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ABSTRACT

Background: Guidelines are increasingly used to guide clinical practice, with the expectation that guidelines improve clinical outcomes and minimize health care expenditure. In recent years a number of guidelines for vaginal birth after cesarean section (VBAC) have been released or updated. The range of nationally produced guidelines for VBAC has created dilemmas for clinicians and consumers. The purpose of this study was to summarise the recommendations of existing guidelines and assess their quality using a standardized and validated instrument to determine which guidelines, if any, are best able to guide clinical practice.

Methods: English language guidelines on VBAC were purposively selected from national and professional organisations in the UK, USA, Canada, New Zealand and Australia. The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was applied to each guideline. Each guideline was analyzed to determine the range and level of evidence on which it was based and the recommendations made.

Results: Six guidelines published or updated between 2004 and 2007 were appraised. Only two of the six guidelines scored well overall using the AGREE instrument. There was heterogeneity in the evidence used. Most of the guidelines cited expert opinion and consensus as evidence for some recommendations. Reported success rates for VBAC ranged from 30-85 percent; and reported rates of uterine rupture ranged from 0-2.8 percent.

Conclusions: VBAC guidelines are characterized by quasi-experimental evidence and consensus based recommendations which lead to wide variability in recommendations and undermines their usefulness in clinical practice.

Keywords: Vaginal Birth After Cesarean, VBAC, Guidelines, AGREE

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INTRODUCTION

There is an increasing emphasis on developing guidelines for clinical practice to ensure the provision of high quality care, with a view to improving clinical outcomes and minimising health care expenditure (1). Effective guidelines should be based on high quality evidence, be clearly and practically written and accessible to health care providers and consumers. The impact of guidelines on practice is difficult to ascertain. According to the Institute of Medicine (2), “disproportionately more attention is paid to developing guidelines than to implementing or evaluating them”.

In recent years, vaginal birth after cesarean section (VBAC) has received considerable attention from policy makers, clinicians and consumers. The safety and success of attempted VBAC has been debated in the literature, resulting in a wide variety of opinions and practices internationally. A number of countries have developed and implemented guidelines for VBAC but their impact on VBAC rates is unclear. A 1995 survey of American College of Physician Executives demonstrated an inconsistent implementation of national VBAC guidelines, with a reluctance to hold physicians accountable for VBAC rates (3).

This study sought to critically appraise a sample of nationally produced guidelines regarding birth after cesarean section. We sought to determine the major recommendations in each guideline, the similarities and differences between the guidelines and the evidence on which each guideline was based. The null hypothesis was that there would be minimal differences in recommendations made by each guideline as the recommendations would be based on the highest quality evidence available, and this would be similar across guidelines, with allowances for the date of publication.

METHODS

Guidelines regarding VBAC were purposively sought from the following organisations: Royal College of Obstetricians and Gynaecologists (RCOG) United Kingdom (UK), Women's Hospitals Australasia (WHA), New Zealand Guidelines Group (NZGG), National Institute of Clinical Excellence (NICE) UK, the Society of Obstetricians and Gynaecologists of Canada (SOGC), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), American College of Obstetricians and Gynecologists (ACOG) and the Scottish Intercollegiate Guidelines Network (SIGN). This sample was selected as they represented the key national authorities in relation to obstetrics/maternity care in each of the six countries and are widely used to develop local clinical policies.

The eight organizations were contacted regarding their VBAC guideline (Table 1). Six guidelines were obtained, either electronically or in hard copy. Two organizations, RANZCOG and SIGN, did not have published VBAC guidelines and were not included in the analysis.

Insert Table 1 here

Each guideline was analyzed using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument, which evaluates the validity of a guideline (4, 5) and is becoming the international gold standard for the evaluation and development of guidelines (6). The AGREE instrument is organised into six domains: Scope and purpose; Stakeholder involvement; Rigor of development; Clarity and presentation; Applicability; and Editorial independence. The instrument is endorsed by the World Health Organization (WHO) and has been used internationally for the development and quality of clinical practice guidelines (6, 7). Two assessors independently analyzed each guideline using the AGREE instrument.

Each guideline was evaluated with respect to the recommendations concerning advice to women, clinicians and obstetric practices. Content analysis was undertaken on each guideline in relation to quotes from the respective guidelines.

RESULTS

The results are presented in four areas: (1) the results using the AGREE instrument; (2) success rates of VBAC; (3) rate of uterine rupture; and (4) recommendations for clinical practice.

