**“If you do what you always did, you will get what you always got.” RCOG Green-top Guideline No. 26 Assisted Vaginal Birth: a commentary**

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Running title: GTG no.26 on AVB, the shortcomings of a new guideline

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JW de L and JO D were both responsible for the conception and writing of this paper

Like all RCOG Green Top Guidelines (GTG), the recently updated GTG No 26. Assisted Vaginal Birth (AVB) guideline will be a key document informing institutional and clinician practice, as well as patient decision making, about instrumental delivery with forceps or vacuum. 1 This RCOG GTG will also have a significant international impact, especially as it is endorsed by the National Institute of Clinical Excellence (NICE).

As stated by the authors two new developments have occurred since the former 2011 guideline was published: the Montgomery ruling by the UK supreme court and the increasing risk of litigation

With the Montgomery ruling of 2015 the importance of informed consent is clearly defined and the ruling states that clinicians are:2

”*under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”*

In daily practice this means that the doctor has to ask the patient actively which parameters in the process of decision making are important for her or him, which means that the doctor needs to ask for this actively and has to inform patients of risks and whether these risks are material and if so whether the proposed treatment should be undertaken.

Therefore it is imperative that the GTG provides sufficient information to support the consent process by producing recommendations that are based on an accurate assessment of the *current* evidence, particularly with regard to the risks of assisted vaginal birth and risk-reducing interventions. In our opinion this isn’t the case in the sections dealing with the comparison of risks of maternal pelvic floor injury associated with vacuum and forceps AVB, and the role of mediolateral episiotomy for reducing the risk of Obstetric Anal Sphincter Injury (OASI). This warrants a critique of the evidence used to inform the relevant recommendations in the GTG and a commentary of the current evidence to ensure clinicians and patients are informed and can make well informed decisions that may reduce the risk of pelvic floor trauma and longer-term dysfunction, as well as reducing the risk of litigation.

Addressing the issue of comparative risk of maternal pelvic floor trauma with forceps versus vacuum, section 5.4 of the guideline provides little relevant or current evidence that may be used to support the recommendation that “Operators should be aware that forceps and vacuum extraction are associated with different benefits and risks”. In particular, the authors do not report the significantly greater risk of levator injury associated with a strongly increased risk of prolapse after assisted vaginal delivery with forceps. Instead the authors state that both vacuum and forceps birth are associated with pelvic floor pathology but seem to forget pelvic organ prolapse as they state ”Symptoms associated with pelvic floor trauma include pain, dyspareunia, and urinary and bowel incontinence”. As evidence that pelvic floor disorders are not associated with the type of instrument used, the authors rely on the results of a nested prospective study with a RCT describing only 200 primiparous women with a maximum follow-up of one year, As pointed out by the authors, their results may be limited by a sample size for a RCT powered to investigate the risk of OASIS with selective vs routine episiotomy at the time of OVD.3

Furthermore, in the risk-based information on page 23, there is a lack of current evidence presented about the impact of mode of delivery on the pelvic floor. It is well known that the risk of levator ani muscle avulsion associated with forceps delivery is 40-50% and that this risk is increased more than fourfold when forceps is used instead of vacuum for AVB (OR: 4.57, 95%-CI: 3.21–6.51).5 This type of pelvic floor damage is very important with regard to the risk of pelvic organ prolapse (POP) in later life with the accompanying risk of one or more operations to treat this condition. In a large register based study from Scotland, having delivered with forceps at least once, was an independent risk factor to undergo POP-surgery in later life.6 The prospective PROLONG study reported a 20% higher risk of prolapse symptoms, 12 years after one or more forceps deliveries.7

The GTG also states in the same information that bowel incontinence is common 6 weeks after delivery but that it improves over time. This is in contrast with the results of the PROLONG study which state that, in contrast with vacuum delivery, forceps delivery itself was associated with a higher risk of faecal incontinence 12 years later when compared with spontaneous delivery (OR: 2.08, 95%-CI:1.53– 2.85).8

Forceps delivery appears to carry a double risk for developing faecal incontinence as obstetric anal sphincter injury (OASI) is significantly more common after forceps delivery compared to vacuum delivery (8-12% with forceps vs 1-4% with vacuum). A large body of evidence shows that after OASI the risk of bowel incontinence does not improve over time and may even increase long after delivery with rates up to 40-50%.9

