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Delayed cord clamping with stabilisation at all preterm births – feasibility and efficacy of a low cost technique

Sarah E. Bates[a,*], Thomas C.W. Isaac[a], Rose L. Marion[a], Victoria Norman[b], Joanna S. Gumley[a], Charlotte D. Sullivan[c]

[a] Department of Paediatrics and Neonatology, Great Western Hospital, Marlborough Road, Swindon, SN3 6BB, UK
[b] Department of Midwifery, Great Western Hospital, Swindon, Wiltshire, UK
[c] Department of Obstetrics, Great Western Hospital, Swindon, Wiltshire, UK

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ABSTRACT

Objectives: Meta-analysis data suggests that Delayed cord clamping (DCC) in preterm infants is associated with a 32% reduction in mortality. Reported rates of this intervention are low, particularly for caesarean deliveries. Perceived difficulties providing respiratory support and thermal care during DCC may be barriers to implementation of this intervention. Commercially available equipment to facilitate this can be expensive. This study aimed to evaluate the feasibility and efficacy of a simple, low cost technique to deliver respiratory support and thermal care during DCC at all preterm deliveries (including caesarean), with the hypothesis that this could increase rates of preterm infants receiving DCC.
Study design: Data was collected retrospectively from 46 infants born at <32 weeks gestation in 2015. The technique was introduced in early 2017, as part of a perinatal Quality Improvement project. Data was collected prospectively from 63 infants born at <32 weeks gestation in 2017-2018.
Results: Rates of DCC in infants born <32 weeks gestation have increased from 12.5% in 2015 to 89.4% in 2017-2018. In 2017–2018, thermal care and respiratory support was provided to all infants who received DCC.
Conclusion: Multidisciplinary perinatal team working allowed development of a simple, low cost technique to deliver DCC at all preterm deliveries. We have demonstrated feasibility and efficacy of this technique, and a significant and sustained improvement in rates of DCC in our preterm population. We hope that by sharing this approach, other centres will be able to implement a similar strategy, closing the gap between evidence base and translation into clinical practice, and allowing provision of DCC for preterm infants as a standard part of high quality perinatal care.

Introduction

As survival after extremely premature birth increases [1], focus is now on optimising outcomes for this vulnerable population. This includes implementation of evidence based perinatal interventions to minimise brain injury in preterm infants [2]. One such intervention is Delayed Cord Clamping (DCC). The Cochrane Review on this topic states "*delaying cord clamping for 30–120 seconds, rather than early clamping, seems to be associated with less need for transfusion (risk ratio (RR) 0.61, 95% confidence interval (CI) 0.46–0.81), better circulatory stability, less intraventricular haemorrhage (all grades) (RR (Risk Ratio) 0.59, 95% CI (Confidence Interval) 0.41–0.85) and lower risk for necrotising enterocolitis (RR 0.62, 95% CI 0.43–0.90)*" [3]. An updated meta-analysis demonstrated a significant reduction in hospital mortality in preterm infants who had received DCC (RR 0.68; 95% CI 0.52–0.90) [4].

European and International consensus guidelines now recommend DCC for preterm infants [5–7]. The 2015 Resuscitation Council UK (RCUK) Newborn Life Support (NLS) guidelines recommend that all "*uncompromised infants* [should receive] *a delay in cord clamping of at least one minute*" [5]. Despite the increasing evidence of benefit, available figures suggest suboptimal delivery of this intervention. The Canadian Neonatal Network in 2016 reported only 48% of infants born at less than 29 weeks gestation received DCC [8]. Similar rates are reported from a large cohort in Nepal [9]. Data from our unit reflect that in 2015, only 15% of infants born at less than 32 weeks gestation received DCC [10].

Barriers to implementation of evidence based change are well recognised, and include "*knowledge (ie: lack of awareness or familiarity with the guidelines), attitudes (ie: lack of agreement with the evidence or differences in perception of the risk to benefit ratio), and behaviour (ie: external barriers, including insufficient time or*

* Corresponding author.
E-mail address: Sarah.bates16@nhs.net (S.E. Bates).

