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Safety and feasibility of the paediatric post-cardiac catheterisation Wrap: a pilot study

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Abstract

Objective: The paediatric post-cardiac catheterisation Wrap (Wrap), an innovative medical safety device, swaddles young paediatric patients in a supine position aiding in immobilisation post-cardiac catheterisation. This pilot study investigated the feasibility and safety of using the Wrap on young paediatric patients during their bed rest period following cardiac catheterisation with femoral access. *Setting:* Boston Children's Hospital Cardiac Catheterization Lab. *Participants:* 20 patients, ages 1–5 years and weighing 3–25 kg. *Methods:* Investigator-developed tools used to collect data included the Demographic and Outcome Measures Data Tool, the Parent/Caregiver Satisfaction, and Provider Ease of Use tools. They measured:

1. The feasibility of using the Wrap
2. Wrap ease of use from the nurse providers' perspective
3. Parent satisfaction related to the Wrap
4. Frequency of Wrap non-bleeding-related adverse events
5. Frequency of rebleeding at femoral groin access sites

Results: The Wrap was feasible and safe; increased nurse provider satisfaction by allowing visualisation of the groin access sites while minimising the need for hands-on care; and increased parent satisfaction by allowing parents to hold and provide comfort while their child was on bed rest. *Implications for Research:* The Wrap is a safe alternative to the current practice of swaddling with a bath blanket. Further studies are warranted to assess the Wrap's effectiveness in reducing the incidence of rebleeding events in the post-cardiac catheterisation period and explore clinical use outside of the Cardiac Catheterization Lab.

This study examines the implementation of the novel post-cardiac catheterisation Wrap (Wrap) to manage the care of young paediatric patients following cardiac catheterisation. Trans-femoral cardiac catheterisation is an invasive medical procedure undertaken in adult and paediatric patients with congenital cardiac defects and other forms of heart disease for therapeutic or diagnostic purposes. Although risks exist for adult patients undergoing this procedure, it is without question more challenging when performed on young paediatric patients with congential heart disease. The procedure's major risk or complication, especially in young paediatric patients, is rebleeding from the catheterisation sites after the procedure is complete.

Rebleeding is defined as bleeding that occurs after initial control of bleeding is achieved following the procedure.[1] The risk of rebleeding can have serious consequences and make it necessary to implement procedures to keep children safe post-cardiac catheterisation. The multifactor risks for rebleeding in young paediatric patients include large bore size catheters used to access the vessels, anti-thrombotic medications given systemically during the procedure, and the paediatric patient's immature haemostatic system, predisposing them to thrombolytic events and bleeding.[1,2] Complications of rebleeding can include thrombosis in the accessed vessel, aneurysms, retroperitoneal bleeding, blood loss requiring transfusion or haematoma, making it essential that rebleeding is prevented.[3] Most cardiac catheterisations in young paediatric patients, performed via femoral arterial and venous access sites, require 4–6 hours of immobilisation and supine bed rest to maintain haemostasis and prevent rebleeding.[4,5]

In addition to the physiologic and procedural risks, the developmental stages of young paediatric patients make them more vulnerable to rebleeding complications. Developmental characteristics of children aged 1–5 years can include not following directions, difficulty remaining supine for long periods, and medical provider stranger anxiety.[6] During the recovery phase of general anaesthesia, young paediatric patients can also experience post-operative emergence agitation and delirium. Emergence agitation and delirium are terms used to describe restlessness, crying, agitation, thrashing, and inconsolability, among other behavioural disturbances in the post-operative period.[7,8] When a child experiences these behavioural disturbances, they do

not respond to behavioural techniques and comfort measures from parents. Thus, emergence agitation and delirium can increase the risk of post-catheterisation rebleeding and parent dissatisfaction with the quality of care.[9,10] In this study, the term parent(s) consists of biological parents, caregivers, or legal guardians.

Behavioural techniques, such as distraction and encouraging the child to lay still, are generally difficult to carry out when caring for young paediatric patients less than or equal to 5 years of age and older children with developmental delays.[6] When young paediatric patients rebleed from the groin access sites post-cardiac catheterisation, multiple staff members are needed to provide continuous immobilisation to regain haemostasis. This form of immobilisation can cause overstimulation, loss of control, increased distress to the child, and is human resource intensive. Additionally, this experience can be highly traumatic for the child and parent(s).[11–13] These situations can escalate, and interventions such as increased sedation may be necessary to calm the child, reduce negative memories, and alleviate future distress during stressful medical procedures.[14]

At the time of this study, rebleeding prevention practices were highly variable and not standardised across the medical community. To prevent rebleeding, nursing interventions at the study site included creative measures to immobilise and comfort patients, such as the commonly used practice of swaddling a paediatric patient's torso and lower limbs with a bath blanket. As nurses swaddled a child, they would leave a viewing window open over the femoral groin area to allow for visualisation of the catheter insertion site dressings and to monitor for rebleeding. However, a bath blanket is often too large, tends to loosen, and opens on its own. The Wrap was developed to replace the bath blanket to help manage the post-cardiac catheterisation care needs of young paediatric patients.

