Title: Clinical Review: Third stage of labour care

Abstract

Introduction Concerns exist regarding the suitability of international and national guidance informing third stage of labour care for some women. Review The robustness and appropriateness of the research evidence underpinning this guidance has been assessed, and areas for further research identified which may address gaps in knowledge. Findings International and national third stage of labour practice guidance, recommending active management for all women, probably cannot be generalised to women at low risk of PPH giving birth in a midwife-led unit or a home birth setting. This is due to reduced reliability, validity and generalisability of the evidence informing this guidance, to this group of women. Conclusions Expectant management may be more appropriate for women at low risk of PPH who choose to birth in a midwife-led unit or home birth setting and want to experience a birth with minimal intervention. However, more research into third stage management practices in midwife-led and home birth settings is needed.

Introduction

Labour is traditionally divided into three artificial divisions. The first stage consists of the woman giving birth experiencing regular, painful contractions, with progressive cervical dilation from 4 cm until fully dilated at 10 cm. The second stage continues from when the woman's cervix is fully dilated until the birth of the baby. The third stage is the period of time between the birth of the baby and the birth of the placenta and membranes (NICE, 2017). There is always some blood loss during this third stage, and care aims to reduce excessive blood loss. In clinical practice care is managed by two distinct clinical approaches: active management and expectant

management (often referred to as physiological management) (Begley et al. 2019). This paper reviews evidence on the effectiveness of these approaches and the implications of this research for current practice guidelines for some women.

Current use of active and expectant management

Active management aims to accelerate delivery of the placenta to reduce blood loss. A prophylactic uterotonic drug (exogenous oxytocin) is given to accelerate the contractility of the uterus, to cause the placenta to separate from the uterus wall more quickly. Other components of active management include delayed cord clamping, cutting of the cord and controlled cord traction (NICE, 2017; RCOG, 2016). The main principle of expectant management is to support the woman during labour and birth so her body can produce optimal levels of endogenous oxytocin. The practitioner also watches and waits for signs of placental separation, after which the placenta is birthed spontaneously or with the aid of gravity and maternal pushing (NICE, 2017). Anything that interferes with this oxytocin release by the woman's body will reduce the effectiveness of a physiological third stage of labour (Buckley, 2004; 2015; Fry, 2007; Inch, 1985). Hence, expectant management would not be appropriate. Consequently, expectant management of the third stage of labour is only appropriate for women who have had a normal physiological birth*.

In practice, although not recommended in clinical guidelines and perhaps not intentional by the practitioner, a mixed management approach often occurs (Begley et al. 2019; Harrison, 2006; Winters et al. 2007). This approach combines some of the components of both expectant and active management, but without completely containing all the components of either (Begley, et al. 2019), for example: (1) early

uterotonic administration, cord clamping after pulsation ceases and controlled cord traction; or (2) delayed uterotonic administration until cord pulsation ceases, then cord clamping and controlled cord traction.

At present, active management of the third stage of labour is the more common approach in the UK and Ireland, as in most high-income countries (Begley et al., 2019); although expectant management is sometimes practiced by midwives in the UK, other northern European countries and New Zealand; mainly in midwife-led units and home birth settings (Begley et al. 2009; Blackburn 2008; Fry, 2007; Kanikosma 2007) or by midwives providing continuity of carer models of maternity care (Homer et al, 2017; Sandal et al. 2016).

Midwives who work in midwife-led units or home birth settings and women who choose to birth in these setting are more likely to value minimal intervention (Shallows 2003; Walsh 2012). Women who choose to birth in midwife-led units and home birth settings are also more likely to be at low risk of obstetric complications; hence the use of expectant management may be more suitable for them. In low-income countries expectant management is more commonly practised for community and home births (Begley et al. 2019).