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resources)" [11]. Locally, we found that concerns around ability to provide thermal care and respiratory support during DCC were significant barriers to implementation [10]. As hypothermia amongst preterm infants is associated with increased morbidity and mortality [12] it is essential to provide appropriate thermal care during DCC.

Regarding provision of respiratory support during DCC, NLS (RCUK) guidance states that: *"For infants requiring resuscitation, resuscitative intervention remains the immediate priority"* [5]. There is a growing body of evidence, predominantly from animal studies, to suggest lung inflation is important prior to clamping the cord [13,14]. Provision of ventilatory support during DCC in preterm infants has been demonstrated to be feasible and safe [15]. For preterm infants, the ability to provide airway and respiratory support with thermal care during DCC should be viewed as a crucial part of its successful delivery.

Emerging evidence suggests that, for infants who appear to require resuscitation (who often would have early cord clamping to facilitate this), providing resuscitation and stabilisation with the cord intact is beneficial [15], thus allowing these infants to experience the benefits of DCC. Work has also been undertaken to explore prolonged stabilisation with the cord intact, including for those infants who appear to require resuscitation [16–18].

DCC with respiratory and thermal support can be delivered at vaginal birth using a standard plastic bag and hat (non-sterile) for thermal care. Respiratory support can be delivered by moving a resuscitaire device close to the mother, using a T-piece device such as a NeoPuff™ (Fischer & Paykel, Berkshire, UK) to provide PEEP (Positive End Expiratory Pressure) or inflation breaths as required, to establish lung aeration prior to cord clamping. The infant can be managed by the perineum, or skin to skin on the mother's abdomen (depending upon cord length), during DCC.

However, it is the sterile nature of caesarean delivery that has seemed to pose a major barrier to implementation of effective respiratory and thermal support during DCC. With around half of all preterm infants being delivered by caesarean delivery and rates reported to be increasing [19], it is vital that this significant proportion of the preterm population do not miss out on the benefits of DCC.

There has been increasing attention paid to overcoming these barriers to provide delayed cord clamping with thermal care and respiratory support during DCC at all types of preterm deliveries [16–18,20–22]. Some of the solutions include bespoke medical devices to enable resuscitation during DCC, such as the Bedside Assessment, Stabilisation and Initial Cardiorespiratory Support (BASICS) trolley (Department of Women's and Children's Health, University of Liverpool, Liverpool, UK, in collaboration with Inditherm Medical, Rotherham, UK) [20]; the Lifestart™ bed (Inditherm Medical, Rotherham, UK) [21]; and the Concord Neonatal™ (Luris, Leiden, The Netherlands)22]. However, the cost of these devices can be prohibitive for many Maternity and Neonatal Units, and certainly may present a barrier to implementation in low income or resource-poor settings. 'Alongside' techniques may also not be feasible where the cord length is short.

This project aimed to develop and implement a technique to deliver thermal care and respiratory support during DCC at all preterm deliveries, with the goal that almost all preterm infants would be able to experience the benefits of DCC. This report aims to share this technique with other perinatal teams, to increase the number of preterm infants receiving DCC.

Methods

Setting

The Great Western Hospital (GWH), in Swindon, Wiltshire, averages 4500 births per annum. It has an 18 cot Local Neonatal Unit (LNU) operating within the South West Neonatal Operational Delivery Network, with a Consultant Led Maternity Unit, and co-located Midwifery Led Birth Centre.

Development of technique and overcoming barriers

In 2016, neonatal, obstetric and midwifery teams worked together using simulation to develop a simple, low cost technique to enable the delivery of thermal care and respiratory support during DCC at all preterm deliveries (including caesarean). During the development of this, we trialled an alongside technique (such as those used by the medical devices listed above [20–22]), but often found that cord length prevented this from being a feasible method. A recent review talked about the importance of ensuring the cord is not kinked or stretched during DCC [23]. Papers have reported average cord length being between 35 and 50cm [24]. In our experience, this could make an alongside technique challenging, as the cord is often not long enough to facilitate this.

