Clinical Green Top Guidelines

Instrumental Vaginal Delivery (26) - Oct 2000

1. Purpose and scope

The aim of this guideline is to provide up-to-date information on the use of the vacuum extractor and forceps for both rotational and non-rotational instrumental deliveries. Obstetricians should be competent and confident in the use of both instruments.[1] The emphasis of the guideline will be on the relative merits of the two instruments, the indications for their use and their associated complications.

A guideline is needed because of wide variation in current practice and because of significant maternal and infant morbidity, which can be reduced with improved training. Assisted vaginal delivery rates vary both between and within countries.[2] In United Kingdom hospitals figures range from 4%-26%.[3,4] Given that operative vaginal delivery has been identified as a major risk factor for later maternal morbidity (including faecal incontinence)[5-8] this is a cause for concern. An analysis of RCOG annual returns shows that for the period 1 April 1998 to 31 March 1999, of the 661,934 births recorded 74,824 (11.3%) were assisted with forceps/ventouse. A consultant consensus group had considered the previous rate of 10.5% (RCOG annual returns 1997) to be higher than necessary and that a rate of about 8.5% would be more acceptable.[9] A variety of interventions can be considered to ensure that operative vaginal delivery rates are kept to a minimal safe level (e.g. 'companionship' in labour).[10] Surveys in the UK and the USA suggest that vacuum is becoming more popular,[10,11] thus confirming a move away from forceps to vacuum.[2] The relative merits of the two instruments are widely debated.[12,13]

2. Identification and assessment of evidence

The Cochrane Library and the Cochrane Register of Controlled Trials were searched for relevant RCTs, systematic reviews and meta-analyses. A search of Medline from 1966-1999 was also carried out. The author also liaised with the MIDIRS midwifery database and utilised the results of their latest search (November 1999). MIDIRS hand search 300 journals in-house. Contents pages of a further 150 journal titles are scanned on-line and copies of relevant articles obtained. Coverage is English language journals worldwide and includes the majority of midwifery and obstetrics journals, plus a selection of other general medical and specialist journals on subjects which include epidemiology, primary health, health education, statistics, dietetics, anaesthesia and ultrasound. Items added to the MIDIRS database all include an abstract or short summary and are indexed using indexing terms based on the MeSH headings used in Medline.

The databases were searched using the relevant MeSH terms; exp extraction obstetrical and extraction obstetrical or extraction forceps, this was combined with a Key-Words search using - Childbirth; Delivery; Instrument*, Vacuum extractor; Ventouse; Forceps; Morbidity; Randomised Controlled Trials; Meta-analysis and limiting the search to human.

The definitions of the types of evidence used in this guideline originate from the US Agency for Health Care Policy and Research and Quality. Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are highlighted and annotated as 'Good Practice Points'.

3. Indications and contraindications

✓ **Practitioners should be aware that no indication is absolute and be able to distinguish 'standard' from 'special' indications.**

Although it has been customary to distinguish 'standard' from more complex or 'special' indications1,14 for both instruments, no indication for operative vaginal delivery is absolute and each case should be considered individually.[1] Traditional 'standard' indications include 'delay' and 'distress' as well as a need to shorten the second stage.[1,14] The complexity of the delivery is particularly related to the level and position of the head. Use of either instrument for rotational deliveries at the level of the spines demands a high level of clinical and technical skill and the operator must have received adequate training. The most important contraindications are therefore operator inexperience with the chosen instrument and an inability to achieve a proper application due to the fetal position or station. The operator should be aware of the manufacturer's recommendations for the instrument that is being used.[15]

The vacuum extractor is contraindicated with a face presentation. It has been suggested that it should not be used at gestations of less than 36 weeks because of the risk of cephalhaematoma and intracranial haemorrhage.[14,16] One case control study suggests that this restriction may be unnecessary,17 but this study was small and undertaken outside the UK. There is minimal risk of fetal haemorrhage if the extractor is applied following fetal blood sampling or application of a spiral scalp electrode.[18,19] No bleeding was reported in two randomised trials comparing forceps and ventouse.[20-22]

Forceps and vacuum extractor deliveries before full dilatation of the cervix are contraindicated. A possible exception would be a vacuum delivery of a second twin where the cervix has contracted or with a prolapsed cord at 9cms, if rapid delivery is anticipated. Forceps are indicated for the after-coming head of the breech and in situations where maternal effort is impossible or contraindicated.[1]

