

Innovation in immediate neonatal care: development of the Bedside Assessment, Stabilisation and Initial Cardiorespiratory Support (BASICS) Trolley

Andrew D Weeks¹, RJ Peter Watt², David JR Hutchon³, Charles W Yoxall⁴, Andrew Gallagher⁵, Amanda Burleigh⁶, Susan Bewley⁷, Anne M Heuchan⁸, Lelia Duley⁹

¹ Department of Women's and Children's Health, University of Liverpool; ² Department of Clinical Engineering, University of Liverpool; ³ Retired Obstetrician, Darlington Memorial Hospital; ⁴ Neonatal Unit, Liverpool Women's Hospital; ⁵ Worcestershire Royal Hospital; ⁶ St James Hospital, Leeds; ⁷ Kings College, London; ⁸ Royal Hospital for Sick Children and Southern General Maternity Hospital, Glasgow; ⁹ Nottingham Clinical Trials Unit, University of Nottingham

Summary

Background

Current international guidelines for management of babies at birth state that there should be a delay before the umbilical cord is clamped as this may confer some benefit to the baby. This is not currently possible for the babies who require resuscitation at birth because standard practice in newborn resuscitation is to take the baby away from the mother to be resuscitated. As well as preventing delayed cord clamping, this causes considerable distress for parents. There is evidence from other patient groups that there is benefit from allowing relatives to witness resuscitation.

The aim of this project was to develop a trolley that would enable resuscitation of newborn babies at the bedside with an intact umbilical cord.

Following an initial design meeting, a series of prototypes were developed. At each stage the prototype was reviewed by a team of experts both in the laboratory and on a labour ward to determine ease of use and fitness for purpose. A commercial company was identified to collaborate on the trolley's development and secure marking with the Conformité Européenne (CE) mark, allowing the trolley to be introduced into clinical practice.

Results

The trolley is a small mobile resuscitation unit based on the concept of an over-bed hospital table. It can be manoeuvred to within 50 cm of the introitus irrespective of whether the mother is having a spontaneous or operative vaginal birth or caesarean section. Warmth comes from a heated mattress and the trolley has the facility to provide suction and assisted ventilation with oxygen or air.

Conclusions

This is the first mobile resuscitation device designed specifically to facilitate newborn resuscitation, at the bedside and potentially with an intact cord. The next step is to assess safety and acceptability to clinicians and parents, and to determine whether it allows resuscitation with an intact cord.

Keywords

Resuscitation, Infant, Newborn, Equipment design

Background

Obstetricians have encouraged early, or even immediate cord clamping since the 1960s as part of the active management of the third stage of labour to prevent maternal haemorrhage [1]. For term births, timing of cord clamping does not have a clear effect on post partum blood loss. However, immediate clamping reduces neonatal haemoglobin and neonatal jaundice [2]. Although these effects are generally transient and well tolerated, reduced iron levels are still seen at age 3–6 months, an effect associated with developmental delay [3]. The World Health Organisation [4], the International Federation of Gynaecology and Obstetrics / International Confederation of Midwives [5] and Royal College of Obstetricians and Gynaecologists [6] now recommend deferring cord clamping.

In the UK, about a quarter of newborn babies are attended at birth by neonatal resuscitation staff. For most, all that happens is an assessment, stimulation, thermal care and simple airway management. Around 15% of babies receive active resuscitation at birth, such as mask ventilation, intubation, cardiac massage or drug administration.

When a baby requires assessment or stabilisation and support at birth, standard practice is to clamp and cut the cord immediately and then take the baby to a resuscitation platform, usually at the side of the room or in another room. This means that the period of transitional circulation is foreshortened. In addition, parents are often not able to see or touch their baby at birth, a factor that is known to cause considerable parental anxiety [7]. Evidence from other areas of adult and child resuscitation has shown that family presence is preferred by relatives and by staff [8-12]. Family presence at resuscitation is now standard in these settings. This issue has not been explored for care after birth, and newborn resuscitation has to date always been away from the woman and her partner.

The need for immediate neonatal care and support increases with increasing prematurity. For preterm infants, deferred cord clamping is associated with decreased transfusion for anaemia, decreased low blood pressure requiring inotropic support and less low-grade intraventricular haemorrhage compared with immediate clamping [13]. Again there is an increase in jaundice, but the long-term effects are unclear. Thus, whilst there is a desire to defer cord clamping, it is uncertain whether any benefits would be negated by delayed resuscitation [14]. The current European Resuscitation Council recommendation therefore states that, "for babies requiring resuscitation, resuscitative intervention remains the priority" [15].

Very preterm babies are those most likely to experience major morbidities and, potentially, might benefit from deferred clamping. It therefore seems important to develop a strategy to allow initial resuscitation with the cord intact. A survey of the UK Extended Neonatal Network in 2009 to assess views on timing of cord clamping and placental transfusion found that two thirds of those surveyed thought that initial care with the cord intact is potentially feasible for preterm vaginal births. Just under half thought this was possible for preterm caesarean births (Duley, personal communication 2009).