It is clear that any vaginal delivery causes damage to the pelvic floor and that some form of damage is inevitable. However, clinicians have the choice of an instrument for AVB that may possibly avoid unnecessary pelvic floor damage. It is therefore worrisome that the guideline gives only minor attention to the counselling process for an eventual AVB. As stated in paragraph 4.6 verbal consent is supposed to be sufficient for birth room procedures but written consent should be obtained for a trial of AVB in theatre. But, how to incorporate this in daily practice? If verbal consent is obtained anywhere in the antenatal period and during delivery a trial of AVB in theatre is indicated, who gives written consent and when will it be given? With the Montgomery ruling in mind, a special consent consultation anywhere in the late preterm period may be helpful during which every nulliparous woman, with her chance of one in three to end up with an AVB, can be properly counselled for all aspects of AVB. Women and clinicians may find support in their decision making and counselling in the recently developed model that estimates the risks of pelvic floor disorders in later life.10

The GTG also states that neither routine nor restrictive use of episiotomy during AVB is corroborated by evidence. According to the authors, the referenced two-centre pilot RCT is provided as the strongest evidence to support this overall conclusion.11 However, the weight given to this study is questionable as this was only a pilot study containing only 200 women. This suggests that a larger RCT would be conducted and published later, but this hasn’t happened to date. Furthermore, in the guideline only the general conclusion with regard to the outcome of OASI in operative vaginal delivery is used and states that there was no difference between a both policies of episiotomy during operative delivery. However, there was a huge difference between vacuum and forceps deliveries with regard to the actual rates of episiotomy. These differences makes both groups incomparable with regard to the policy of restrictive versus routine use of episiotomy and both groups should be interpreted separately. The separate results of forceps and vacuum deliveries show that this study was much too small to show a difference, leaving the authors conclusion to be based on the relatively unreliable scientifical evidence of an underpowered RCT

Evidence of observational studies on this subject is also mentioned. While smaller observational studies from single units are particularly prone to bias, large observational studies from prospective national databases should have warranted consideration in the guideline. Four such studies addressing the issue of episiotomy during OVD were published within the deadline of this guideline, with a recent review of these studies showing that use of mediolateral or lateral episiotomy is associated with a significantly reduced risk of OASI.12

Another possible problem arising from this GTG is that it contradicts the recommendation on the use of episiotomy in the NICE clinical guideline 190 “Intrapartum care for healthy women and babies”. Recommendation 1.13.21 states: “perform an episiotomy if there is a clinical need, such as instrumental birth or suspected fetal compromise”.13 As this new GTG is NICE endorsed, we think that the responsible reviewers may have overlooked this issue which may create a source of confusion for clinicians and pregnant women.

When comparing vacuum and forceps as possible instruments for AVB, the risk of failure is an important issue in the guideline which may form an important part of the counselling process antenatally. The GTG states that vacuum delivery is associated with failure rates up to 36% dependent on the type of vacuum cup used. This phenomenon, however, seems to be much less common in countries with possibly a stronger tradition of use of vacuum extraction. The argument that replacement of forceps delivery with vacuum delivery inevitably leads to a higher Caesarean rate in the second stage of labour isn’t necessarily true. Other European countries, e.g. the Nordic countries and the Netherlands, have much lower rates of forceps deliveries with still an acceptable overall rate of caesarean sections.14

The patient information associated with this guideline also states that vacuum extraction and forceps are both safe and effective. In the light of what we have written here, this statement seems to ignore important differences between both instruments. If concern for failure of vacuum extraction leads to an increased use of forceps to avoid the risk of an increased rate of caesarean sections in the second stage of labour, women may end up with merely an exchange of serious complications and consequences of their delivery. If vacuum extractions have a higher failure rate in the UK, whereas this seems to be a much lesser problem in other countries, modifications in training and circumstances in which this instrument is used may lead to a higher success rate. Exchange programs and international collaboration may be a possible way to solve this problem.

It is clear that use of merely mentioning pros and cons of different techniques of AVB without clear description of the actual rates of all, short and long-term, complications and consequences does not meet the conditions for counselling set out with the Montgomery ruling. This guideline gives insufficient basis for a balanced counselling of women with regard to AVB and possible pelvic floor disorders in later life.

Unfortunately, this guideline has missed the opportunity to provide clinicians with up-to-date evidence to support the informed counselling of pregnant women for, and performance of, assisted vaginal deliveries. Instead, it is merely a consolidation of the current practice and this inevitably leads to the situation that “if you do what you always did, you will get what you always got.”

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