AGREE guideline analysis

The appraisal of the guidelines based on the six domains of the AGREE instrument demonstrated a range of scores (Table 2). The NZGG and NICE guidelines scored highest on almost all domains especially *Rigour of Development*. This domain includes having a systematic approach to gathering the evidence; clear descriptions of the search methods and way of formulating recommendations; evidence of considering benefits and risks; demonstration of links between recommendations and the evidence; be externally reviewed by experts; and discuss updating procedures.

Insert Table 2 here

All guidelines received low scores for *Applicability* which includes the barriers and costs associated with implementation, monitoring and audit of outcomes. Only the NICE guidelines scored highly for *Editorial Independence* which includes conflicts of interest and independence. A low score was also given if the guideline did not address the criteria.

Vaginal birth after cesarean section success and uterine rupture rates

The reported VBAC success and uterine rupture rates vary markedly between guidelines (Table 3) as does the evidence on which the reported rates were based. The lowest rate for VBAC success is reported by NICE (30 – 51 percent success rate) and is based solely on a UK national cesarean section audit (8). The WHA guideline does not provide explicit in-text referencing. In the four remaining guidelines, there were only three references that were common to more than one guideline (9-11) and none was cited in more than two guidelines. Despite being published in 2005, the SOGC guideline references tended to be older, with all but two of the nine references published before 1999. In contrast, the RCOG guideline references six papers, all published between 2000 and 2004. The published range for VBAC success is narrowest in the RCOG guidelines and widest in the SOGC guidelines.

Insert Table 3 here

Uterine rupture rates

Uterine rupture is a significant complication of VBAC. Quoted rates of uterine rupture vary between guidelines but are all less than 3 percent and most are less than 1.5 percent (Table 3). The highest rate comes from NICE. This guideline states that the range of 0-2.8 percent is derived from a review of 39 quasi-experimental studies quoting rupture rates, however only six studies are directly cited. In two other places in the guideline, rates of 0.35 percent (p.15) and 0.5 percent (p.18) are also reported as overall rates of uterine rupture, without explanation as to the source of these rates. The guideline states that the larger and better conducted studies report lower rates of uterine rupture with VBAC. The International Classification of Diseases, ninth revision – clinical modification (ICD-9-CM –now ICD-10-

CM) codes used in hospital discharge data to identify uterine rupture have been notably inaccurate (12) and may have contributed to the wide ranges in these guidelines.

The NZGG report a range of 0.2 - 1.5 percent for uterine rupture, which is taken from a literature review of VBAC (12) but elsewhere in the guideline quotes the rate of 0.52 percent for women attempting VBAC who labor spontaneously (13). The SOGC guideline quotes the same rates as NZGG but only two references are common to both guidelines. The references cited in the SOGC guideline are not common to the review by Scott (13) on which the overall NZGG rate of 0.2-1.5 percent is largely based. Across all guidelines, there are 22 individual references for uterine rupture. Five references are cited in two guidelines (9, 11, 15-17) and two references are cited in three guidelines (10, 18). Although this shows greater similarity than the evidence cited regarding VBAC success 15 of the references across the guidelines only appear in one guideline. Overall the highest rates for uterine rupture quoted in each guideline ranged from 0.3 percent (WHA) to 2.8 percent (NICE).

Figure 1 provides the upper and lower range of VBAC success and the highest rate of uterine rupture across the six guidelines and reveals the ‘outlier’ position assumed by the NICE guideline on both rates.

Insert Figure 1 here

Recommendations for clinical practice

The guidelines provide a range of recommendations in relation to clinical practice (Table 4).

Insert Table 4 here

Only two guidelines recommend that women ‘should be offered’ a planned VBAC or trial of labor (NZGG, SOCG). The remaining four guidelines use language that is more ambiguous

ranging from ‘should be provided with information’ (WHA) to ‘ultimate decision should be between the woman and her physician’ (ACOG).

Continuous electronic fetal monitoring in women having a VBAC is ‘recommended’ in two guidelines (SOGC, WHA); ‘advised’ in one (RCOG) and ‘should be offered’ in another (NICE). The NICE guideline also recommends fetal blood sampling if fetal acidosis is suspected. The ACOG guideline states that ‘most authorities recommend continuous electronic fetal monitoring’. The NZGG states that there is no evidence to support or refute the use of continuous electronic fetal monitoring in women having a VBAC, although fetal heart rate abnormalities are the most common indicator of uterine rupture.

