Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques

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Title: Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques

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ABSTRACT

Study Objective: Manual techniques of intravascular fluid administration are commonly used during paediatric resuscitation, though it is unclear which technique is most efficient in the hands of typical health care providers. We compared the rate of fluid administration achieved with the Disconnect-Reconnect and Push-Pull manual syringe techniques for paediatric fluid resuscitation.

Methods: This study utilized a randomized crossover trial design and enrolled sixteen consenting Health Care Provider participants from a Canadian paediatric tertiary care center. The study was conducted in a non-clinical setting using a model simulating a 15 kg child in decompensated shock. Participants administered 900mL (60mL/kg) of normal saline to the simulated patient using each of the two techniques under study. The primary outcome was the rate of fluid administration, as determined by two blinded independent video reviewers. We also collected participant demographic data and evaluated other secondary outcomes including total volume administered, number of catheter dislodgements, number of technical errors, and subjective and objective measures of provider fatigue.

Results: All sixteen participants completed the trial. The mean (SD) rate of fluid administration (mL/s) was greater for the Disconnect-Reconnect technique at 1.77 (0.145) than it was for the Push-Pull technique at 1.62 (0.226), with a mean difference of 0.15 [95% CI 0.055 - 0.251] (p=0.005). There was no difference in mean volume administered (p=0.778) or participant self-reported fatigue (p=0.736) between techniques. No catheter dislodgement events occurred.

Conclusion: The Disconnect-Reconnect technique allowed for the fastest rate of fluid administration, suggesting that use of this technique may be preferable in situations requiring rapid resuscitation. These findings may help to inform future iterations of paediatric resuscitation guidelines.

Trial Registration: This trial was registered at ClinicalTrials.gov [NCT01774214] prior to enrolling the first participant.
ARTICLE SUMMARY

Key messages:

- There is little data available to guide healthcare providers in selecting a technique for rapid paediatric fluid administration where this is clinically required
- This randomized crossover trial compared two common manual techniques for rapid paediatric fluid administration in a simulated setting
- The Disconnect-Reconnect technique (DRT) yielded a faster rate of fluid administration (1.77 mL/sec, SD 0.145 mL/sec) than did the Push-Pull technique (PPT) (1.62 mL/sec, SD 0.226 mL/sec) (p=0.005), with fewer technical errors
- The total volume administered, number of catheter dislodgements, and subjective provider fatigue were the same for both techniques

Strengths and limitations of the study:

- A randomized crossover trial design was the most rigorous method to address the research question
- Findings provide objective data for clinicians who must select a method by which to perform rapid paediatric fluid administration, and may help inform future resuscitation guidelines
- Limitations of this research include use of a non-clinical model as a patient surrogate and that we did not evaluate set-up time for each technique
- The clinical significance of our findings are unknown
INTRODUCTION

Background:

Paediatric shock is a recognized medical emergency which, when left untreated, inevitably leads to further deterioration and cardiac arrest.[1] For children in particular, hypotension is a late clinical finding, which requires immediate action to avert disaster.[2] Current resuscitation guidelines recommend rapid intravascular administration of isotonic crystalloid and/or colloid as an essential component of the initial resuscitation and stabilization of paediatric shock.[3,4,5,6]

The American College of Critical Care Medicine (ACCM) guidelines for haemodynamic support in paediatric septic shock recommend that fluid boluses of 20 mL/kg be initiated immediately and repeated until perfusion is restored or signs of fluid overload develop.[7] Although the FEAST trial has led to questions regarding the role of fluid resuscitation in paediatric shock management, it is far from clear that these findings should be extrapolated to the European and North American clinical settings where anemia and malaria are comparatively rare.[8,9] Guidelines therefore continue to recommend prompt and rapid fluid administration for the treatment of paediatric shock in these settings,[10] as this has been linked with improved survival odds.[11-15]

Importance:

Although various paediatric resuscitation guidelines recommend rapid intravascular fluid administration, there is a paucity of evidence regarding how to best achieve this in the clinical setting. Recommended benchmarks for timely fluid administration are often not met in practice, suggesting that further research to improve knowledge translation is warranted.[12,13,16,17] Survey data from one Canadian paediatric academic center demonstrates that acute care providers utilize a number of techniques to perform fluid resuscitation for children, with manual syringe techniques being most common.[18]
There are two commonly used syringe techniques for manual fluid resuscitation: the Disconnect-Reconnect Technique (DRT, Figure 1) and the Push-Pull Technique (PPT, Figure 2). Though previous research has separately evaluated these two techniques,[19,20] their relative efficiency in the hands of typical health care providers has not been studied.