Another challenge was to find a sterile mode of delivering thermal care to prevent evaporative heat loss during DCC at caesarean delivery, as most of the polythene wrap and bag products that are available are not sterile. We initially trialled the use of a sterile adult arm burns dressing bag, with the infant laid on a thermal gel mattress (TransWarmer™, CooperSurgical, CT, USA), with the gel mattress inside a sterile Mayo stand cover. This was placed on the mothers thighs, immediately below the caesarean field. Later, a bespoke sterile Neonatal Heat Loss Prevention Suit (NeoHELP™, Vygon, Swindon, UK), became available, this was used at caesarean delivery. Review of neonatal admission temperature data demonstrated that the thermal gel mattress was not required in addition to the NeoHELP™, the technique was modified to reflect this. At caesarean section, respiratory support is provided by a scrubbed, sterile member of the Neonatal team using a new T-piece respiratory support device such as a NeoPuff™ (Fischer & Paykel, Berkshire, UK) to provide PEEP (Positive End Expiratory Pressure) or inflation breaths as required, to establish lung aeration prior to cord clamping. The T-piece is held by the Neonatal team member and does not directly encroach upon the caesarean field. Our experience demonstrates it is feasible to provide effective PEEP (and lung inflation, if required) using this technique on the mother's thighs.

We describe the techniques in flow charts (Figs. 1 and 2):

Studies have looked at the application of 'Pit-stop techniques' used in motor racing (such as Formula One) to neonatal resuscitation, particularly in the use of team positioning diagrams [25,26]. Utilising these techniques, we created aerial viewpoint positioning diagrams to aid with positioning of staff and equipment during DCC (Figs. 3 and 4):

Implementation

We started using these techniques for DCC with increasing frequency in late 2016 and early 2017 as part of a Quality Improvement Project (QIP) to implement a perinatal package of care for all infants born at less than 32 weeks gestation. We recruited QI champions (authors CS (Obstetrics), SB (Neonatology), VN (Midwifery)), who were principally responsible for driving forward practice in DCC, both in terms of increasing awareness about the benefits, but also with staff training, including numerous simulation sessions. A simulated caesarean section preterm delivery with DCC using the above technique was filmed. This was used to ensure implementation of effective DCC in our unit was maintained despite turnover of medical, nursing and midwifery staff.