Four guidelines base their claims of recommending continuous electronic fetal monitoring in labor on it being a ‘good practice point’ (that is, Level C evidence - a consensus opinion). The SOGC guideline states that the recommendation is based on Level II-2A evidence (evidence obtained from at least one well-designed controlled study without randomisation). However, the evidence cited in support of this statement does not relate to Level II evidence: one reference is to the 1999 version of the ACOG VBAC guidelines, one is a literature review of VBAC in which the author states “I prefer to use continuous electronic monitoring for all these patients” (13) and the final reference is for a (now superseded) SOGC guideline for fetal surveillance in labor in which VBAC is not specifically covered (19). None of these publications provide high quality evidence regarding the use of continuous electronic fetal monitoring for women having a VBAC.

Epidural anaesthesia is addressed in four of the guidelines, but two (NICE, SOGC) make no comment at all. Two that make comment on epidural anaesthesia (RCOG, ACOG) state that

epidural anaesthesia is ‘not contraindicated’ and the others state that it ‘may be used as indicated’ (WHA) and ‘may be offered’ (NZGG).

Each of the guidelines is supportive of induction of labor with a range of qualifying recommendations regarding the methods of inducing labor. Three specifically recommend against the use of prostaglandins for cervical ripening/induction of labor (WHA, SOCG, ACOG). The NZGG guideline distinguishes between PGE1 and PGE2 stating that “there is no evidence to suggest that induction of labor with [synthetic] oxytocin or PGE2 has significantly higher rates of uterine rupture compared to spontaneous labor” (page 44).

Augmentation of labor is also supported with statements such as ‘not contraindicated’ (RCOG, WHA); ‘can be offered’ (NICE) and ‘careful use of syntocinon [synthetic oxytocin] may be considered’ (NZGG). One guideline fails to mention augmentation at all (SOCG) and the ACOG mentions augmentation by stating ‘spontaneous labor is more likely to result in successful VBAC than induction of labor or augmentation’.

DISCUSSION

This paper has highlighted significant differences between six national guidelines concerning VBAC published between 2004 and 2007. The diversity of quality and the range of reported success rates, risks of uterine rupture, use of continuous electronic fetal monitoring and induction of labor are the main differences across the guidelines. We recognise that VBAC is a challenging area of practice as the clinical issues for each woman vary. For example, the situation of a woman who had not had a prior vaginal birth who is 41.5 weeks gestation with an unripe cervix facing induction is significantly different in terms of VBAC success and uterine rupture risk than a woman with a prior successful VBAC in spontaneous labour. The

variation in outcomes makes guideline development difficult as a ‘one size fits all’ approach will not always work. Nonetheless, many institutions and clinicians use the guidelines to dictate policy and practice for all women and the clinical nuances that guide decision making are lost.

Guideline development is also hampered by timing. New evidence invariably emerges soon after a guideline is published and may put the guideline at odds with the most recent evidence and clinical practice, adding to the inconsistencies. Since three of the guidelines were produced, a large prospective multicenter observational study of over 33 000 women with prior cesarean delivery undergoing trial of labor and elective repeat operation has been published (20). This landmark study demonstrated that a trial of labor was associated with a greater perinatal risk than is elective repeated cesarean delivery without labor, although absolute risks were low. Symptomatic uterine rupture occurred in 124 women who underwent a trial of labor (0.7 percent). None of the guidelines reviewed has been updated to include this important study.

The AGREE instrument

The AGREE analysis demonstrated considerable limitations in all six guidelines. Only two guidelines (NICE, NZGG), scored high in the majority of domains. The AGREE instrument does not distinguish guidelines in relation to accuracy of interpretation of evidence. AGREE is a generic tool used to assess bias regarding the rigor of guideline development and methodology. It is not designed to assess the clinical content of a guideline nor does it assess the quality of the evidence on which recommendations are based (5). Vlayen et al. (21), in an assessment of 24 clinical practice guideline appraisal tools (including AGREE), concluded

that the examination of evidence within a guideline should be incorporated into appraisal tools and this was lacking in all the appraisal tools evaluated.

Our study further highlights limitations in the AGREE instrument. Although the NICE guideline scored highest using AGREE, analysis of the evidence on which some of the recommendations are based caused some concern. VBAC success rates reported in the NICE guideline were based solely on a national audit of cesarean section conducted in the UK. Better quality evidence, such as rates reported in large cohort studies, would be more appropriate and likely provide a more accurate estimate of VBAC success. There appears to be no assessment of trial quality within the guideline when reporting on uterine rupture despite inclusion of trials of lower quality which can greatly exaggerate an effect (22). Other studies have also found a lack of validity of evidence when using the AGREE tool (23, 24).