Studies have shown that when women are offered expectant management as a reasonable option, they will choose it (Begley et al. 2011a; Davies et al. 2012, Dixon et al. 2009; 2013; Fahy et al. 2010; Gottvall et al., 2011, Grigg et al. 2017; Kataoka et al. 2018; Laws et al. 2014; Monk et al. 2014; Rogers et al. 1998). Furthermore, the UK National Collaborating Centre for Women and Children's Health (2014) also

acknowledges that some women may want to experience a birth with minimal intervention and request a physiological third stage of labour.

Guidance on management of the third stage

Current international and national guidance on management of third stage of labour advocates active management (International Confederation of Midwives [ICM] and the International Federation of Gynaecology and Obstetrics [FIGO] [ICM-FIGO] 2006; 2003; NICE, 2017; Royal College of Obstetricians and Gynaecologists [RCOG] 2016; WHO 212, 2018; Royal College of Midwives [RCM] 2018). This is as a result of the reduction in and treatment for postpartum haemorrhage (PPH) found in research studies with active management compared with expectant management in women identified as at high and low risk of PPH (Begley 1990; Begley et al. 2011b, 2015; de Groot van Roosmalen et al. 1996; Prendiville et al. 1988; Prendiville et al. 2000; Rogers et al.1998; Thilaganathan et al.1993). PPH is defined as blood loss of 500 mL or more from the vaginal tract after the birth of the baby (WHO, 2012).

Below we examine the robustness of the research evidence underpinning these third stage of labour guidelines. We highlight a number of concerns about the appropriateness of some aspects of the guidance for women at low risk of PPH, who choose to birth in a midwifery-led unit or home birth setting who want to experience a labour and birth with minimal intervention. Indications for future research are also suggested.

Research studies informing current guidance

The Cochrane systematic review by Begley et al. (2011b) included Begley (1990); Prendiville et al.'s (1988); Rogers et al.'s (1998) and Thilganathan et al.'s (1993) research studies, that compared active verse expectant management for women expected to give birth vaginally within an obstetric-led hospital unit. The review findings were that when generalising across all women, irrespective of their risk factors for bleeding, active management reduced maternal blood loss after birth and the incidence of "minor PPH", (estimated blood loss of 500 -1000 mL) or "severe PPH" (estimated blood loss of 1000 mL or more), compared to expectant management. Active management also reduced the treatment needed for this excessive blood loss, leading to a reduction in the use of therapeutic oxytocic drugs, anaemia and blood transfusion. The duration of the third stage of labour was also found to be shorter with active management.

However, for women identified only as at low risk of PPH, the Begley et al. review did not identify any statistically significant difference for severe PPH or incidences of anaemia. This is important, as research studies have found that well-nourished, healthy women are able to compensate for a blood loss of up to 1000 mL (Blackburn 2008; Cunningham & Williams 2001; Oishi et al. 2017). Therefore, active management may be of limited value to this group of women. The most recent Cochrane review Begley et al. (2019) also commented that potential harms of active management are more concerning in women at low risk of PPH. This was because the potential benefits of reducing severe PPH through active management in the RCTs were less evident for this group. Begley et al. (2019) advocated further studies

comparing active with expectant management in women at low risk of PPH to confirm if there is a difference in severe bleeding.

Begley et al. (2011b)'s review also found that compared with expectant management, active management showed a statistically significant increase in the need for postnatal analgesia. The review also found an increase in women returning to hospital as an outpatient, because of bleeding and a decrease in the baby's birth weight. This reduction in birth weight was possibly caused by the practitioner clamping the umbilical cord early, therefore reducing the volume of placental blood transfusion. In term infants, this may reduce the baby's blood volume at birth by about 20% (Werner, 2005).

Cutting the cord before it stops pulsating has also been found to increase the risk of iron deficiency anaemia in term infants (Anderson et al. 2011; Chararro et al. 2006). As a result of these adverse effects, NICE (2017), RCM (2018) and the WHO (2014; 2018) recommend not clamping and cutting the cord for at least 1 minute after the birth in an actively managed third stage.