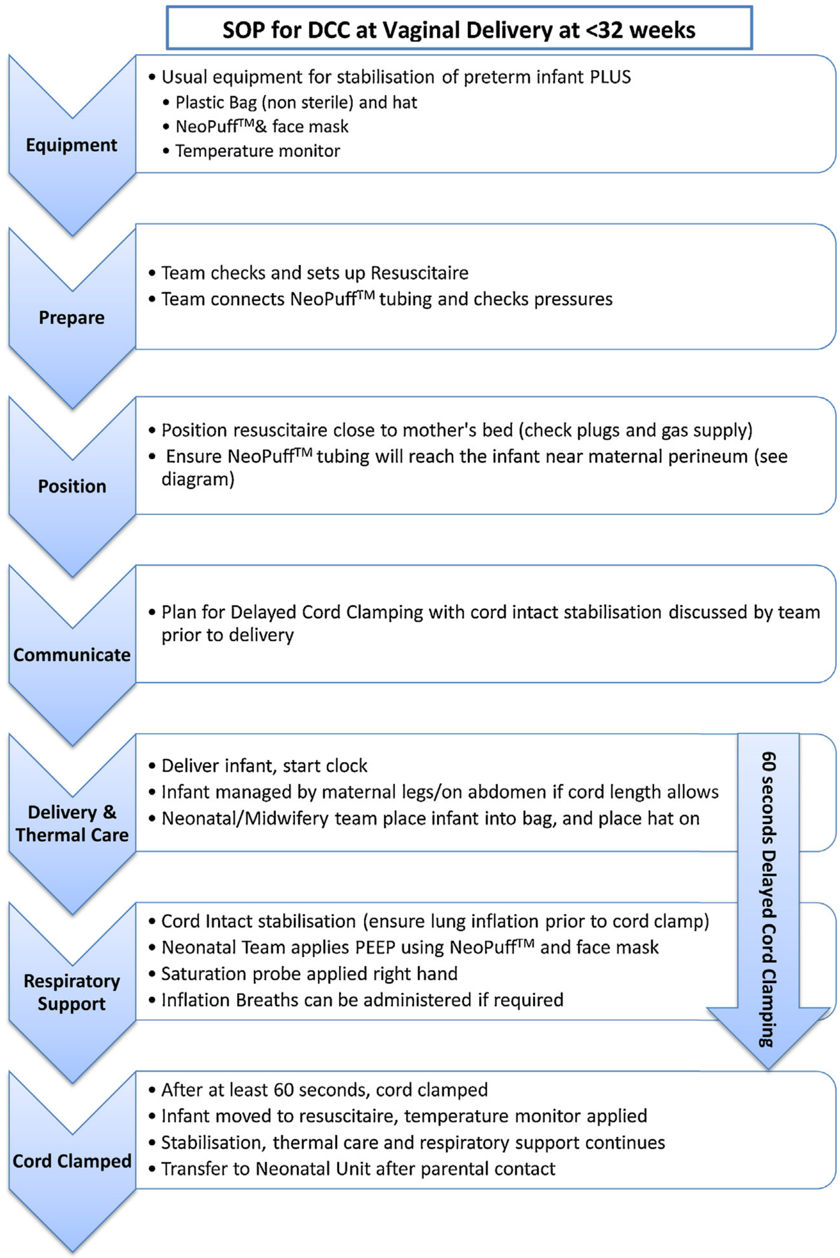

Fig. 1. Standard Operating Procedure for Delayed Cord Clamping at Preterm Vaginal Delivery.

Data collection

Data was obtained retrospectively for a cohort of infants born in our unit between January 1st to December 31st 2015. The Perinatal QI Project launched in January 2017. Data was collected prospectively and contemporaneously from every infant born at less than 32 weeks gestation admitted to our unit from January 2017 to July 2018. Infants were excluded if they were outborn, or delivered before arrival to hospital.

Outcomes

Primary outcome data included: provision & timing of DCC, provision of simultaneous respiratory support during DCC, and temperature on admission to the Neonatal unit.

Secondary outcome data included: survival to discharge; severe necrotising enterocolitis (NEC), defined as Bell Stage II or III [27]; and severe perinatal brain injury, defined as Grade 3–4 IVH on cranial ultrasound (Papile criteria [28]), or the presence of MRI or Cranial ultrasound changes of periventricular leukomalacia at term equivalent age. MRI changes were reported by a Consultant Radiologist with expertise in Paediatric neuro-imaging.

The development of this technique formed part of a wider Quality Improvement Project to increase rates of evidence-based perinatal interventions. Data was collected as part of routine neonatal care, and therefore it was determined that parental consent and ethical approval was not required. The data was anonymised pre-analysis.

Statistical methods

Rates of DCC were reviewed using run charts as part of QI methodology [29]. Admission temperature was also reviewed using run charts. The number of preterm infants receiving DCC, DCC for more than 60 s, DCC with thermal and respiratory support,