Goals of This Investigation:

The primary objective of this study was to compare two commonly used manual fluid resuscitation techniques (DRT and PPT) to determine which facilitates a faster rate of fluid administration in a simulated paediatric resuscitation scenario. We also evaluated additional outcomes relevant to overall fluid resuscitation efficiency.

METHODS

Full trial protocol was published prior to trial commencement.[21] The following represents an abbreviated version of the trial protocol.

Study Design and Setting:

The study was a single-blind, non-clinical, randomized crossover trial with two study arms. The trial was conducted at McMaster Children’s Hospital, an academic tertiary paediatric care center in Hamilton, Canada. Approval for study conduct was obtained from the Hamilton Integrated Research Ethics Board, and trial registration with ClinicalTrials.gov (NCT01774214) was completed prior to enrolment of the first study participant. All participants provided written informed consent and participated voluntarily.

Selection of Participants:

Eligible participants included nursing staff, physicians and medical trainees at McMaster Children’s Hospital who would be expected to perform manual fluid resuscitation as part of their
clinical activities. Participants were to be excluded if they had poor English, physical limitations affecting performance of the required tasks, or had acted in a physically strenuous capacity (for example providing CPR) in the 30 minutes preceding participation. Coffee gift cards ($25 value) were offered to all subjects as a participation incentive, with a second coffee card available as a prize to the participant in each group with the best performance.

**Model Setup:**

The trial setup included a model simulating a 15 kg child with a 1 inch 22-gauge, IV catheter. The distal end of the catheter was secured in an unobstructed manner within conduit tubing leading to a graduated cylinder. The graduated cylinder, used to collect and measure fluid effectively delivered to the model, was kept hidden from the view of participants. The proximal end of the IV catheter was connected via a catheter extension set to the appropriate technique-dependent setup. For the DRT method an excess supply of 60 mL syringes was provided, as well as a 1-litre bag of normal saline attached appropriately to a needle-less syringe adaptor. For the PPT setup, the proximal end of the catheter extension set was connected to a triple stopcock, with a 60 ml syringe at the second port, and standard IV tubing leading to a 1-litre bag of normal saline at the third port.

**Randomization:**

A third party randomization technique was used to assign participants to one of the two study arms in a 1:1 ratio, determining the order in which the two interventions were performed. The allocation sequence was generated by the third party, who was also responsible for the randomization of participants, and for keeping the randomization schedule secret from and inaccessible to the study investigators. Simple randomization was utilized, with no blocking or stratification.
Blinding:

We considered our trial as single-blind. Participants were provided with trial details sufficient
to allow for informed consent but were unaware of the hypotheses of the investigators. Participants
were also blinded to the amount of fluid being collected in the graduated cylinder (by physical
shielding during the intervention). Research assistants in this study were blinded to the randomization
schedule but could not be blinded to the allocation of participants, given the need for direct
observation. It is conceivable that they were aware of the purpose of the trial, though there were no
conflicts of interest with respect to study outcomes. The outcome assessors were blinded to the
purpose of the study. Collected data was input by EC.

Intervention and Participant Testing:

The study intervention involved administration of 60mL/kg (900mL) of normal saline to the
simulated patient as rapidly as possible using DRT or PPT. Pursuant to the crossover design, each of
the two interventions was applied in turn to each participant, with a washout time of 30 minutes to
mitigate any potential impact of fatigue on subsequent performance.

After obtaining informed consent, participants were randomized and underwent a
standardization procedure to orient them to the study procedures and techniques to be performed.[21]
The participant was then provided with a clinical vignette for the simulated scenario describing a
hypotensive child with suspected septic shock. Formal evaluation was initiated upon verbal prompt
from the research assistant. Participants were required to recall the volume of fluid that they had
administered and completed the intervention when they believed 900mL had been given.