The findings of Begley et al. (2011b) informed the RCOG (2016) and WHO (2012; 2018) third stage of labour guidelines and recommendations. Begley et al. subsequently updated and replaced the Cochrane review (Begley et al. 2015). Their updated 2015 review informed the RCM (2018) third stage of labour practice recommendations. This review has recently been updated and replaced again by Begley et al. (2019). Despite conducting more up to date literature searches, no new studies were identified in these updated reviews (Begley et al., 2015; 2019), that

compared active versus expectant management of the third stage of labour in women identified as at low risk of bleeding or its effects or in women irrespective of their risk. Therefore, the in these updated reviews the recommendations for these women, regarding active compared with expectant management remain the same as Begley et al. (2011b) initial review.

The RCTs by Prendiville et al. (1988), Rogers et al. (1988) and Thilaganathan et al., (1993), which were included in Begley et al.'s (2011b) Cochrane review, were also used to inform NICE (2017) guidance, regarding active versus expectant management approaches during the third stage of labour for women at low risk of obstetric complications. Another RCT by de Groot et al. (1996) which compared intramuscular oxytocin with a placebo and was also used to inform the recommendation of active management within the NICE (2017) guidelines.

Assessing the research evidence

The evidence regarding third stage of labour care has not only informed the above international and national third stage of labour guidelines and recommendations, but also influenced local maternity guidelines. However, the evidence underpinning these guidelines is not without question, particularly for women at low risk of PPH who choose to birth in a midwifery-led unit or home birth setting and want to experience a birth with minimal intervention.

Appropriateness of comparisons/evidence

The Cochrane reviews by Begley et al. (2011b, 2015, 2019) included 4 RCTs, consisting of 4829 women in total that compared active versus expectant management (Begley 1990; Prendiville 1988; Rogers et al. 1998; Thilaganathan et

al. 1993). Although in all the RCTs, women were identified as healthy pregnant women expected to give birth vaginally within a hospital obstetric-led unit only three out of these four RCTs identified women at the beginning of the study that were classified as being at low risk of bleeding or its effects (Begley 1990; Rogers et al. 1998; Thilaganathan et al.1993).

The Begley et al. reviews (2011b, 2015, 2019) themselves noted a lack of rigour, even though some of the RCTs included in these reviews did present power calculations and PPH rates. The RCTs may have been biased towards active management: for example, the RCT by Prendiville et al. (1988) included women identified as at high risk of PPH, and so were not suitable for expectant management. This is because expectant management is only appropriate for women who are at low risk of PPH and have had a normal physiological birth. Furthermore, many of the women in these RCTs developed risk factors for PPH during labour. Therefore, by the time they reached the third stage of labour, despite being identified to be of low risk of PPH on trial entry, they were at high risk of PPH (Begley 1990; Rogers et al. 1998). Again, these women should also not have been included in studies comparing active with expectant management, as expectant management was clearly not appropriate for them. For example, in the study by Begley (1990) 27% of women in both active and expectant management groups had their labour induced, accelerated, or augmented using synthetic oxytocin, and as a result clearly did not have a normal physiological birth. Additionally, in the Prendiville et al. (1988) RCT, 24% of women who received expectant management had their labour inducted or augmented by oxytocin.

However, Begley (1990) found no significant difference between the use of synthetic oxytocin for labour induced, accelerated, or augmented in the active and expectant management group (p=0.9). Additionally, the number of women who received oxytocin to induct or augment their labour was similar in expectant and active management groups within the study by Prendiville and colleagues (1988).

Nevertheless, the use of oxytocin in labour can interfere with the woman's own physiological production of oxytocin (Buckley, 2009; 2015; Uvnaas & Moberg, 2011). Consequently, the use of synthetic oxytocin for labour induction, acceleration or augmentation would be riskier, with regards the increasing the risk of bleeding during the third stage of labour with expectant management. Therefore, including these women in both groups in these RCTs is not a fair test of expectant management and hence skews findings towards active management. NICE (2017) also state that the use of oxytocin in labour is among the risk factors for PPH.

