = 0·54$	
	n = 113	*n* = 115		

*Trend test.

reported by 47% of all the women, bowel habit urgency was reported by 44% of all the women (98/225) and loss of bowel control 'sometimes' or 'frequently' by 20% of all the women (46/226). No significant differences between instruments were found in terms of either bowel or urinary dysfunction. A larger proportion of women (26%) in the ventouse group had loss of bowel control compared with forceps (15%), but this was not statistically significant. There were, on the other hand, more women in the forceps group than in the ventouse group who had to strain to open their bowels (77% *vs* 61%).

Overall 13% of the children (20/158) were noted to have visual problems (Table 4). There was no significant difference between the two groups: ventouse 11/86 (12·8%) compared with forceps 9/72 (12·5%); odds ratio 0·9, 95% CI 0·38–2·5. Among the 20 children with

Table 4. Vision. Anisometropia = difference in refracture error between 2 eyes; Hypermetropia = long sightedness; Esotropia = convergent squint; Exotropia = divergent squint; Amblyopia = lazy eye.

Name and nature of problem	Diagnosis
Ventouse group	
No family history	Anisometropia, right amblyopia
Family history: glasses	Anisometropia, right amblyopia
Strong family history	Hypermetropia, left esotropia and amblyopia
Family history	Myopia and glasses
Family history: glasses	Anisometropia, right amblyopia
Family history	Exotropia
Family history: glasses	Hypermetropia, left esotropia
Strong family history	Anisometropia, right amblyopia
Family history: glasses	Hypermetropia, right amblyopia
Strong family history	Right esotropia
Family history squint	Anisometropia, right amblyopia
Forceps group	
Strong family history	Hypermetropia, right esotropia
Family history: squint	Hypermetropia, left esotropia
Family history: squint and amblyopia	Nystagmus (albinism)
Family history: squint and glasses	Hypermetropia, right esotropia
Family history: squint and glasses	Hypermetropia, right esotropia and amblyopia
Family history: glasses	Astigmatism
Family history: squint and glasses	Hypermetropia, right esotropia and amblyopia
Strong family history	Reduced vision: normal last visit
Family history: squint and glasses	Hypermetropia, left esotropia

visual problems a family history was known in 18. Seventeen of the 18 (94%) had a positive family history for visual problems.

The results of the questions on the child's development are shown in Table 5. Once again, no significant differences between the two groups were found. However, the incidence of developmental problems was low and the numbers followed up are insufficient to rule out small but clinically important differences between instruments.

DISCUSSION

This is the first study of late follow up of an assisted delivery cohort of patients. The two groups in the current cohort had similar baseline characteristics, reflecting the validity of the original randomisation. Although the response rate was not complete, there was no reason to suspect self-selection. The results do not suggest any differences in terms of long term symptoms of bowel or urinary dysfunction between forceps and ventouse. Although there is good

Table 5. Child development. Values are given as *n* (%).

Tasks undertaken	Ventouse	Forceps	*P* (exact)
Walking			
With difficulty	1 (0·9) *n* = 113	2 (1·7) *n* = 115	1
Hops on one foot			
With difficulty	5 (4·4) *n* = 113	4 (3·5) *n* = 114	0·75
Throwing a ball			
With difficulty	3 (2·7) *n* = 110	2 (1·8) *n* = 114	0·68
Use of knife and fork			
With difficulty	4 (3·6)	1 (0·9)	0·21
Unknown	1 (0·9) *n* = 112	0 *n* = 115	
Dressing Self			
With difficulty	5 (4·4) *n* = 113	3 (2·6) *n* = 115	0·50
Washing hands			
With difficulty	0	0	
Holding and gripping			
With difficulty	1 (0·9) *n* = 113	4 (3·5) *n* = 114	0·37
Copying circles			
With difficulty	0	2 (1·7) *n* = 115	0·50
Hearing			
With difficulty	3 (2·7) *n* = 113	3 (2·6) *n* = 115	1
Treatment for a hearing problem	9 (8·0) *n* = 112	13 (11·3) *n* = 115	0·50
Understanding child's speech			
With difficulty	2 (1·8) *n* = 112	8 (7·0) *n* = 115	0·10
Child's understanding of other people			
With difficulty	0	3 (2·6) *n* = 115	0·25
Shares toys			
Sometimes	11 (9·7)	11 (9·6)	1
Not known	1 (0·9) *n* = 113	1 (0·9) *n* = 115	
Use of 4 word sentences			
Nonuse	0	1 (0·9)	1
Not known	0	1 (0·9) *n* = 115	
Ability to say full name			
Not able	0	1 (0·9) *n* = 115	1

evidence to support the claim that the forceps is more traumatic to the mother at the time of delivery[3], the finding of no difference at five years may therefore be a reflection of the body's ability to heal over the course of time, and it may also be a basis for questioning the importance and validity of early outcomes. Alternatively, it may reflect the crudeness of a postal questionnaire in terms of eliciting symptoms that are private, although the original randomisation minimises the effect of this form of bias. Finally, it may reflect on the smaller numbers of respondents than were calculated for in the original power. With 228 in the study the power to detect a 15% difference in bowel disorder symptoms remains above 80%, but the study only had a power of 50% to detect a smaller, but clinically significant, difference of 10%. The specific effects of the two instruments could also be masked by the intention-to-treat analysis. In a secondary analysis of a small subgroup of patients from this study more long term morbidity was found in the group delivered by forceps[10].

The study is reassuring in other respects. The increased finding of retinal haemorrhages noted in previous studies comparing the ventouse and forceps does not appear to be related to any increase in long term visual problems. Similarly, there do not appear to be any differences in development between children delivered with the different instruments. It would not appear, therefore, that there is any compensatory child benefit to be derived from using the forceps in place of the ventouse.

Overall, a large number of women in both groups complained of long term problems. Unfortunately data on the women's health prior to childbirth are not available. Although some of these problems will be related to the delivery with forceps or ventouse many will not. Five years is a long time and unrelated causes of symptoms exist. These, however, should be balanced in the two groups. MacArthur *et al.*[11,12] have documented a relatively high incidence of post-delivery morbidity even in those women having normal deliveries. Within our project we also followed up a similar cohort of normal deliveries and we found a high incidence of problems in this group of women as well (study submitted for publication).

CONCLUSIONS

At five year follow up we were unable to find significant differences between forceps and vacuum extractor in terms of maternal morbidity. Clear child health advantages or disadvantages have not been demonstrated for either instrument. Further studies will be needed on much larger numbers of children if small differences between the instruments were to be found.

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