Differences across guidelines

The guidelines reviewed are characterised by quasi-experimental evidence which leads to wide variability in recommendations and undermines their usefulness in clinical practice. Despite the guidelines being developed in similar time frames (2004-2007) the evidence selected for inclusion differs widely. For example, of the 22 individual publications cited across the six guidelines regarding VBAC success rates, only three are cited in two guidelines. Although there was a higher degree of agreement for uterine rupture rate references, a large proportion (15/22) of the references cited did not appear in more than one guideline. This questions the search strategies of the guideline developers given the similarity in scope and purpose.

The range of reported uterine rupture rates in the guidelines poses a challenging issue for clinicians and consumers alike. NZGG report a range of 0.2 - 1.5 percent for uterine rupture, which is taken from a literature review of VBAC (13) but elsewhere quotes the rate of 0.52 percent for women attempting VBAC who labor spontaneously (14). This discrepancy suggests the guideline authors believe that the original range of 0.2-1.5 percent includes women who undergo induction of labor. If so, this is particularly misleading given that induction, particularly with the use of prostaglandins, had been shown to increase the risk of uterine rupture (17). Comparisons of uterine rupture rates are compounded with limitations in coding and verification of uterine rupture. In addition, prospective population-based studies may yield different results than retrospective audits that depend on accurately coded data. The wide variability in quoted rates challenges clinicians when counselling women as to the most appropriate mode of birth. It also creates confusion and uncertainty for pregnant women.

The variation in clinical practice recommendations in relation to mode of birth, continuous electronic fetal monitoring, epidural anaesthesia, induction and augmentation of labor also creates dilemmas for clinicians and consumers. Many of these recommendations are based on consensus decision-making rather than research evidence. Although a consensus opinion of experts may be appropriate where evidence is lacking, it is important that guidelines are transparent in their methodology and clearly outline areas where there is insufficient evidence and expert opinion has been used. Many of the recommendations within the VBAC guidelines are written with a degree of certainty which, given the lack of evidence, is incongruous.

The influence of guidelines in clinical practice

There are few studies that assess the impact of national VBAC guidelines on local practice (25, 26). In the 1980s and 1990s, ACOG took a very pro-VBAC stance as a strategy to reduce the rising cesarean section rate. In 1999, however, ACOG revised the guideline to take a more conservative approach involving close monitoring in labor and offering VBAC only where there is a “physician immediately available to provide emergency care” (27). This recommendation was based on Level C evidence (a consensus opinion of experts) that VBAC may be associated with increased neonatal mortality (25). Despite the lack of high quality evidence on which the changes were based, the effect on services providing VBAC was very significant. Roberts et al. (25) reported that over 30 percent of services that were previously offering VBAC no longer continued to do so after the change in guidelines. Smaller and more isolated hospitals were more likely to discontinue offering VBAC. Of those that continued to offer VBAC, the majority (68 percent) changed their policies in line with the provision of onsite surgical and anesthetic staff. Similarly, in California, attempted VBAC fell from 24 percent to 13.5 percent following the new guidelines (26).

The outcomes of these studies highlight the influence that national bodies such as ACOG can have on clinical practice. Given that the changes to the ACOG guidelines were not based on high quality evidence, but on a consensus of expert opinion, and many organisations choose not to include all ACOG’s recommendations (28), the impact on the practice of VBAC across the US is concerning.

Our study is limited in a number of ways. The selection of guidelines was purposive in that it chose guidelines that are widely used, and referred to, and have a high profile in the clinical arena. There are many other guidelines from professional associations and hospitals, health services or health departments. It was outside the scope and purpose of this study to appraise

all of these. In addition, it is highly likely that these less prominent guidelines would have drawn heavily on the ones that were selected. The study was a document analysis of the guidelines. Discussion with the guideline developers and/or the issuing authority did not occur. In addition, only two reviewers undertook the AGREE analysis.

CONCLUSION

This review of a number of high profile guidelines for the care of women who have had a previous cesarean section demonstrated wide variation in terms of rigor and applicability of the guideline itself. The majority of the guidelines scored poorly using the AGREE instrument. The AGREE instrument is significantly limited as a means to assess the quality of guidelines as it does not assess the accuracy of the evidence reported. It is only a means to assess the process of development.