Data Collection and Outcomes:

All testing was directly observed by the research assistant and video recorded. Two video
cameras captured video data during testing: Camera 1 filmed the catheter site where fluid was being
administered by the participant, while Camera 2 filmed the graduated cylinder where fluid accumulated over the course of the intervention. Two reviewers who were not informed of the purpose of the trial independently reviewed the videos for specific outcome data (below). The primary outcome was fluid administration rate (total fluid administered/total time). Total intervention time was determined by the video assessors, based on the “start” and “stop” signals from the research assistant and participant respectively. The research assistant determined the total volume administered upon completion of the intervention.

Secondary outcomes included:

1. Total volume effectively administered as a measure of technique accuracy.

2. Interval rates of fluid administration for the first, second and third 20 mL/kg aliquots administered.

3. Self-reported fatigue as determined from a 7-point Likert scale on a post-intervention questionnaire.

4. The proportion of catheter dislodgement events that occurred.

5. Technical issues encountered during the intervention that resulted in a significant departure from intended procedural technique.

Sample Size:

For the purposes of sample size calculation, infusion time and standard deviation data from our previously completed DRT trial [19] were used as nuisance parameters. The POWER procedure in SAS(r) V9.2 statistical software was used to calculate a required sample size of 16 to detect a mean difference of 0.2mL/s (deemed significant based on clinical experience of investigators), with power 0.9 and alpha 0.05.
Analysis:

The reporting of the trial was done in accordance with the CONSORT criteria (www.consort-statement.org). We used a flow-diagram to summarize the flow of participants in the study. The baseline characteristics are analyzed using descriptive statistics reported as count (percent) for each categorical variable. We planned to perform all analyses according to an intention-to-treat basis. The primary outcome was analyzed by a two-tailed paired Student t-test. Differences in volume of fluid effectively administered were evaluated with a two-tailed paired Student t-test. Interval rates of fluid administration were analyzed with a repeated-measures analysis of variance (ANOVA). Self-reported fatigue comparisons were analyzed using a Wilcoxon signed-rank test. We planned to compare the proportion of catheter dislodgement events using McNemar’s test. The criterion for statistical significance was set at alpha = 0.05. The results are reported as estimate of effect, 95% confidence interval (CI) and associated p-value. All analyses were performed using IBM SPSS Statistics Version 20 (Chicago, IL).
RESULTS

Characteristics of Study Participants:

Sixteen eligible healthcare providers (Table 1) were consented for testing with no excluded participants. All participants completed the assigned interventions and questionnaire as per protocol, and were included in the final analysis (Figure 3). Enrolment and testing were completed between April and June 2013.

Table 1: Participant demographic data from post-intervention trial questionnaire.

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<th>Responses (%)</th>
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<tr>
<td>&lt;20</td>
<td>0 (0)</td>
</tr>
<tr>
<td>20 – 29</td>
<td>5 (31.3)</td>
</tr>
<tr>
<td>30 – 39</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>40 – 49</td>
<td>4 (25)</td>
</tr>
<tr>
<td>≥50</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Participant profession</td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>13 (81.3)</td>
</tr>
<tr>
<td>Nursing Student</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Staff Physician</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Resident/Fellow</td>
<td>2 (15.5)</td>
</tr>
<tr>
<td>Medical Student</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Participant student status</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Resuscitation experience</td>
<td></td>
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<td>---------------------------</td>
<td>--</td>
</tr>
<tr>
<td>None</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Minimal</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Some Experience</td>
<td>5 (31.3)</td>
</tr>
<tr>
<td>Experienced</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>Very Experienced</td>
<td>3 (18.8)</td>
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<td>15 (93.8)</td>
</tr>
<tr>
<td>No</td>
<td>1 (6.3)</td>
</tr>
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<table>
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<tr>
<th>Participant’s preferred bolus method in paediatric fluid resuscitation</th>
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<tr>
<td>Regular IV Pump</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Syringe (DRT)</td>
<td>14 (87.5)</td>
</tr>
<tr>
<td>Syringe (PPT)</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Rapid Infuser</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pressure Bag</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>0 (0)</td>
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**Legend for Table 1**

DRT – Disconnect-Reconnect Technique

PPT – Push-Pull Technique
Main Results:

Outcome analysis results are summarized in Table 2. The primary outcome of total fluid administration rate (mL/s) significantly differed between the two techniques, with a mean difference of 0.15 [95% CI 0.05 - 0.25] (p=0.005). DRT was more efficient with a mean (SD) fluid administration rate (mL/s) of 1.77 (0.145) compared to 1.62 (0.226) for PPT. Of note, one participant’s administration rate was a significant outlier in the PPT group. Exclusion of this outlier from analysis did not significantly impact the primary outcome result.