Due to the lack of an available commercial product, nurses designed the Wrap to promote immobility and prevent complications in young paediatric patients following a cardiac catheterisation procedure. The Wrap is an adjustable, passive medical positioning device that assists with lower body immobilisation and accommodates patients 1–5 years of age. The Wrap's benefits include increasing patient comfort, increasing visualisation of the groin access sites, decreasing healthcare provider/patient interaction to decrease a patients' anxiety, and potentially decreasing the risk of rebleeding. The Wrap provides a family-centered care focus by allowing parent(s) to play an active role in the child's care and recovery.[11,15] The investigators believed that the Wrap increases the opportunity for the patient to be comforted by their parent(s), thus serving as a calming, stress-relieving mechanism while minimising the need for increased sedation.[16] This is particularly important since the administration of sedation after the reversal of general anaesthesia can result in airway obstruction, necessitating respiratory support, and a prolonged hospital stay.[6,12,13]

This pilot study measured the feasibility and safety of the Wrap for young paediatric patients following cardiac catheterisation. The specific aims of this study were to describe the Wrap's: (1) feasibility, (2) ease of use from the nurse's perspective, (3) satisfaction from the parent's perspective; as well as frequency of (4) Wrap-related adverse events, and (5) rebleeding events at femoral groin access sites.

Materials and methods

Study setting, population, and sample

This study was undertaken in a large quaternary paediatric hospital in the northeast United States. Providers in the cardiac catheterisation lab care for more than 2000 patients per year undergoing cardiac catheterisation.

The sample included 20 young paediatric patients following a trans-femoral cardiac catheterisation procedure, transferred to the recovery area for a period of prescribed bed rest. Patients discharged to home following the cardiac catheterisation procedure and not admitted to an inpatient unit, 1–5 years of age, weighing ≥3 and ≤25 kg, and receiving medical team clearance were eligible to participate in the study. Patients were excluded from participation if they did not meet age or weight criteria, did not fit in the Wrap, had truncal or lower body skin lesions such as red areas, ulcerations, abrasions and haemangiomas or non-intact skin, or had a known allergy or sensitivity to cotton, flannel, polyester, or spandex material.

Education

Before study implementation, the Principal Investigator trained the study team and cardiac catheterisation lab staff about the study purpose and procedures. The Principal Investigator also provided nursing staff with instructions on Wrap use and on how to complete data collection and documentation. Training of nurses included applying the Wrap to the patient's torso/lower body area to maintain visual inspection of the access sites and perform assessments of circulation (distal dorsalis and pedal pulses), temperature, sensation, and movement of the feet and toes.

Enrolment procedures

Enrolment began with identifying potential study subjects by reviewing the cardiac catheterisation pre-operative schedule 2 weeks before the scheduled procedure. The study staff then screened potential subjects for eligibility using the inclusion/exclusion criteria.

During the cardiac catheterisation pre-procedure testing day, usually 1 day before the procedure, the advanced practice providers supplied the parent(s) with a written copy of the consent and a parent information sheet to review. On the day of the cardiac catheterisation procedure, in the pre-operative holding area, the primary nurse had the parent(s) review the study materials provided to them and asked if they were interested in hearing about the study. If interested, a member of the study team approached the parent(s) to explain the study and gave them an additional copy of the written consent form that described the study and their child's involvement. Next, the study team member provided the parent(s) the opportunity to ask questions. Once the parent(s) indicated they were fully informed and consented to study participation, they signed the informed consent/Health Insurance Portability and Accountability Act form.

Study device

The Wrap's design was to facilitate a stable bed rest period (Fig 1). Fabrics were carefully selected and consisted of a quilted outer layer to provide durability, a foam middle layer for added stability, and a soft fleece interior layer for comfort and warmth. The tapered design of the Wrap is wide at the top compared to the bottom. It is unrestricted at the top and bottom, with an additional opening over the child's groin (viewing area). The viewing area of the Wrap allows nurses and other providers easy access to view the dressings over the femoral catheterisation sites, and the distal end of the Wrap is left open to allow easy access to assess peripheral pulses and perfusion of the feet. A wide elastic band and lengthwise

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Figure 1. Paediatric post-cardiac catheterisation Wrap.

Velcro closure held the Wrap in place beneath the child's axilla and over the torso and lower limbs. When secured around the patient's torso and lower limbs, the Wrap's design reinforced the immobilisation of the child while at the same time allowed the upper body to move freely. The child could use a tablet, play with a toy, hold a stuffed animal or a parent(s)' hand to feel safer, more comfortable, and to decrease anxiety. When the Wrap was applied, a foam supplemental rectangular divider placed between the child's legs helped to provide additional support, prevent chafing, and limit movement of the lower extremities.