The RCTs by Begley (1990), Prendiville et al. (1988) and Rogers et al. (1998) also included women who had episiotomies and although the Begley (1990) study showed that there was no significant difference in episiotomies performed between active and expectant management groups, and the study of Rogers et al. (1998) showed that the episiotomy rates in active and expectant management groups were similar (11.6% compared with 12.3%), episiotomies are identified as a risk factor for PPH (NICE, 2017). This is due to the increased risk of bleeding from the episiotomy site, as the third stage of labour can potentially take longer with expectant compared with active management consequently delaying repair of the episiotomy site, resulting in increasing blood loss. Therefore, episiotomies would be riskier with regards to the increasing the risk of bleeding during the third stage of labour with

expectant management. Hence including these women who had an episiotomy in both groups is again not a fair test of expectant management and so skews findings towards active management.

Additionally, the RCT by de Groot et al. (1996), which informed NICE (2017) third stage guidance, did not compare active with expectant third stage of labour management. This study compared intramuscular oxytocin or a placebo. No other component of active or expectant management was reported. This questions the relevance of Begley (1990), Rogers et al. (1998) and Prendiville et al. (1988) and de Groot et al.'s (1996) findings when examining active versus expectant management of the third stage of labour for women identified as low risk of PPH who have had a normal physiological birth.

The RCT by Begley et al. (1990) also reported the use of intravenous ergometrine as the uterotonic drug for women having active management. The use of ergometrine alone is no longer recommended in current practice for active third stage of labour management, which calls into question the contemporary relevance of this study. The smaller scale RCT by Thilaganathan et al. (1993), including women at low risk of PPH, failed to present a power calculation or PPH rates and presented only rounded mean blood loss figures. Hence this study may have reported biased results.

The effect of midwives' experience in third stage management

In all these RCTs, active management of the third stage of labour was routine. As a result, midwives were more experienced in conducting active management. The experience of healthcare professionals in conducting third stage management

approaches is important in reducing blood loss during the third stage of labour or shortly after (Begley et al. 2011a; Davis et al. 2012; Dixon et al. 2009; Fahy et al. 2010; Grigg et al. 2017; Laws et al. 2014; Monk et al. 2014). This is evident in the RCTs by Begley (1990) and Rodgers et al. (1998). These studies found that midwives who did not routinely use expectant management needed time to become familiar with it. Once midwives in these studies were familiar with expectant management, the blood loss during the third stage of labour reduced. In Begley's (1990) RCT, the PPH rate in the expectant management group dropped during the trial from 21% in the pilot study to 12% in the first 4 months, and to 7% in the last 6 months of the main study.

Additionally, blood loss in these RCTs was assessed mainly through visual estimation from the healthcare practitioner. It is widely acknowledged that blood loss during the third stage of labour or shortly after birth is difficult to assess accurately and is frequently under-or over-estimated by practitioners (Razv, Chua, Arulkumaran & Ratnam, 2008; Schorn, 2010). Additionally, it was not possible to double blind assessment of blood loss in these RCTs. Therefore, the estimation of blood loss was open to considerable observer/assessor bias in these RCTs and if active management was the routine third stage of management approach in these studies this observer/assessor bias may have skewed findings towards active management.

Place of birth and third stage of labour

All of these RCTs also focused on women giving birth in hospital obstetric-led units.

Place of birth is important as more recent cohort studies conducted outside of the UK have shown that women who birthed in midwife-led as opposed to obstetric-led units,

experienced a reduced blood loss during the third stage of labour or shortly after, with expected management as opposed to active third stage management (Davis et al. 2012; Fahy et al. 2010). Additionally, a lower incidence of PPH have been found in midwife-led units, despite an increased rate of expectant management and a reduced rate of active management, in comparison to the obstetric-led units (Dixon et al. 2009, Grigg et al. 2017, Laws et al. 2014; Monk et al. 2014). An RCT by Begley et al. (2011a) also found that despite an increase in expectant management, in a midwife-led unit compared to obstetric-led units, there was no statistically significant difference in estimated mean blood loss during the third stage of labour or shortly after, or in the incidence of PPH.