There was no difference in the volume (mL) of fluid effectively administered, -6.25 [95% CI -52.76 - 40.26] (p=0.778), with mean volumes for each group close to the 900 mL target [DRT (891, SD 36.6) and PPT (898, SD 58.1)].

A significant change in fluid administration rate occurred over the DRT intervention (p<0.001) and the PPT intervention (p=0.003). Pairwise comparisons of mean (SD) infusion rates (mL/s) were performed. DRT Rate 1, 1.63 (0.143) was significantly different from Rate 2, 1.83 (0.176) and Rate 3, 1.88 (0.180); (p<0.001), while Rates 2 and 3 did not differ (p=0.114). PPT Rate 1, 1.62 (0.223) did not differ from Rate 2, 1.58 (0.237); (p=0.356) or Rate 3, 1.67 (0.265); (p=0.197), but Rate 2 was significantly different from Rate 3 (p=0.003).

Participant self-reported fatigue (mean rank) did not differ between DRT (5) and PPT (5) (p=0.755). No catheter dislodgements occurred during the trial.

Three technical issues were noted during performance of PPT, however none occurred with DRT. One subject performing PPT accidentally drew air into the line, leading to a procedural delay of greater than 60s. Two additional subjects made technical errors while performing PPT: one drew back on the syringe plunger while the stopcock was open to the simulated patient, while a second incorrectly administered fluid to the bag of saline rather than the simulated patient.
Table 2: Outcome analysis results reported with statistical significance.

<table>
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<tr>
<th>Study Outcomes</th>
<th>Disconnect-Reconnect Technique (DRT) n=16</th>
<th>Push-Pull Technique (PPT) n=16</th>
<th>Effect Estimate</th>
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<tr>
<td>Primary Outcome</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean Difference [95% CI]; p</td>
</tr>
<tr>
<td>Overall fluid infusion rate (mL/s)</td>
<td>1.77 (0.145)</td>
<td>1.62 (0.226)</td>
<td>0.153 [0.055, 0.251], p=0.005</td>
</tr>
<tr>
<td>Secondary Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid infusion rate by bolus (mL/s)†</td>
<td>Bolus 1: 1.63 (0.143)</td>
<td>Bolus 1: 1.62 (0.223)</td>
<td>0.016 [-0.088, 0.121]; 0.744</td>
</tr>
<tr>
<td></td>
<td>Bolus 2: 1.83 (0.176)</td>
<td>Bolus 2: 1.58 (0.356)</td>
<td>0.246 [0.136, 0.357]; &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Bolus 3: 1.88 (0.180)</td>
<td>Bolus 3: 1.67 (0.265)</td>
<td>0.214 [0.087, 0.340]; 0.003</td>
</tr>
<tr>
<td>Total fluid volume infused (mL)</td>
<td>891.8 (36.60)</td>
<td>898.13 (58.11)</td>
<td>-6.250 [-52.760, 40.260], p=0.778</td>
</tr>
<tr>
<td>Subjective fatigue rank (mean rank)</td>
<td>5.75 (1.0)</td>
<td>5.63 (1.20)</td>
<td>0.125 [-0.650, 0.900]; 0.736</td>
</tr>
<tr>
<td></td>
<td>Median (Q1, Q3)</td>
<td>6.0 (5.0, 6.5)</td>
<td>5.5 (5.0, 7.0)</td>
</tr>
<tr>
<td>Catheter Dislodgement</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Events (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical Issues</td>
<td>0</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td>Encountered (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

**Legend for Table 2**

† DRT infusion rates differ between bolus 1, 2, and 3; p<0.001
DRT infusion rates differ between bolus 1 and bolus 2; p<0.001
DRT infusion rates differ between bolus 1 and bolus 3; p<0.001
PPT infusion rates differ between bolus 1, 2, and 3; p=0.003
PPT infusion rates differ between bolus 2 and bolus 3; p=0.003
N/A – not applicable

DISCUSSION

This study demonstrates that use of the DRT technique allows for a faster rate of fluid administration than PPT. While fluid resuscitation speed was the primary outcome in this study, other measures of efficiency such as volume of fluid effectively delivered and catheter dislodgement events did not differ between the two techniques under study. Together these findings provide practical information for health care providers who must select a method of IV fluid administration when faced with a child who requires rapid intravascular volume expansion. While statistically significant, these findings are of unknown clinical importance suggesting a need for further research in this area.