Finalising the Wrap's design included testing it on a life-sized simulation infant and toddler manikin to ensure a proper fit on the young paediatric patients' torso/lower body. Following manufacturing of the Wraps, they were professionally cleaned and sequentially numbered with a study identification number, which also served as the participants' study identification. Each single use Wrap was stored in a plastic bag and placed in a plastic bin following use.

Human subjects

Boston Children's Hospital Institutional Review Board approved this study (IRB-P00029501). All study staff was trained using the Collaborative Institutional Training Initiative Programme. The Data Safety and Monitoring Committee reviewed all adverse events that occurred during the study period. The participants' names did not appear on any data collection forms to ensure anonymity, only participant study identification numbers. Parents received a $25.00 gift card as a token of appreciation for their study participation.

Data collection tools

Three investigator-developed tools were used to collect data. The two-part Demographic and Outcome Measures Data Tool was used to collect patient demographic information, medical history, outcome measures, skin assessments, and adverse events. The Principal Investigator or study team member completed part one of the tool (demographic information and medical history), and the bedside nurse completed part two. The Nurse/Provider Ease of Use Tool, also completed by the bedside nurse, had four Likert scale questions and one open-ended question related to the Wrap's feasibility. Finally, the Parent Satisfaction Tool completed by the parent(s) had three Likert scale questions and one open-ended question related to parent satisfaction with the Wrap.

Study procedures

Before the catheterisation procedure, the bedside nurse and study team member performed a standard skin assessment of the child. After completion of the catheterisation procedure when the child was extubated, stable, and haemostasis was achieved, a study team member and the cardiac catheterisation lab nurse assessed and documented the child's skin, body temperature, and access sites. In place of the usual bath blanket, the Wrap was placed around the patient's torso/lower limb area starting beneath the axilla. When properly applied, the Wrap's opening over the groin area allowed for visualisation of the access sites and the open distal end allowed for visualisation, palpation, and circulation assessments of the feet and toes to occur using capillary refill, temperature and Doppler probe assessments. The patient remained wrapped upon arrival to the recovery room and throughout the prescribed bed rest period (typically 4–6 hours). A study team member completed part one of the Demographic and Outcome Measures Data Collection Tool. The Wrap was opened and closed as needed during the bed rest period at the discretion of the cardiologist, anaesthesiologist or bedside nurse for any concerns or medical care, including repositioning, personal hygiene, patient discomfort, itchiness, failure to achieve immobility, hyperthermia, or clinical decompensation. Utilisation of the Wrap only occurred when it was safe for the patient.

The bedside nurse performed data collection in the recovery room post-cardiac catheterisation completing part two of the Demographic and Outcome Measures Data Collection Tool. The nurse followed the usual care and management of the patient consisting of visual groin site checks and distal extremity pulse checks every 15 minutes for 1 hour, every 30 minutes for the next 2 hours, and then every hour for the remainder of bed rest with the addition of hourly body temperature checks instead of every 4 hours, per study protocol.

Upon completing bed rest in the recovery area, the Wrap was removed from underneath the patient's lower body, and a final skin assessment was performed. Also, at that time, the parent(s) was asked to complete the Parent Satisfaction Tool, and the bedside nurse completed the Nurse/Provider Ease of Use Tool.

Data safety and monitoring committee

A Data Safety and Monitoring Committee, consisting of an experienced cardiac catheterisation nurse, interventional cardiologist, cardiac anaesthesiologist, and physician assistant specialising in cardiac catheterisation, provided study oversight. The Data

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Table 1. Adverse events, descriptions, and plans.

Event	Problem	Plan
Device malfunction/ poor fit	Affords too much movement of the young paediatric patient increasing their risk of rebleeding	End of study participation and failure of device for that size patient moving forward. • Notify PI • PI notifies DSMC • PI notifies IRB per policy
Inadequate adherence of Velcro strips	Inadequate closure and failure to maintain movement restriction increasing rebleeding risk	End of study participation and failure of device for that size patient moving forward. • Notify PI • PI notifies DSMC • PI notifies IRB per policy Study team will evaluate need to modify device design and materials if problem noted with other study participants.
Hyperthermia (>100.5 degrees Fahrenheit)	Hyperthermia can cause detrimental effects such as increasing the metabolic demand placed on the child's body, hypotension, tachycardia, and impaired oxygenation	End of study participation. The nursing staff or research team will open the Wrap to allow cooling of the patient. • Notify PI • PI notifies DSMC • PI notifies IRB per policy
Rash, erythema, pressure sores or lesions on the lower body	Indicative of sensitivity to the device	End of study participation. Device will be removed. • Notify PI • PI notifies DSMC • PI notifies IRB per policy Study team will evaluate need to modify device design and materials if problem noted with other study participants.
Clinical decompensation	Clinical decompensation includes but is not limited to increased metabolic demands placed on the child's body, hypotension, tachycardia and impaired oxygenation	May be indicative of sensitivity to the device, related to device use (i.e. positioning restriction) or unrelated to device. • Notify PI • PI notifies DSMC • PI notifies IRB per policy If severe allergy is suspected, the study team will evaluate need to modify device design and materials if problem noted with other study participants.