Strength of the evidence

Therefore, the reliability, validity and generalisability of these RCTS informing NICE (2017), RCOG (2016) and WHO (2012; 2018) and RCM (2018) third stage of labour guidance is questionable, particularly for women at low risk of PPH who choose to birth in midwife-led units or home birth settings. In fact, the National Collaborating Centre for Women's and Children's Health (2014) graded the quality of evidence supporting NICE's (2017) guidelines; regarding active compared with expectant management and incidence of PPH as low (de Groot et al. 1996, Prendiville et al.1988; Rogers et al. 1998) and severe PPH as very low (de Groot et al.1996; Prendiville et al. 1988; Rogers et al. 1998). This was as a result of the risk of bias, inconsistencies and indirectness in the studies.

Additionally, the latest Cochrane review (Begley et al. 2019) graded the quality of evidence examining the incidence of PPH as low quality (Begley 1990, Rogers et al. 1998) and the quality of evidence examining the incidence of severe PPH (Begley

1990, Rogers et al. 1998) and haemoglobin less than 9 at 24 hours (Thilaganathan et al.1993) as very low-quality. The quality of evidence regarding mean maternal blood loss (Begley 1990, Rogers et al. 1998; Thilaganathan et al. 1993) and maternal blood transfusions was also graded as low quality. However, the quality of evidence examining the use of therapeutic uterotonic during the third stage and/or within the first 24 hours was graded as moderate (Begley, 1990, Rogers et al. 1998; Thilaganathan et al. 1993). This was again as a result of the risk of bias, inconsistencies and indirectness in the studies.

Conclusions

Practice guidelines and recommendations by NICE (2017); RCM (2018); RCOG (2016) and WHO (2012; 2018) which recommend active management for all women probably cannot be generalised to women at low risk of PPH, giving birth in a midwife-led unit or at home, who want to experience a birth with minimal intervention. This is due to the discussed limitations in the reliability, validity and generalisability of the evidence informing these practice guidelines.

Expectant management may be more appropriate for women at low risk of PPH who choose to birth in a midwife-led unit or home birth setting and want to experience a birth with minimal intervention. However, more research into third stage management practices in midwife-led and home birth settings and midwives' perspectives on these is needed. This research could help to clarify the extent to which the apparent risks of expectant management might be a consequence of limited training, confidence or experience of the practitioner or organisational culture rather than a consequence of the management approach.

Keywords:

Third stage of labour management; Active management; Expectant management; Physiological management, postpartum haemorrhage

Key points:

There is always some blood loss during this third stage, and care aims to reduce excessive blood loss.

In clinical practice care during the third stage of labour is managed by two distinct clinical approaches: active management and expectant management (Begley et al., 2019)

At present, active management of the third stage of labour is the more common approach in the UK, Ireland and in most high-income countries (Begley et al., 2019). Expectant management of the third stage of labour is only appropriate for women, who have had a normal physiological birth and want to experience birth with minimal intervention.

The reliability, validity and generalisability of the RCTs informing third stage of labour guidance is questionable, particularly for women at low risk of PPH who choose to birth in midwife-led units or home birth settings.

Reflective questions:

- 1. Do you think third stage of labour practice guidelines and recommendations present robust evidence regarding third stage of labour management approaches for women at low risk of PPH, who birth in midwife-led units or at home?
- 2. How have you come to this conclusion?

- 3. Do you think current third stage of labour guidelines and recommendations can be generalised to women at low risk of PPH, who birth in midwife-led units or at home and want to experience a normal with minimal intervention?
- 4. How have you come to this conclusion?
- 5. What influences your own third stage of labour practice?

*A normal physiological birth is one defined by World Health Organisation (WHO, 1997) as one where labour occurs spontaneously, and the woman is at low risk of obstetric complications at the start of labour and remains low risk throughout labour and birth. The baby is born spontaneously and in the head-down position between 37 and 42 completed weeks of pregnancy. After birth, woman and baby are in good condition, meaning that there are no concerns regarding the woman's or the baby's physiological wellbeing after the birth.

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