For cases requiring instrumental assistance during caesarean section, Wrigley's or modified short straight forceps are usually used, although the vectis blade or vacuum have also been employed.[23-25]

4. Choice of different types of instruments

✓ **Practitioners should use the most appropriate instrument for individual circumstances**

There are over 700 different makes of forceps.[1] Most authors subscribe to a classification system that divides forceps into classic and specialised subtypes. Classic forceps include Simpson, Anderson and Neville-Barnes forceps, whilst specialised forceps include Kielland, Piper and Laufe (of divergent design). Variations in cephalic curvature, fenestration and design of shank allow selection to be made on the basis of individual circumstances.[1] There have been no RCTs comparing different instruments and it is recognised that the choice is often subjective. One RCT was identified; in this study decreased facial marking was found when soft blade pads were used.[26]

5. Relative merits

A **The use of ventouse compared to forceps is associated with a higher risk of failure, more cephalhaematomata, more retinal haemorrhages but less use of regional/general anaesthesia, less maternal perineal or vaginal trauma. No significant differences between ventouse and forceps were found in caesarean section rates, low Apgar scores at five minutes or long-term follow-up of mothers and children (five years).**

A Cochrane systematic review[22] of nine randomised controlled studies, involving 2,849 primiparous and multiparous women, showed the vacuum extractor compared to the forceps to be: • Significantly more likely to fail at achieving a vaginal delivery (OR 1.7; 95% CI 1.3-2.2) (Number Needed to Harm (NNH)=20) (i.e. for every 20 vacuum deliveries there is one 'extra' failure) • Significantly more likely to be associated with a cephalhaematoma (OR 2.4; 95% CI 1.7-3.4) (NNH=17) • Significantly more likely to be associated with retinal haemorrhage (OR 2.0; 95% CI 1.3-3.0) (NNH=50) • Significantly more likely to be associated with maternal worries about the baby (OR 2.2; 95% CI 1.2-3.9) (NNH=17) • Significantly less likely to be associated with use of maternal regional/general anaesthesia (OR 0.6; 95% CI 0.5-0.7) (NNT=12)• Significantly less likely to be associated with significant maternal perineal and vaginal trauma (OR 0.4; 95% CI 0.3-0.5) (NNT=10) • Significantly less likely to be associated with severe perineal pain at 24 hours (OR 0.54; 95% CI 0.31-0.93) (NNT=17) • No more likely to be associated with delivery by caesarean section (OR 0.6; 95% CI 0.3-1.02) • No more likely to be associated with low 5 min Apgar scores (OR 1.7 ;95% CI 0.99-2.8) • No more likely to be associated with the need for phototherapy (OR 1.08; 95% CI 0.7-1.8). In view of the reduction of maternal injuries the vacuum has been considered to be the instrument of first choice.[13] In each of these studies this outcome was judged by the operator, and not by an independent blinded observer, which could allow it to be biased. Nevertheless, objective assessments in larger observational studies and a small randomised cohort have shown increased anal sphincter injuries with forceps[5,6,8] However, a five year follow-up of women enrolled in one of the RCTs did not show any	Evidence Level 1a

significant differences in long-term outcome between the two instruments for either the mother or the child.[27] The degree of rotation required is a significant indicator of potential morbidity.[1] However the data available from the published controlled trials cannot be analysed separately to compare the ventouse and forceps (e.g. Kiellands) in their use for rotational deliveries.	

A **The use of soft rather than rigid vacuum extractor cups is associated with more failures but with fewer neonatal scalp injuries.**

A Cochrane systematic review[28] of nine randomised controlled studies involving 1,368 primiparous and multiparous women showed that soft vacuum extractor cups when compared to rigid cups were associated with a significant increase in the rate of failure (OR 1.6; 95% CI 1.2-2.3) (NNH=17) but a significant reduction in scalp trauma (OR 0.4; 95% CI 0.3-0.6) (NNT=9).	Evidence Level 1a

A **Either an electrical or mechanical pump is appropriate for generating a vacuum, which can be undertaken using a rapid method.**

A recent controlled study demonstrated no advantage between the use of the foot and electric pumps.[29] In a controlled trial of stepwise versus rapid application, the total duration of ventouse vacuum extractor application in the rapid method was eight minutes compared to 14 in the stepwise method, with no significant differences in terms of cup detachment (soft or rigid) or scalp injury.[30]	Evidence Level 1b