The aim of this paper is to describe development and preliminary testing of a mobile trolley to enable newborn care and support at the bedside, potentially with an intact cord.

Methods

Initial concept

Resuscitation with an intact cord has been described by several authors [16-18], but no agreed technique had emerged. In January 2010 DH convened a one-day meeting in Worcester of eight UK clinicians and researchers (AB, SB, LD, AG, AMH, DH, DO, AW) with a common interest in exploring practical methods for initiating neonatal assessment and resuscitation at birth before the cord is clamped and cut. From this came the idea of a small mobile bedside resuscitation trolley, extending the concept of the platform that had been used for a cord clamping study in Glasgow (Figure 1). The acronym BASICS for ‘Bedside Assessment, Stabilisation and Initial Cardiorespiratory Support’ was proposed, and this established a working title of the ‘BASICS trolley’. The key concepts were that this trolley would need to keep the baby warm, allow suction and respiratory support within a 50 cm radius from the mother’s uterus. AW drew up designs during the meeting (Figure 2). It was agreed that he would formalise these, take the design of the trolley forward with the medical engineering department in Liverpool and register the design rights.

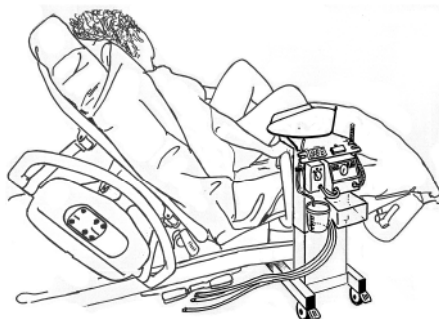
Figure 1. The Glasgow trolley used in the study by Aladangady (2006) that inspired the first designs of BASICS trolley (photograph courtesy of AMH)

Figure 2. The design drawing that came out of discussions at the first group meeting in Worcestershire showing (a) the trolley design and (b) the way in which it might be positioned over the operating table at caesarean section (drawings in February 2010 by AW)

Development of the prototypes

Funding to support development of the concept into a prototype was secured from the National Institute of Health Research (NIHR; LD), with additional support from the Liverpool Women’s Hospital ‘Newborn Appeal’. In collaboration with the Department of Clinical Engineering at the Royal Liverpool University Hospital the first prototype was developed by PW, using a modified hospital over-bed table (Figure 3).

Figure 3. Drawing of the trolley’s position for normal delivery (drawing by PW in March 2011)



This first early prototype was developed with support from the development team (LD, AG, DH, PW, AW, CWY) with input from a service user representative, which met in Liverpool. Various mock delivery scenarios were staged to assess the optimum size and reach of the trolley platform, as well as discussion about what equipment needed to be available on the trolley to provide blended oxygen and air and to provide positive end-expiratory pressure (PEEP). The Liverpool prototype (Figure 4) was awarded 'Best Redesign in Cardiovascular Medicine' at the Medical Futures Awards in June 2011.

Figure 4. The first BASICS prototype (by PW in April 2011). Note that the problem of how to keep the baby warm was still not resolved



A key problem for the first prototype was how to keep the baby warm. Traditional resuscitators have an overhead heater, but this was not practical for a trolley designed to go under the legs of a woman in lithotomy position or over an operating table. A commercial company (Inditherm plc) was identified by DH and approached to adapt their heated mattresses for the trolley. The company then agreed to collaborate on further development, with the aim of taking the product to market.

The second prototype, developed in collaboration with Inditherm and manufactured by them (Figure 5), has improved mobility and flexibility that allows the height and position of the trolley platform to be adjusted. The overall base size is 570x590mm, the platform height ranges from 800 mm to 1200 mm from the floor. The resuscitation surface is horizontal to ensure a suitable platform for resuscitation and avoid inadvertent slipping of the patient. Warming is provided by a neonatal warming mattress with Inditherm proprietary carbon polymer using low voltage electrical power, the temperature range of this mattress is adjustable between 35°C and 40°C. Additional resuscitation equipment can be mounted on two configurable rails provided, total available lengths approximately 600 mm and 450 mm respectively. Initial testing of the prototype was performed on the hospital labour ward and theatres by clinical staff using both maternal and baby mannequins in a variety of delivery settings (caesarean section, spontaneous vaginal delivery on a bed, forceps delivery in lithotomy position on a bed) to ensure that the trolley could be used in a clinical setting without obstructing the working space of the midwife or obstetrician and to ensure that it would not lead to contamination of the sterile field in operative deliveries.

Figure 5. The LifeStart® trolley manufactured by Inditherm (October 2012)



This trolley was marked with the Conformité Européenne (CE) logo in October 2012 and is now marketed by Inditherm as ‘LifeStart®’.