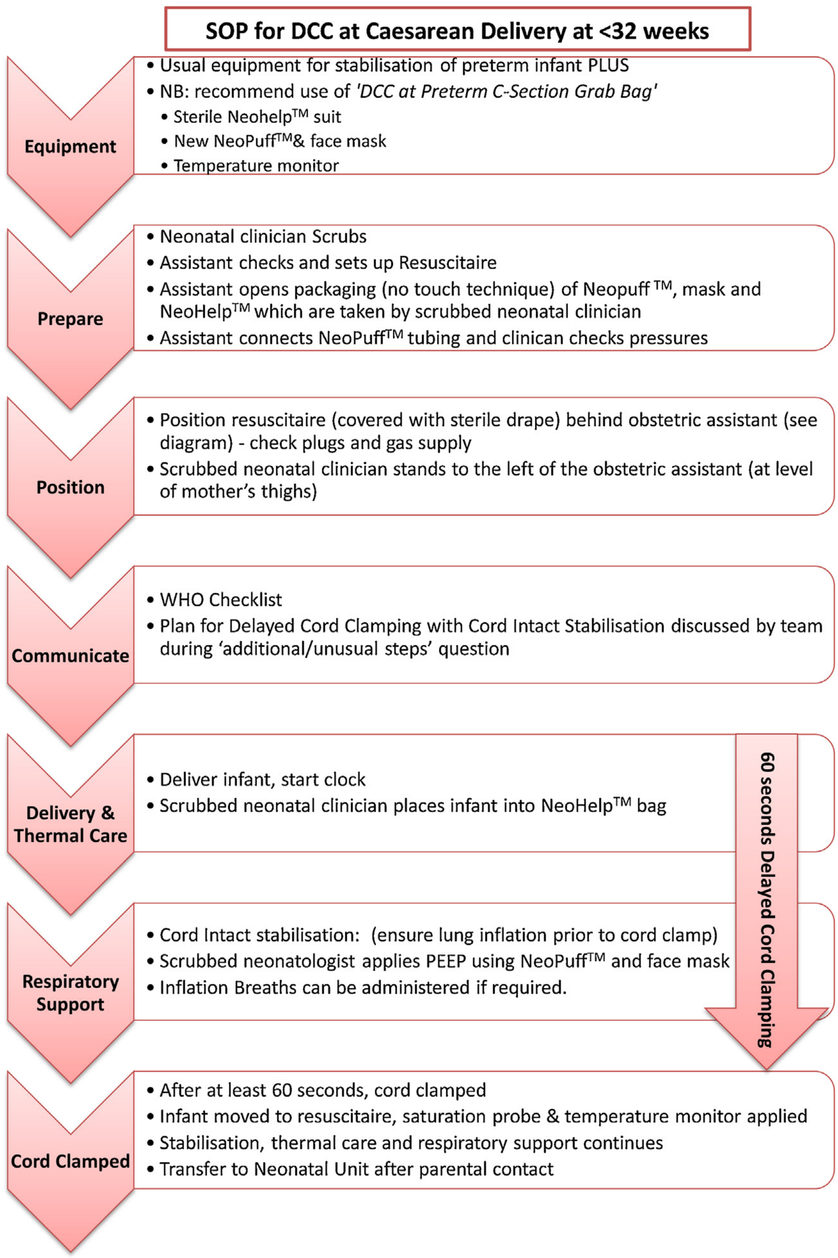

Fig. 2. Standard Operating Procedure for Delayed Cord Clamping at Caesarean Delivery.

and the incidence of secondary outcomes pre and post QIP were analysed using the Fisher's Exact test.

Results

Between January 1st and December 31st 2015, 46 infants were admitted at less than 32 weeks gestation. 14 infants outborn were excluded. Data was collected on 32 infants, the pre QIP cohort.

Between January 15th 2017 and 29th June 2018, 63 infants were admitted at less than 32 weeks gestation. 16 infants were excluded because they were outborn or unexpected home deliveries. Data was collected on 47 infants for analysis, the post QIP cohort.

Demographic characteristics

Both cohorts had similar demographic characteristics in terms of gestation, birth weight, and similar rates of administration of antenatal steroids and Magnesium sulphate (Table 1).

Outcomes

We have seen sustained improvement in the proportion of infants receiving DCC ($p < 0.00001$). All infants who received DCC in the post intervention cohort also received thermal care and respiratory support, with PEEP and inflation breaths if required, during DCC. This has been demonstrated in both caesarean and vaginal deliveries (see Table 2, and Figs. 5 & 6). During September to November 2017, there were no caesarean deliveries at less than 32 weeks, resulting in a missing data point for this date range.