Our previous work demonstrated that health care providers experience increasing fatigue with the ongoing performance of manual fluid resuscitation,[19] and so it was anticipated that a similar finding would be observed in the present study. Contrary to our hypothesis and opposite to our previous findings, fluid administration rate actually increased between the first and second 300mL boluses for DRT, and between the second and third boluses for PPT. This unexpected improvement in manual fluid resuscitation performance over the course of the intervention may have been due to a learning effect, despite our use of a standardization procedure. If a learning effect was indeed present, then it is also interesting that this was observed early on with DRT and later with PPT, suggesting that skill in performing PPT is more difficult to acquire.

The idea that PPT may be challenging for health care providers to perform under stressful conditions is further corroborated by our finding of multiple technical issues during performance of the intervention with PPT. In contrast, no technical issues were observed with DRT. We witnessed three technical errors when health care providers performed PPT: 1. air drawn into the IV line and inability...
of the provider to problem solve, 2. stopcock toggling error leading to an attempt to ‘pull’ from the patient instead of the bag, and 3. stopcock toggling error leading to an attempt to ‘push’ fluid back into the bag of saline rather than into the patient. We have in fact observed stopcock toggling errors with performance of PPT in the setting of real resuscitations, which is why we chose to evaluate this outcome in our study. Intravascular air injection can lead to pulmonary air embolism resulting in ventilation-perfusion mismatching, right-heart strain and total cardiovascular collapse.[22,23,24] In the setting of congenital heart disease systemic air embolism may occur, leading to serious sequelae including stroke.[22] Stopcock toggling errors are also problematic in that these may lead to delays in fluid administration or jeopardize the integrity of the IV catheter if blood is withdrawn. Together these findings would also favor selection of DRT when rapid manual fluid administration is required.

It is important to note that DRT is a two-provider technique. In situations where limited healthcare personnel are available to assist with resuscitation, the use of DRT instead of PPT may interfere with a second provider’s availability to perform other simultaneously required vital tasks. Fluid resuscitation is also often performed in the prehospital environment, and use of the DRT technique may be less practical than PPT in a moving ambulance or helicopter. There is also, theoretically, a greater risk of introducing infection with use of DRT, which requires repeated syringe connection and disconnection from the IV line. Studies of central line infection suggest that catheter hubs can be an important infectious source, and that aseptic technique (which may not occur in an urgent scenario) effectively reduces risk.[25] Since DRT requires the use of multiple syringes, the technique also entails a slightly increased cost and production of waste relative to PPT.

Administration of a 300 mL bolus requires five 60-mL syringes for DRT versus one syringe for PPT, though DRT does not require use of a triple stopcock. Table 3 provides a summary of the advantages and limitations to consider for the two manual fluid resuscitation techniques evaluated in this study.
Table 3. Advantages and limitations of two provider-endorsed manual paediatric fluid resuscitation techniques.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Disconnect-Reconnect (DRT) | - Facilitates a faster rate of fluid administration  
                          |   - Simple technique; likely easier to learn           
                          |   and possibly easier to recall and perform           | - Requires two providers  
                          |                                 | - Many syringes required which may increase cost and waste production  
                          | | - Requires multiple connections to the IV line which may increase risk of contamination |
| Push-Pull (PPT)    | - Can be performed by a single provider         | - Facilitates a slower rate of fluid administration    | - Risk of adverse events as a result of stopcock toggling errors  
                          | - Likely better suited to space-limited environments i.e. out-of-hospital setting  
                          | - May require only a single connection to the IV line (closed system) which may decrease risk of contamination  |

The majority of participants in this study were staff nurses. Participant career stage ranged from trainee to experienced staff member, and all but one were familiar with the use of manual syringe techniques for performing fluid resuscitation. Our study population is therefore a good sample of the healthcare providers who would be asked to perform fluid resuscitation in a paediatric tertiary care setting. We would expect health care providers working at smaller or non-specialized centers to have less experience with paediatric fluid resuscitation techniques compared to our subjects.
There are a number of limitations of our study that warrant mention. All materials were set up in a clinically appropriate fashion for the participants beforehand, unlike in a real resuscitation. While the setup time for each technique was similar, this was not specifically evaluated in our trial.