6. Complications

✓ **Deficient knowledge and incorrect technique contribute to increased complications of instrumental vaginal delivery. Practitioners should be aware of potential risks and of necessary safety measures.**

Vacuum and forceps can be associated with significant complications, both maternal and fetal. There have been two maternal deaths reported with the vacuum.[31] Both mothers died when the cervix had been torn with delivery prior to full dilatation. Despite this, over 60% of obstetricians who responded to a survey would consider using the vacuum extractor in this way.[10] In the most recent report of the Confidential Enquiries into Maternal Deaths32 the only traumatic uterine rupture was associated with forceps delivery. Instrumental vaginal delivery is also recognised to be a source of significant long-term morbidity; other maternal complications have been reviewed extensively.[1,8]

The combined evidence obtained from all available controlled trials (1,175 babies in the vacuum extractor groups and 1,155 babies in the forceps groups) allows conclusions to be drawn only about relatively common neonatal outcomes. Concerns about risks of intracranial and subgaleal haemorrhage remain.[12,15,33-35] However, in a recent review of 583,340 live born singleton infants born to nulliparous women, the rate of subdural or cerebral haemorrhage in vacuum deliveries did not differ significantly from that associated with forceps use or caesarean during labour.[36] Overall, the risks of perinatal trauma using the vacuum extractor correlate with the duration of application, the station of the fetal head at the commencement of the delivery, as well as difficulty of the delivery and the condition of the baby at the time of commencement of the procedure.[14,37] Risks increase significantly amongst babies who are exposed to attempts at both vacuum and forceps delivery.[36] Further assessment of factors contributing to adverse neonatal outcome may be possible by examining large cohorts of deliveries where complications are recorded (e.g. the Confidential Enquiry into Stillbirths and Deaths in Infancy).

7. Training

✓ **Practitioners who are appropriately trained are more likely to provide a consistently high standard of care.**

Only adequately trained and supervised practitioners should undertake vacuum or forceps deliveries. With the reduction in junior doctors' hours and training opportunities, trainees may have less possibility of developing their labour ward skills through experience alone. Adequate training can only be guaranteed if there is a consultant presence on the delivery suite for as many hours as possible each week. Whilst supervised experience on labour ward has generally been regarded as the 'gold-standard' in terms of learning practical procedures, it may be possible to supplement this clinical experience with other teaching resources, including CD-ROM, video material and educational sessions using models in a variety of scenarios.[38-41]

8. Risk management and audit

✓ **Audit of quality of routine care and documentation, as well as complications (e.g. failed vacuum**

delivery), should contribute to the ongoing provision of high standards of clinical care.

The bulk of malpractice litigation42 results from failure to:

- exercise adequate and informed medical judgement in selection and training of procedures;
- understand or accept the limitations of the procedure and to agree an alternative in the event of failure;
- abandon the procedure at the appropriate time, particularly the failure to eschew prolonged, repeated or excessive traction efforts in the presence of poor progress;
- properly assess the position of the fetal head in relationship to the pelvic outlet.

It is essential that every instrumental vaginal delivery is fully documented in the woman's obstetric records. Information should include the indication for the procedure, anaesthesia, personnel present, instruments used, examination findings and procedure, time of commencement and conclusion of the operation and any complications (with a detailed description of how they were managed).42 The records should be completed in black ink, and the operator should sign and print his/her name clearly beside these data. Paradoxically, the tendency to poor documentation is probably greater where the delivery has been complicated.

The following should be audited routinely:

- The overall rates and indications for instrumental delivery
- Complications, e.g. failed instrumental delivery, neonatal admissions for intensive care
- Adequacy of documentation, e.g. level of head assessed abdominally and vaginally
- Complaints and medico-legal cases

A goal for the future that all units should consider is the ability to audit individual practitioner's training, supervision, success and complication rates. This information will eventually become part of each specialist's annual appraisal and is therefore an important component of clinical governance implementation.

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APPENDIX

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in 'Clinical Governance Advice No 1: Guidance for the development of RCOG green-top guidelines' (available on the RCOG website). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these

guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels

Ia	Evidence obtained from meta-analysis of randomised controlled trials.
Ib	Evidence obtained from at least one randomised controlled trial.
IIa	Evidence obtained from at least one well-designed controlled study without randomisation.
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study.
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grades of recommendations

A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B	Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Good Practice Point

✓ Recommended best practice based on the clinical experience of the guideline development group.

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Valid until October 2003
unless otherwise indicated