DSMC = Data Safety and Monitoring Committee; IRB = Institutional Review Board; PI = Primary Investigator

Safety and Monitoring Committee met halfway through study enrolment and then again after completion of enrolment. The Data Safety and Monitoring Committee classified adverse events according to the event seriousness and made recommendations to protect the safety of study participants and scientific validity of the study (Table 1).

Data coordinating centre

The project coordinator and programme manager performed data management and coordination for this study, including: (1) conducting data management activities, (2) database development and data entry, (3) monitoring the quality of data submitted, (4) monitoring adherence to the protocol, (5) monitoring device accountability, (6) coordinating activities of the Data Safety and Monitoring Committee, and (7) directing data analysis. The study personnel maintained a logbook with the participants' names, medical record numbers, and corresponding study identification numbers. To verify data accuracy, study personnel double-checked every database entry.

Data analysis

Data from the three investigator developed tools were summarised utilising descriptive statistics within the REDCap electronic data capture tools platform.[17,18] In addition, qualitative analysis of free-text comments offered from parents and nurse providers was accomplished using a manual inductive coding approach to ensure the viewpoints of the respondents were fully represented.[19]

Results

Of 27 patients screened for enrolment in the study, 6 were ineligible based on the study's criteria and 21 participants were consented and enrolled. One patient did not complete the study due to a procedural delay, and the remaining 20 patients completed the study (Fig 2).

Demographically, 45% (n = 9) of the participants were male and 55% (n = 11) female. The mean participant age was 3.36 years (1.37–5.62 years), mean weight was 13.16 kg (8.8–20.4 kg), and mean height was 91.01 cm (75.8–114.5 cm). Participant's ethnicity varied with 55% (n = 11) identifying as Caucasian, 30% (n = 6) African American, 5% (n = 1) Asian, 5% (n = 1) Latino, and 5% (n = 1) of unknown origin. Participants had a range of CHD primary diagnoses (Table 2).

The majority of the study participants (35%, n = 7) had the Wrap in place for a minimum of 6 hours, 15% (n = 3) over 5 hours, 15% (n = 3) over 4 hours, 20% (n = 4) over 3 hours, 5% (n = 1) over 2 hours, 5% (n = 1) over 1 hour, and 5% (n = 1) for 30 minutes (Table 3). The majority of study participants (60%, n = 12) had the Wrap in place for their prescribed bed rest period, ordered by the provider or until transfer to an inpatient unit. Of the study participants (40%, n = 8) who required removal of the device before completion of their prescribed bed rest period, 10% (n = 2) had it removed due to fever or bleeding, 10% (n = 2) opened the device themselves, and the remaining 20% (n = 4) became agitated after wearing it for 3–5 hours.

The majority of parents (80%, n = 16) reported their child appeared comfortable in the Wrap. In addition, nearly all parents (95%, n = 19) reported the Wrap allowed the nurse providers to

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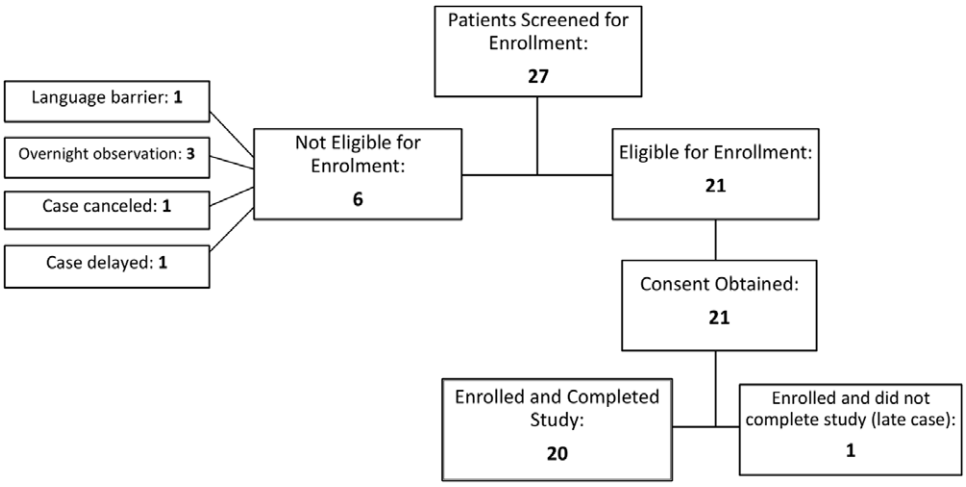

Figure 2. Participant screening and enrolment.

care for their child with minimal disruption to their recovery. Amongst parents with a child who had undergone a previous catheterisation (70%, n = 14), all (100%, n = 14) reported the Wrap was equal to or better than the care with the bath blanket (Table 4).