There are two periods in which the proportion of infants receiving DCC was reduced (Jul-Sept' 17 and Jan-Mar' 18). The reason for early cord clamping in these cases was reviewed, and found to be:

- 'obstetric concerns' in a second twin, delivered by caesarean section.

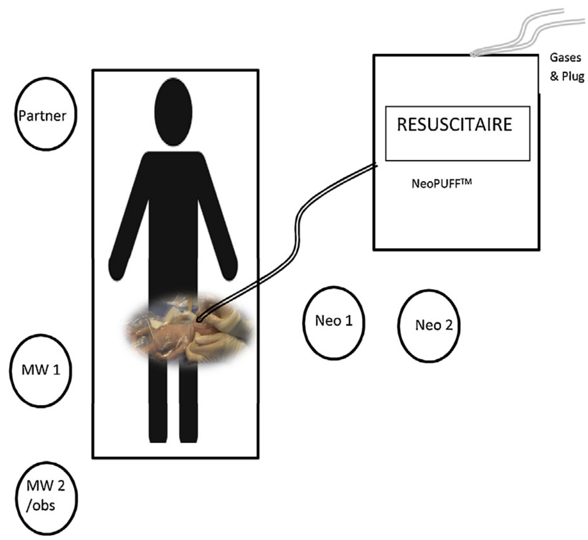

Fig. 3. Positioning Diagram for Delayed Cord Clamping at Preterm Vaginal Delivery.

- two precipitous deliveries: one infant born with cord and arm prolapse requiring extensive resuscitation, and one delivery with no paediatricians present until 40 s of life.

Mean temperature during 2015 was 36.6 °C (SD 0.42 °C). Since intervention mean admission temperature has been 37.25 °C (SD 0.91 °C). We have now implemented temperature monitoring in delivery suite prior to transfer as part of our protocol.

Secondary outcomes

Outcome data was available for all 32 infants in the pre QIP cohort, and 46/47 infants in the post QIP cohort. Encouraging outcome data is noted with respect to reduction in mortality (9.4% to 2.1%), and incidence of severe Necrotising Enterocolitis (NEC) (12.5% to 4.1%) and severe brain injury (15.6%–8.2%), see Fig. 6. These changes did not achieve statistical significance.

Comment

The gap between research evidence and translation into clinical practice is well recognised for preterm infants, as is the benefit for those infants who receive a package of evidence based perinatal interventions [30,31]. With evidence suggesting a 32% reduction in hospital mortality for preterm infants who receive DCC [4], it seems clear that this intervention should be part of a perinatal preterm package of care. However, provision of thermal care and respiratory support at preterm delivery are also very important [12–16].

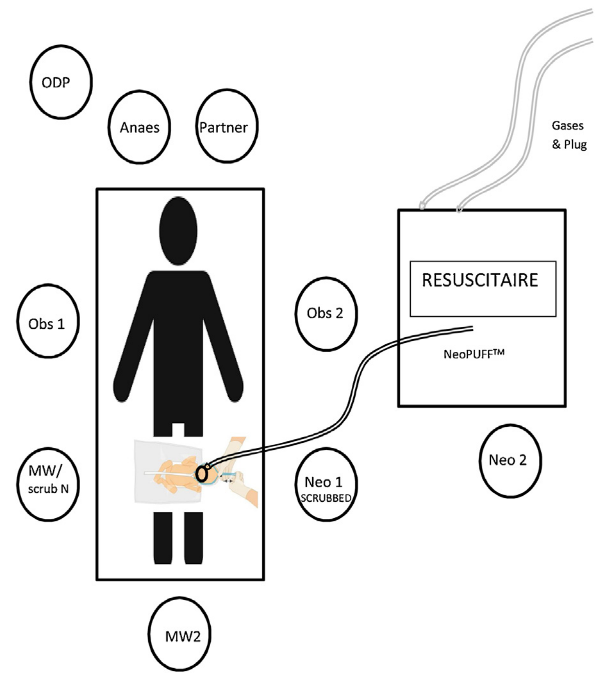

Fig. 4. Positioning Diagram for Delayed Cord Clamping at Preterm Caesarean Delivery.