Secondly, the testing environment was quiet with no interruptions. A lack of distractors may have allowed participants to focus more effectively than is possible in practice, leading to greater accuracy and fewer errors. No catheter dislodgments occurred during testing, raising the possibility that our model may have offered some protection from this. However, catheter dislodgement from the model was indeed possible and occurred during pilot testing. Evaluation of PPT in a previous clinical trial found catheter dislodgement events to be a rare occurrence, experienced by only 1/57 children.[20] Finally, while our study demonstrated a statistically significant difference between DRT and PPT fluid administration rates, these findings are of unknown clinical significance. Notwithstanding this, our work provides new data for the resuscitation community to consider, in light of current paediatric resuscitation guidelines.[3,4,5,7,12]

CONCLUSION

This study demonstrates that DRT facilitates a faster rate of fluid administration than PPT, and that PPT is associated with more technical errors. It may therefore be appropriate to recommend DRT as the preferred method of manual paediatric fluid resuscitation using syringes, though patient and environmental factors will also affect provider choices. Further study in the clinical setting is required to support recommendations in future iterations of paediatric resuscitation guidelines regarding the safest and most effective way to perform rapid fluid resuscitation for children.
AUTHORS’ CONTRIBUTIONS

EC developed the trial protocol including study objectives, under the mentorship of MP and with input from GH. EC prepared the REB submission and produced revisions as required. EC and GH trained the research assistants and assisted with subject recruitment. EC was responsible for input of results data to the study database. EC was involved with data analysis and interpretation of study results, and produced the first version of this manuscript. GH assisted in revision of the manuscript draft, and participated in all stages of trial planning, document production and analysis. SU was primarily responsible for participant recruitment and scheduling. She ensured all testing was conducted appropriately, with assistance from EC and MP. GF and LT participated in trial design and statistical analysis planning. GF performed the sample size calculations. LT was responsible for the analysis of the data. MP conceived of the research question, played a major role in development of study objectives, and was responsible for scientific oversight of the trial. She played a key role in protocol development, preliminary data analysis and interpretation. She also revised the first draft of the manuscript and played a supervisory role in overseeing the work of EC, GH and SU. All authors reviewed and contributed to the submitted version of the paper.

ACKNOWLEDGEMENTS

We thank participating healthcare providers from McMaster Children’s Hospital for their time and effort, without which this trial could not have been completed. Mark Duffett organised the randomisation schedule and assisted with randomisation of trial participants. Michael Chong and Zach Arnott volunteered their time and served as our blinded video reviewers. Dr. Lawrence Mbuagbaw (PhD) provided assistance with statistical analyses. Figure 1 and Figure 2 are reproduced in this paper, from the original source article, with the permission of MP.
CONFLICTS OF INTEREST

EC has no competing interests to declare.

GH has no competing interests to declare.

SU has no competing interests to declare.

GF has no competing interests to declare.

LT has no competing interests to declare.

MP has no competing interests to declare.

FUNDING

This work was supported by the following funding sources. A CIHR Health Professional Student Research Award supported Evan Cole for his work on this study. A Regional Medical Associates Research Scholarship supported Dr. Greg Harvey by providing operating funds for trial conduct. Dr. Melissa Parker is supported by a Hamilton Health Sciences Research Early Career Award. New Faculty Start-up Funding from McMaster University (held by MP) also supported conduct of this work. None of the funding sources were in any way involved with trial design, conduction or data analysis.

CONTRIBUTORSHIP

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**DATA SHARING**

The data presented in this manuscript represent the analysis of all the available data related to this work. The primary dataset for this study is available to the corresponding author, MP. Study participants did not consent to the publication of the full dataset.
REFERENCES


FIGURE CAPTIONS

Figure 1: The ‘Disconnect–Reconnect’ technique (DRT) for fluid administration requires an assistant. The assistant prepares syringes of fluid while the provider repeatedly selects a syringe (A), attaches it to the IV line and depresses the plunger (B), then disconnects and discards the empty syringe (C).