Nurse provider response was positive, with nurses reporting the Wrap was equal to or better than the current standard of post-catheterisation care (94.8%, n = 18). All nurse providers reported the Wrap was easy to apply (100%, n = 20) and remove (100%, n = 19). Most nurse providers reported the Wrap did not interfere with other medical devices (95%, n = 19) or medical procedures (89%, n = 18) (Table 5).

Two participants (10%) experienced adverse events determined by the Data Safety and Monitoring Committee. One participant developed hyperthermia which resolved within 1 hour and 45 minutes of discontinuing the Wrap. The other participant had a small imprint on the anterior portion of their foot from the Wrap's seam. This event resolved within 20 minutes after placing a gauze pad between the patients' skin and the Wrap, removing pressure on the site.

Two participants (10%) experienced rebleeding events during the study, and haemostasis was achieved following intervention in both cases. One participant (5%) had the Wrap reapplied after haemostasis, the other participant (5%) had the Wrap removed, and it was not reapplied. This participant was one of the largest children in the study and could sit up with the Wrap in place.

Open-ended responses totalled 33, 17 from nurse providers and 16 from parents. Figures 3 and 4 highlights these responses.

Discussion

Feasibility

This pilot study demonstrates the feasibility and safety of the Wrap when used with young paediatric patients aged 1–5 years old during the bed rest period following cardiac catheterisation. The Wrap provided a consistent method of maintaining immobility while allowing visualisation of the femoral access sites and palpitation of peripheral perfusion. By having clear views of the dressing sites, the Wrap enabled the nurses to keep a distance from their young paediatric patients while performing required assessments and care, preventing unnecessary stimulation which could upset the child.

During bed rest, it is essential that patients remain supine and immobile to prevent the complications of rebleeding. Children <10 kg or 0–2 years old at the time of the cardiac catheterisation are at a higher risk for post-procedural bleeding events than adults because of the procedural effects on their underdeveloped haemostatic system.[2] In the present study, 20% (n = 4) of participants were in this weight or age range. Of those patients, two had the Wrap in place for the entire prescribed bed rest period, and the other two had it on for the majority of their bed rest. This is an important acknowledgement because these very young paediatric patients are at a greater risk for rebleeding and are the least likely to respond to distraction, follow directions, or lay supine on bed rest for extended periods of time.

The findings from the study showed that the Wrap was a feasible, successful intervention in immobilising the majority of the study participants for their prescribed bed rest period. With the identification of eight participants that did not wear the Wrap for the entire time, the study team recognised that there may be a subgroup of participants for whom the Wrap or other immobiliser may not be appropriate. Children who are developmentally mature and patients who get agitated when covered with blankets or restrained at baseline may resist wearing the Wrap. In these situations, the use of a bath blanket, or any other immobiliser, may be equally disturbing to the child. Future investigations of the Wrap should include a larger sample of children and a control group to better evaluate the feasibility of the Wrap with specific patient populations and to compare the Wrap against any current standards or commonly used practices for immobilisation following cardiac catheterisation.

Ease of use

Overall, the majority of participating nurses agreed that the Wrap was equal or better to the current nursing interventions at the study site, and most felt the Wrap improved their ability to deliver care during the post-catheterisation recovery period. In addition, all nurses who participated in the study reported that the Wrap was easy to apply and remove as needed. Nurses also confirmed that when the Wrap was applied, study participants appeared comfortable, and it was easy to view the femoral access site dressings through the open viewing window.

The study team found that most study participants achieved a good fit with the one-size-fits-all Wrap. No children were withdrawn from the study due to poor fit. One nurse indicated they had difficulty checking pulses with a Doppler probe on one subject; a second nurse stated the Wrap brushed against the child's gastrostomy tube site, and a third indicated use of the device caused an indentation on the child's foot from the binding around the edge of

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Table 2. Demographics.