Key findings

We have described a simple, low cost, and effective method of facilitating DCC with thermal care and respiratory support. The efficacy and sustainability of the technique is evidenced by the statistically significant improvement in the number of preterm infants (including those delivered by caesarean section) receiving DCC noted within 1 month of the introduction of this technique and maintained at 18 months post introduction. The technique is well embedded into local maternity and neonatal practice.

In this quality improvement project, outcomes for infants pre and post QIP suggest a lower incidence of severe perinatal brain injury and severe NEC, and an increase in survival to discharge in the post QIP cohort. However, these differences were not statistically significant, the amount of data is small and could be subject to confounding. 2 year neurodevelopmental follow up data will be collected on both cohorts.

Strengths & limitations

The technique designed and used at GWH, has several strengths:

- **Simplicity** of the model enables it to be easily replicable across a wide variety of Maternity & Neonatal Services.

Table 1
Demographic Characteristics of study population, pre and post QIP (Quality Improvement project).

Characteristic	Pre QIP (n = 32)	Post QIP (n = 47)
Male : Female ratio	1.3:1	1:1.04
Gestation (Median & Range)	30 weeks (24–31)	29 weeks (24–31)
Birth weight (Median & Range)	1301.5 g (785 g-1867 g)	1239 g (650-1938 g)
% born by Caesarean Section	68.75%	53.2%
% Antenatal Steroids (full/partial/none)	62.5% / 31.25% / 6.25%	59.6%/ 34%/ 6.4%
% Antenatal Magnesium Sulphate	78%	83%

Table 2
Primary Outcomes, pre and post QIP (Quality Improvement project).

Outcome	Pre QIP (n = 32)	Post QIP (n = 47)	P value
Delayed Cord Clamping Performed for >60 seconds (all deliveries)	12.5%	89.4%	p < 0.00001 (Fisher's exact)
Delayed Cord Clamping Performed for >60 seconds (caesarean section)	18% (4/22)	92% (23/25)	p < 0.00001 (Fisher's exact)
Provision of Thermal Care & Respiratory Support (PEEP +/- inflation breaths) support during DCC (all deliveries)	0%	89.4%	p < 0.00001 (Fisher's exact)
Provision of Thermal Care & Respiratory Support (PEEP +/- inflation breaths) support during DCC (caesarean section)	0%	92% (23/25)	p < 0.00001 (Fisher's exact)

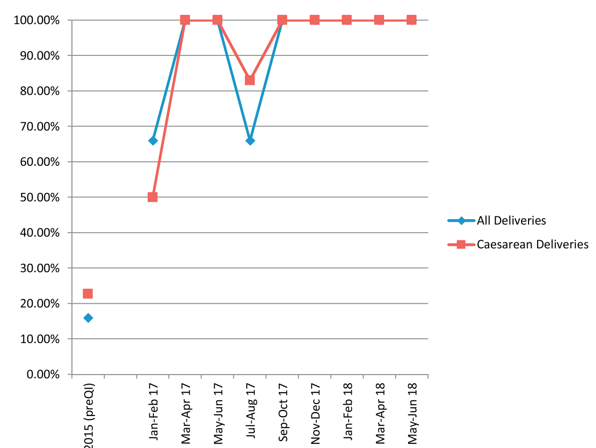

Fig. 5. Run Chart showing proportion of infants receiving delayed cord clamping for all deliveries and for those born by Caesarean delivery. Post QIP, all infants received thermal care and respiratory support during DCC.

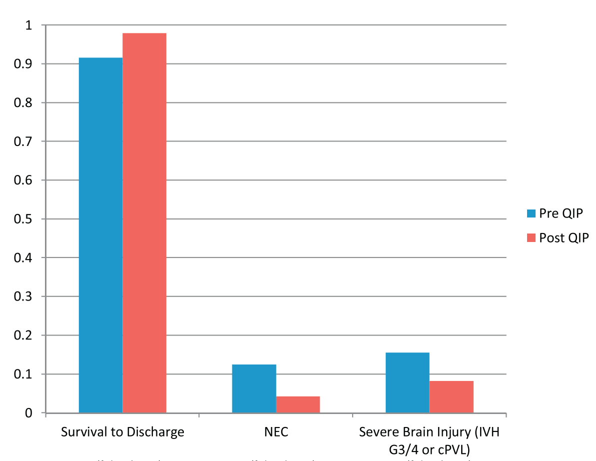

Fig. 6. Paired Bar chart demonstrating incidence (Percentage) of outcomes pre and post QIP.