Results and discussion

The trolley has been successfully designed and manufactured. A key element in the design is flexibility to allow the baby to be placed on the trolley whilst the umbilical cord is still intact. This required the trolley platform to be manoeuvrable: able to be lowered under the mother’s legs when in lithotomy position or raised up high to reach over the woman on an operating table. The umbilical cord can be short so the platform has to be able to be placed close to the woman’s introitus. This is achieved by having a central pillar that can be adjusted up or down, and a narrow platform that reaches out from the pillar with raised edges for safety. Even if the mother delivers the baby on the floor, the trolley can be moved to the site of birth and provide the necessary resuscitation gases and suction for the baby to remain attached and with the mother.

Thermal support is provided by the CosyTherm® electric heated mattress. This is adjustable through a range of temperatures and takes only a few minutes to heat up. The trolley has a timer built into the platform, with audible Apgar reminder beeps at 1 and 5 minutes.

Fixed around the central pillar are two universal Medirails for additional equipment. These allow each hospital to customise the trolley to their specific requirements. Our early assessments used a Tom Thumb Infant Resuscitator® (Viamed, Keighley, UK), oxygen blender (Inspiration Health Care Ltd. Leicestershire, UK), a suction bottle driven by the wall-supplied air supply (Oxylitre Ltd. Manchester, UK) and the control unit for the CosyTherm® heated mattress (Inditherm, Rotherham, UK). We connect it with hoses to the air and oxygen wall supply. Other pieces of equipment that could be added are a light on a flexible stalk, a saturation monitor, or a storage basket (for keeping the laryngoscope, hats, saturation monitor).

When using the trolley at a caesarean section, a sterile Mayo tray cover is draped over the platform. The neonatal team member who will provide care at birth scrubs and puts on a

sterile gown and gloves so as to prevent contamination of the operating field. Once the baby is on the trolley platform, the sterility rules are relaxed so that the scrubbed neonatal team member can touch and use non-sterile equipment such as the laryngoscope, timer and hat. It is then important that the sterile field is not re-entered or contaminated. If on-going resuscitation is required, then, after the cord is cut, the trolley can be moved away from the operating table to allow care to continue without interrupting the surgeon.

The trolley was introduced into clinical service at Liverpool Women's Hospital after CE marking. A service evaluation has been conducted to establish that it can be used to provide effective newborn resuscitation safely and is acceptable to clinicians. The results of that service evaluation have been submitted for publication.

Clinicians who wish to implement deferred cord clamping for all births have previously faced a problem: how do you achieve this in those babies who appear to require resuscitation? This trolley has demonstrated the feasibility of providing initial neonatal care and stabilisation at the bedside, and to do this whilst the cord is intact. Although parents of premature babies describe their first physical contact as very significant, it is frequently delayed until some time after birth on the special care baby unit [7]. With the BASICS trolley, the mother can touch and speak to her newborn baby whilst it is undergoing assessment, and our initial experience is that the parents value this opportunity. Further qualitative work evaluating the impact of the use of the trolley on the parental experience of newborn resuscitation is underway.

Introducing neonatal care at the bedside requires a multi-disciplinary approach. The attending team needs to prepare, and to be confident in providing neonatal resuscitation under the more direct intense scrutiny of parents. Everyone present at the birth needs to understand their role in supporting this care strategy, and supporting the woman and her partner.

Currently 'deferred' cord clamping for very premature babies occurs after 30 to 45 seconds, even though placental transfusion is likely to continue for longer. This reflects the desire not to delay initial neonatal care and support. The BASICS trolley should allow evaluation of a more physiological approach to cord clamping for all births, including sick and very premature babies. An ongoing pilot randomised trial funded by NIHR compares cord clamping within 20 seconds with clamping after at least two minutes for births below 32 weeks' gestation (ISRCTN21456601). In this study, some units are using the BASICS trolley whilst others are using their normal resuscitaire moved to the bedside [17]. The pilot is to assess feasibility of a large UK randomised trial.

Conclusion

This is the first mobile resuscitation unit designed specifically to facilitate newborn resuscitation at the bedside, with an intact cord. Further evaluation will assess safety and acceptability, and whether it is feasible to allow bedside resuscitation with an intact cord.

Abbreviations

BASICS, Bedside assessment, stabilisation and initial cardiorespiratory support; CE, Conformité Européenne; NIHR, National Institute of Health Research

Competing interests

LD is Chief Investigator for a trial comparing alternative strategies for timing of cord clamping, for which this trolley is one strategy for providing care at the bedside. None of the authors have or will receive any direct financial benefits from the development of the BASICS trolley – it has been agreed that any financial remuneration will be donated to charity.

Author's contributions

The initial trolley concept and design was developed by AB, SB, LD, AG, AMH, DH, DO and AW at the meeting organised by DH in Worcester. Subsequent meetings, attended by AB, NB, LD, AG, GG, DH, AW, PW, and CWY led to the development of the prototype. AW wrote the first draft of the manuscript, which was subsequently revised by AB, SB, LD, AG, AMH, DH, AW, PW and CWY. All authors approved the final version of the manuscript.

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