Demographics	n (%) / median [range]
Gender	
Male	9 (45.0)
Female	11 (55.0)
Race/Ethnicity	
White	11 (55.0)
Black/African American	6 (30.0)
Asian	1 (5.0)
Latino	1 (5.0)
Unknown	1 (5.0)
Previous catheterisation	
Yes	15 (75.0)
No	5 (25.0)
Age (years)	3.36 [1.37–5.62]
Weight (kg)	13.16 [8.8–20.4]
Height (cm)	91.01 [75.8–114.5]
Primary diagnosis	
Tetralogy of fallot	1 (5.0)
Tricuspid atresia	1 (5.0)
Pulmonary artery stenosis	2 (10.0)
Left ventricle fibroma	1 (5.0)
Transposition of the great arteries	3 (15.0)
Pulmonary vein stenosis	1 (5.0)
Ventricular septal defect	1 (5.0)
Double outlet right ventricle	2 (10.0)
Patent ductus arteriosus	1 (5.0)
Hypoplastic left heart syndrome	2 (10.0)
Complete atrioventricular canal	2 (10.0)
Open heart transplant	1 (5.0)
Atrial septal defect	2 (10.0)

the Wrap. None of these situations, however, led to the discontinuation of the device during the study. Adjustment of the Wrap was necessary to increase the width between the feet to accommodate the Doppler probe. Rubbing around the gastrostomy tube was addressed through a minor readjustment in the Wrap's Velcro placement, and the indentation from the binding was relieved by placing gauze between the foot and the Wrap to protect the skin. A consideration for future studies is to include more than one size Wrap to improve the fit for children of varying sizes and needs.

Functional issues when using the Wrap on children reported by nurses included: (1) excessive movement, causing shifting of the viewing window, (2) opening and releasing the Velcro, and (3) sitting up with the device in place. In these situations, the nurses intervened with minimal disruption or stimulation of the children. For excessive movement, the nurse re-adjusted the device to ensure the groin access sites remained visible. Discontinuation of the device was necessary for the children that independently opened the Wrap and the child that sat up with the Wrap in place. Upon closer examination, the child that sat up was at the high end of age, weight, and height for Wrap use. The Wrap may be more applicable for children who are younger and smaller.

Regarding use of other medical devices or procedures required in the post-catheterisation period, 89% of nurses reported the Wrap did not cause any interference. The Wrap can be easily opened intermittently for procedures such as auscultation of the lungs or echocardiograms, increasing its utility in this setting.

One important consideration related to the Wrap's feasibility, not anticipated by the study team, is that some children experience agitation with restraint, immobilisation, or being covered with blankets. In our small study sample, four patients exhibited this type of behaviour, but its use was only discontinued early with two of these children. The Data Safety and Monitoring Committee recommended screening children for these behaviours in the future before use. Children with these behaviours may need special considerations such as opening the Wrap once they are awake and aware of their surroundings, and then reapplying it when they are sleeping.

Parent satisfaction

A notable strength of this study was that most participants and their parent(s) had experience with a previous cardiac catheterisation and 100% of those parent(s) agreed the Wrap was an overall improvement compared to the previous method of care. In addition, parent(s) reported that their child appeared comfortable in the Wrap, constructed of a soft, comfortable, durable material, and that the use of the Wrap allowed them to participate in the post-cardiac catheterisation care of their child. Parental interaction was a main catalyst for the development of the Wrap. When a bath blanket is used as an immobiliser, it has a tendency to unwrap, diminishing its effectiveness, resulting in the child needing to be put back to bed, and limiting the time that parents can hold and comfort their child. Thus, it was reassuring those parent(s) of participants were able to comfort and hold their child while wearing the Wrap following cardiac catheterisation without the risk of disrupting the recovery process.

Following cardiac catheterisation, it is important not to disrupt the recovery process due to the potential for rebleeding from the access sites with activity and agitation. Paediatric patients need special considerations; they are not small adults. Adult patients can remain supine and limit movement, but extended periods of bed rest can be challenging in the paediatric population because of developmental age and short memory spans, which cause them not to cooperate or follow instructions. The prefrontal cortex responsible for logical and regulatory behaviours is still immature in the infant–toddler age group, so logical explanation may fail.[20,21]

While adults can often be given minimal sedation for a cardiac catheterisation procedure, paediatric patients require general anaesthesia in most cases and can suffer from emergence agitation and delirium upon awakening. Paediatric patients aged 2–5 years tend to be the most susceptible group to suffer from these behavioural disturbances. When patients are in these disassociated states, no reassurance, distraction, or reasoning is typically successful. Furthermore, these behavioural disturbances can escalate to prolonged post-procedural agitation if not managed, resulting in decreased patient/parent satisfaction, increased nursing acuity, and use of additional sedatives. Sedation is an option to help patients suffering from emergence agitation or delirium, but some

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Table 3. Patient bed rest.