Figure 2: The ‘Push–Pull’ technique (PPT) for fluid administration requires the healthcare provider to repeatedly perform two steps. With the stopcock positioned “off” to the patient, the provider first pulls on the syringe plunger to fill the syringe with fluid (A). The provider must then toggle the stopcock “on” to the patient and depress the plunger to administer fluid to the patient (B).

Figure 3: CONSORT trial flow diagram.
# CONSORT 2010 checklist of information to include when reporting a randomised trial

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
<td>Title page + 1</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td>3-4</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td>4</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td>N/a</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td>4-5</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td>4</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td>6-7</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td>6-7</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td>N/a</td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>7a</td>
<td>How sample size was determined</td>
<td>7</td>
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<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
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</tr>
<tr>
<td><strong>Randomisation:</strong></td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
<td>5</td>
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<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
<td>5</td>
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<tr>
<td></td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td>5</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td>5</td>
</tr>
<tr>
<td><strong>Blinding</strong></td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those</td>
<td>6</td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
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<tr>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
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<tr>
<td>12a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
<td>8</td>
<td></td>
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<tr>
<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
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<td></td>
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<tr>
<td>13a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
<td>9</td>
<td></td>
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<tr>
<td>13b</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
<td>9</td>
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<tr>
<td>14a</td>
<td>Dates defining the periods of recruitment and follow-up</td>
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<tr>
<td>14b</td>
<td>Why the trial ended or was stopped</td>
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<td></td>
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<tr>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
<td>9-10</td>
<td></td>
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<tr>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td>11-12</td>
<td></td>
</tr>
<tr>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
<td>N/a</td>
<td></td>
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<tr>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
<td>N/a</td>
<td></td>
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<tr>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
<td>N/a</td>
<td></td>
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<tr>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
<td>13</td>
<td></td>
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<tr>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
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<td></td>
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<tr>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td>13-16</td>
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<tr>
<td>23</td>
<td>Registration number and name of trial registry</td>
<td>4</td>
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<tr>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
<td>4</td>
<td></td>
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<tr>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
<td>18</td>
<td></td>
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</tbody>
</table>

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).*
Figure 1: The ‘ Disconnect–Reconnect’ technique (DRT) for fluid administration requires an assistant. The assistant prepares syringes of fluid while the provider repeatedly selects a syringe (A), attaches it to the IV line and depresses the plunger (B), then disconnects and discards the empty syringe (C).

227×563mm (300 x 300 DPI)
Figure 2: The 'Push–Pull' technique (PPT) for fluid administration requires the healthcare provider to repeatedly perform two steps. With the stopcock positioned "off" to the patient, the provider first pulls on the syringe plunger to fill the syringe with fluid (A). The provider must then toggle the stopcock "on" to the patient and depress the plunger to administer fluid to the patient (B).

163x193mm (300 x 300 DPI)
Figure 3: CONSORT trial flow diagram.
225x147mm (72 x 72 DPI)
Study protocol for a randomised controlled trial comparing the efficiency of two provider-endorsed manual paediatric fluid resuscitation techniques

Evan T Cole,1 Greg Harvey,1 Gary Foster,2,3 Lehana Thabane,1,2,3,4 Melissa J Parker1,5

ABSTRACT

Introduction: Paediatric shock is a life-threatening condition with many possible causes and a global impact. Current resuscitation guidelines require rapid fluid administration as a cornerstone of paediatric shock management. However, little evidence is available to inform clinicians how to most effectively perform rapid fluid administration where this is clinically required, resulting in suboptimal knowledge translation of current resuscitation guidelines into clinical practice.

Objectives: This study aims to determine which of the two commonly used techniques for paediatric fluid resuscitation (disconnect–reconnect technique and push–pull technique) yields a higher fluid administration rate in a simulated clinical scenario. Secondary objectives include determination of catheter dislodgement rates, subjective and objective measures of provider fatigability and descriptive information regarding any technical issues encountered with performance of each method under the study.

Methods and analysis: This study will utilise a randomised crossover trial design. Participants will include consenting healthcare providers from McMaster Children’s Hospital. Each participant will administer 900 ml (60 ml/kg) of normal saline to a simulated 15 kg infant as quickly as possible on two separate occasions using the manual fluid administration techniques under the study. The primary outcome, rate of fluid administration, will be evaluated using a paired two-tailed Student t test.