There were also a number of differences in relation to internal consistency with respect to the main rates quoted – rate of successful VBAC and rate of uterine rupture. The variations between, and the lack of appreciation of the limitations or imprecision within, the guidelines create difficulties for clinicians and consumers. None of these guidelines has been recently reviewed or updated despite the availability of new, high quality evidence that may alter many guideline recommendations (20). This needs to be undertaken.

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Table 1: VBAC guidelines analyzed, their source and year of most recent update

<i>Guideline Publisher</i>	<i>Origin</i>	<i>Source</i>	<i>Last update</i>
Royal College of Obstetricians and Gynaecologists (RCOG)	United Kingdom	Website (30)	2007
Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)	Australia and New Zealand	No guideline available	NA
Women's Hospital Australasia (WHA)		Website (31)	2005
Scottish Intercollegiate Guidelines Networks (SIGN)	Scotland	No guideline	NA
National Institute of Clinical Excellence (NICE)	United Kingdom	VBAC is part of a larger guideline for Cesarean Section (32)	2004
New Zealand Guidelines Group (NZGG)	New Zealand	Website (33)	2004
Society of Obstetricians and Gynecologists of Canada (SOGC)	Canada	Journal (34)	2005
American College of Obstetricians and Gynecologists (ACOG)	United States of America	Received hard copy version from ACOG (35)	2004

Table 2: AGREE analysis of the 6 national VBAC guidelines.

	<i>Domain 1: Scope and purpose</i>	<i>Domain 2: Stakeholder involvement</i>	<i>Domain 3: Rigour of development</i>	<i>Domain 4: Clarity and presentation</i>	<i>Domain 5: Applicability</i>	<i>Domain 6: Editorial independence</i>	<i>Recommend for use in practice*</i>
	%	%	%	%	%	%	
RCOG	89	50	55	67	33	0	No
WHA	50	0	0	58	6	0	No
SOGC	100	50	33	75	17	0	No
NZGG	100	71	81	100	33	42	Yes
NICE	100	75	86	100	0	100	Yes
ACOG	100	21	50	58	11	0	No

*Would you recommend these guidelines for use in practice?

Table 3: VBAC success and uterine rupture rates reported in the six VBAC guidelines

<i>Guideline Publisher</i>	<i>Success Rate (%)</i>	<i>Uterine rupture rate</i>	<i>Uterine rupture rate as a percentage range</i>
RCOG	72 – 76	Eight rates quoted ranging from 22/10,000 to 74/10,000	0.2– 0.7%
WHA	70 – 80	One rate quoted: 30/10,000	0.3%
NZGG	60 – 80	Two rates/ranges quoted: 0.2-1.5% and 5.2/1000	0.2–1.5%
NICE	30 – 51	Three rates/ranges quoted: 0 – 28/1000, 35/10,000 and 50/10,000	0.0–2.8%
SOGC	50 – 85	One range quoted: 0.2-1.5%	0.2–1.5%
ACOG	60 – 80	One rate quoted: <1%	<1%

Table 4. Summary of the main practice points as described in each guideline.

	<i>RCOG</i>	<i>WHA</i>	<i>NZGG</i>	<i>NICE</i>	<i>SOGC</i>	<i>ACOG</i>
Choice of mode of birth	Should be able to discuss the option of planned VBAC	Women who want a vaginal birth should be supported with information' to aid their choice	Should be offered a planned VBAC	Women who want a vaginal birth 'should be supported with information' to aid their choice	'Should be offered' a Trial of labor	Ultimate decision should be between the woman and her physician
Electronic fetal monitoring during labor	Should be advised to have	Should be recommended	Possible risks and benefits should be discussed – no evidence that EFM improves outcomes'	Should be offered	Recommended	Most authorities recommend continuous EFM
Epidural anaesthesia during labor	Not contraindicated	May be used as indicated	May be offered	Not examined	Not examined	Not contraindicated
Induction of labor	Discuss risk if induction of labor required	PGs should not be used	IOL may be offered Not PGE1, PGE2 appears OK	Can be offered	Not contraindicated if oxytocin used, PGs should not be used	Use of PGs should be discouraged
Augmentation of labor	Not contraindicated	Not contraindicated	Careful use of syntocinon may be considered	Can be offered	Not mentioned	Spontaneous labor more likely to result in VBAC than IOL or augmentation

Key: IOL = Induction of labor; EFM = electronic fetal monitoring; PG = prostaglandin

Figure 1: Upper and lower range of VBAC success reported in 6 guidelines together with variations in reported uterine rupture rates. The highest reported value of uterine rupture in each guideline is presented.