Subject	Age	Gender	Weight (kg)	Height (cm)	Prescribed hours	Completed hours	Reason for Wrap discontinuation
001	3.9	Male	14.7	101.9	6	6	
002	3.9	Female	13.3	96.5	6	0.75	Patient removed the Wrap themselves
003	5.6	Male	17	103.5	6	5	Patient transferred to cardiac floor
041	3.0	Female	11.6	87.3	6	6	
005	1.4	Female	9.6	76.5	6	5	Patient agitated
006	3.7	Male	12.2	87.5	4	4	
007	2.9	Female	8.8	80.2	4	4	
008	4.7	Female	12.7	93.2	6	6	
009	4.8	Female	20.4	114.5	6	6	
010	2.6	Female	14.5	92.5	6	5	Patient agitated
011	3.1	Male	14.2	95.3	6	3	Patient transferred to cardiac floor
012	1.9	Female	10.9	77.5	6	6	
013	1.5	Female	9.7	77.5	4	3	Patient agitated
014	5.5	Male	16.2	104	6	3	Patient agitated
015	2.1	Male	10.3	75.8	6	6	
016	3.5	Male	10.9	78.5	6	6	
017	2.3	Male	10.8	85.5	6	2	Patient febrile
018	4.1	Female	16.7	105	6	4	Patient removed the Wrap themselves
019	3.9	Male	17.6	103	6	2	Patient rebleed
020	2.8	Female	11	84.5	6	6	

medications can be neurotoxic, lead to a longer recovery time in the hospital, and therefore increase the cost.[7] A safer option should be utilised, when possible, in young paediatric patients due to these concerns.

Another consideration during the post-cardiac catheterisation recovery phase is stranger angst and white coat syndrome contributing to patient and parent anxiety. Scientific evidence shows a link between a child's level of anxiety to that of their parents and vice versa. When a parent witnesses the child's anxiety, it raises their own. This anxiety can lead to decreased satisfaction with provided care.[22,23]

More than half of the parent(s) in this study (55%, n = 11) reported they could hold their child while in the Wrap without disrupting the recovery process. The Wrap helps decrease anxiety by providing a comfortable, contained, secure environment that allows parent(s) to hold their child when needed. Additionally, according to our study results, most parent(s) observed that nurse providers could perform post-catheterisation recovery care with minimal disruption to their care. Increasing parent satisfaction during the post-catheterisation period may decrease anxiety surrounding a stressful procedure for both the parent(s) and the child.

Safety

In this study, two rebleeding events were observed. In both situations, the nurses were able to visualise and intervene during the rebleeding events without interference from the Wrap. A function of the Wrap is to immobilise the child's lower body. Through immobilisation, the Wrap may potentially reduce the risk of rebleeding events caused by disruption of hemostasis from patient movement. However, post-cardiac catheterisation rebleeding events are multifactorial; thus, it is unrealistic to expect the Wrap will eliminate these events completely.

Only two patients experienced adverse events with the use of the Wrap. One patient developed hyperthermia that met protocol requirements for discharge from the study. The patient's temperature normalised within 1 hour and 45 minutes after the removal of the Wrap. The Wrap has three layers, two of fabric and one of foam. The study team anticipated that children might become hyperthermic before reaching the 4–6-hour bed rest endpoint. When the Wrap is in use with children with congenital cardiac defects, it is imperative to assess patients for hyperthermia carefully. A hyperthermic state increases myocardial demand and can place a child at greater risk for hypoxaemia or oxygen desaturation.[24]

Another study participant encountered an adverse event when an indentation developed on the anterior portion of a patient's foot where the distal edge of the Wrap's binding rested. Children with cardiac conditions generally experience lower oxygen saturations and inadequate tissue perfusion. As a result, these patients are at increased risk of developing pressure ulcers, which can be significant adverse reportable events in hospitals.[25] For this child, gauze was placed between the Wrap and the affected extremity, relieving pressure points and resolving the imprint after 20 minutes. With future use of the Wrap, it will be essential to assess for pressure areas so that interventions can be employed to prevent progression to an advanced stage.

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Table 4. Parent/caregiver satisfaction tool.

Parent/caregiver satisfication	n (%)
My child appeared comfortable in the Wrap	
Strongly agree	6 (30.0)
Agree	10 (50.0)
Disagree*	4 (20.0)
Strongly disagree	0 (0.0)
I was able to hold my child during his or her recovery	
Strongly agree	7 (35.0)
Agree	4 (20.0)
Disagree	4 (20.0)
Strongly disagree	0 (0.0)
Not applicable	5 (25.0)
The Wrap allowed the doctors and nurses to care for my child with minimal disruption to my child's recovery	
Strongly agree	11 (55.0)
Agree	8 (40.0)
Disagree	1 (5.0)
Strongly disagree	0 (0.0)
Has your child had a previous cardiac catheterisation	
Yes	15 (75.0)
No	5 (25.0)
Compared to your previous experience with post-catheterisation recovery, the recovery with the Wrap was (n = 14)	
Much better	8 (57.1)
Somewhat better	4 (28.6)
Equal	2 (14.3)
Somewhat worse	0 (0.0)
Much worse	0 (0.0)

*Three of the four parents who disagreed reported that their child had a previous catheterisation; and responded that compared to their previous experience with post-catheterisation recovery, the recovery with the Wrap was equal (1) or somewhat better (2)

Table 5. Nurse/provider ease of use tool.