- **Cost -** In comparison to other techniques, such as the bespoke trolleys [20–22], it is of considerably lower cost, approximately £10 per patient for caesarean deliveries, significantly less for vaginal deliveries; allowing it to be widely financially accessible.
- **Perinatal Teamwork**, multidisciplinary engagement and communication are vital in optimising outcomes for preterm infants, particularly for implementation of successful DCC, as others have similarly reported [32]. We have found that this multidisciplinary approach has improved team working between the perinatal specialities.

A potential limitation of this technique is the time and resources required to ensure satisfactory education within the department to enable safe delivery of the technique. However we have found that involvement across the disciplines and on-going recruitment to our faculty facilitated an increasing pool of enthusiastic trainers.

A further current limitation of this technique is that the T-piece device, (NeoPuff™, Fischer & Paykel, Berkshire, UK) used to establish and support lung aeration prior to cord clamping, is opened and used in a 'clean' technique during caesarean section, but is not yet able to be certified as sterile. As a perinatal team, assessing the risk-benefit profile of this technique, we have opted to continue with this technique, and will switch to a sterile T-piece circuit as soon as one is commercially available. The T-piece circuit is held by the sterile Neonatologist, and does not directly encroach upon the caesarean field. We have not seen any increased incidence of obstetric complications since implementation of the technique, and deliver DCC at almost all preterm deliveries. We urge manufacturers to expedite commercial availability of sterile respiratory circuit equipment.

This technique allows for at least 60 s of delayed cord clamping for all preterm infants (in line with national recommendations [5]), including infants who require initial support with airway and lung inflation. The feasibility of delivering further advanced interventions over a prolonged period of stabilisation or resuscitation, has not been explored during development of this technique. This area of practice is not yet well evidenced. Similarly, our technique does not offer complex monitoring of physiological parameters (such as the technique described by Brouwer et al. [17]) to support a physiological parameter-based approach to the timing of cord clamping.

Conclusion

This study has described a simple technique to deliver DCC to all preterm infants, including those born by caesarean section, at minimal additional cost. Use of this technique can increase the number of preterm infants receiving the benefits of delayed cord clamping, without compromise to thermal or respiratory care.

This technique is feasible, effective, and, with multidisciplinary engagement, can be well embedded into maternity teams. We hope that by sharing this approach, other centres will be able to implement a similar strategy, closing the gap between evidence base and translation into clinical practice, and allowing provision of DCC for preterm infants as a standard part of high quality perinatal care.

Contributors

SB conceptualised and designed the QI project, SB & CS led development of the DCC at c-section technique. VN, CS & SB led on implementation of the technique across the wider perinatal team. TI, JG, RM coordinated data collection and statistical analysis. All authors contributed to preparation and review of the manuscript.

Funding & competing interests

Vygon, UK, who make NeoHELP™, supported this project by filming the video of the Cord Intact Stabilisation technique at a simulated caesarean section, to use for staff training purposes. This included provision of a small number of NeoHELP™ suits. NB: At the time of this project, there was no other commercially available sterile plastic wrap or bag for preterm thermal care. The project therefore utilised NeoHELP™. Other products, when available, may be used, subject to cost-benefit analysis.

Patient Consent & Ethics approval

As this is part of a Quality Improvement Project, to increase rates of evidence-based perinatal interventions, and the data was routinely collected as part of routine neonatal care, it was determined that parental consent and ethical approval was not required. The data was anonymised pre-analysis.

Provenance and peer review

Not commissioned; externally peer reviewed.

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