Nurse provider ease use	n (%)
The Wrap was easy to apply (n = 20)	
Strongly agree	14 (70.0)
Agree	6 (30.0)
Disagree	0 (0.0)
Strongly disagree	0 (0.0)
The Wrap did not interfere with other medical devices (n = 20)	
Strongly agree	14 (70.0)
Agree	5 (25.0)
Disagree	1 (5.0)
Strongly disagree	0 (0.0)
The Wrap did not interfere with any medical procedures (n = 18)	
Strongly agree	11 (61.1)
Agree	5 (27.8)
Disagree	2 (11.1)
Strongly disagree	0 (0.0)
The Wrap was easy to remove (n = 19)	
Strongly agree	13 (68.4)
Agree	6 (31.6)
Disagree	0 (0.0)
Strongly disagree	0 (0.0)
Compared to the standard of care, recovery using the Wrap was (n = 19)	
Much better	12 (63.2)
Somewhat better	2 (10.5)
Equal	4 (21.1)
Somewhat worse	1 (5.2)
Much worse	0 (0.0)

Limitations

This study had several limitations to consider when interpreting the results. First, the sample size was small; therefore, findings related to feasibility and safety may not be all-encompassing. Future studies should examine the Wrap with a larger sample and specific populations such as children diagnosed with autism, developmental delay, and attention deficit hyperactivity disorder, as they may struggle tremendously with bed rest. Wrap use in other patient populations where procedures involve accessing the groin vessels with a supine bed rest requirement such as placement of a central line or neuro embolisation procedures can also be considered. Also, the practice in the cardiac catheterisation lab at the study site does not include routine administration of narcotics and sedatives following cardiac catheterisation procedures. These data were not collected during the course of the study but had the potential to influence the findings. Thus, future studies of the Wrap should consider the collection of narcotic and sedative use for a more comprehensive evaluation.

Additionally, although 55% of participants took advantage of holding their child during the recovery process, it is unclear from the parent satisfaction survey how many had the opportunity to do so. The study team recommends revising the question to parent(s) about holding their child if this study were to be replicated. The question "I was able to hold my child during his/her recovery?" may not accurately capture whether the parent(s) had been given the opportunity to hold their child. Revising this question for future studies is warranted to ensure the accurate attainment of this data.

Conclusions

This study advances the science of managing young paediatric patients following cardiac catheterisation by standardising the care they receive during the recovery, bed rest period. Nurses and other providers may want to consider the child's developmental age and size in order to determine whether the Wrap is warranted or if

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COMMENTS FROM NURSE PROVIDERS
FIT/SIZE POSITIVE
• Had to re-adjust a few times, otherwise was great • Patient was able to hold still for entire 4-hour bed rest without any obvious discomfort • Wrap appropriately fitting without interference to assessment or interventions • The size fit him perfectly - it did not move, easy to view groin sites, easy to access lung sounds and pulses
FIT/SIZE NEGATIVE
• Only able to auscultate upper airway fields, un-Velcro'd top [opened Velcro closure] to assess entire chest • 5 years old might be too old for it, as patient asked to take it off
PATIENT DISLIKES RESTRAINT
• Needed to adjust a few times as it was sliding a bit and obstructing view of dressing - patient was attempting to move
OVERALL SATISFIED
• Patient seemed to be content with Wrap; when Wrap was taken off patient immediately moved his legs, so it works • Overheard mom speaking highly of it to the grandma, they both thought it was a great idea, and that the patient seemed very comfortable
MATERIALS
• Maybe a different fabric for inside Wrap, because of warmth; had to remove early because of patients' temperature, wish I didn't have to because the patient did well with it

Figure 3. Comments from nurse providers.

COMMENTS FROM PARENTS
FIT/SIZE POSITIVE
• The Wrap is a great improvement from standard practice of swaddling with a blanket for the purpose of immobilization
FIT/SIZE NEGATIVE
• I would recommend an age limit of 4 years old, including the child's developmental level
PATIENT DISLIKES RESTRAINT
• My daughter does not like cover being placed over her and as a result it was not as effective overall
OVERALL COMFORT/ SATISFIED
• Our daughter (2.5-year-old) who has had multiple catheterizations has never been more relaxed • We support the Wrap 100% and hope we have the opportunity to use it again after her next catheterization • She was less agitated and was able to focus on relaxing during checks

Figure 4. Comments from parents.

Wraps of various sizes are needed. Recommendations for use and research include screening parent(s) about their child's tolerance of blankets or coverings before applying the Wrap. Future research studies involving the Wrap should aim for a larger sample of participants, including patients with special healthcare needs.

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Conflicts of interest. None.

Ethical standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional review board at Boston Children's Hospital.

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