Ethics and dissemination: This protocol has been approved by the Hamilton Health Sciences Research Ethics Board.

Results: These will be published in a peer-reviewed scientific journal and presented at one or more scientific conferences.

Protocol Registration: Protocol Registered on ClinicalTrials.gov NCT01774214

INTRODUCTION

Paediatric shock is a life-threatening condition with causes including sepsis, haemorrhage, dehydration and allergy.1 Guidelines for the management of paediatric shock from the American Heart Association (AHA) Pediatric Advanced Life Support (PALS) and the Advanced Trauma Life Support (ATLS) recommend rapid fluid resuscitation as an essential component of treatment.2 3 The American College of Critical Care Medicine (ACCM) Surviving Sepsis guidelines require intravenous (IV/IO) administration of up to 60 ml/kg of isotonic fluids within the first 15 min of shock recognition and state that some children may require as much as
For peer review only

Intravascular fluid administration is a critical component of early shock management as this augments preload and improves cardiac output, and has been linked with decreased morbidity and mortality. Indeed, morbidity and mortality associated with paediatric shock has declined significantly in recent decades owing to rapid recognition and resuscitation. While current guidelines stress the importance of timely fluid administration, these benchmarks are often not reached in practice. Practical evidence-based recommendations as to how healthcare providers (HCPs) can best achieve these goals are lacking.

Manual fluid administration is commonly performed in the paediatric resuscitative setting as part of the treatment of shock. Methods of manual fluid resuscitation include the ‘disconnect-reconnect technique’ (DRT, figure 1) and the ‘push–pull technique’ (PPT, figure 2). Other methods of performing rapid fluid administration include use of pressure bag support or a rapid infuser device, although the relative roles of these techniques in paediatric shock resuscitation remain unclear. One previous study determined the PPT method to be equivalent to pressure bag support and superior to gravity flow in terms of fluid resuscitation speed.

Among commonly used manual fluid resuscitation techniques, however, it is unclear whether the DRT or PPT method is most efficient. We therefore decided to conduct a comparative trial to determine which of these manual fluid administration techniques is most efficient and should be recommended in future iterations of paediatric resuscitation guidelines.

Figure 1  The ‘disconnect–reconnection’ technique for fluid bolus delivery involves two HCPs. (A, B) One HCP rapidly prepares fluid-filled syringes. (C) A second HCP takes and connects a fluid-filled syringe to the IV extension tubing and administers the fluid to the patient by depressing the syringe plunger. The empty syringe is then disconnected and the process repeated until the desired volume of fluid has been administered.

Figure 2  The ‘push–pull’ technique for fluid bolus delivery involves one HCP. (A) The stopcock is positioned ‘off’ to the patient. The HCP ‘pulls’ the syringe plunger to draw fluid into the syringe from the bag of saline. (B) The stopcock is then toggled 180 degrees, turning this ‘on’ to the patient. (C) The HCP then ‘pushes’ the syringe plunger to administer the fluid. The process is repeated until fluid resuscitation is complete.
AIMS AND OBJECTIVES

Aims and significance

We seek to compare the speed of fluid administration achievable with two manual fluid resuscitation techniques commonly used in infants and children. This work is significant because the relative performance of these commonly used techniques has not been previously investigated. Results will have practical application in helping to determine how HCPs can most effectively perform fluid resuscitation in children when this is emergently required. Given the high resistance and limitations in fluid flow rates related to use of small radius IV catheters in children, secondary study outcomes related to provider fatigue and catheter dislodgement rates resulting from the performance of manual fluid resuscitation may also be of significance to the resuscitation community and may help to inform future guidelines.19

Primary objective

To determine whether a significant difference exists in the fluid administration rates of two commonly used paediatric fluid resuscitation methods: the DRT versus the PPT.

Secondary objectives

1. To compare HCP participants’ ability to accurately administer the requested volume (60 ml/kg or 900 ml) to the simulated patient while using the DRT versus PPT technique.
2. To compare the level of self-reported fatigue of HCPs as a result of performing the DRT versus PPT technique.
3. To compare the frequency of catheter dislodgement events that occur while fluid resuscitation is performed using the DRT versus PPT technique.
4. To compare the rates of fluid administration between the first, second and third 300 ml aliquots administered to the model for DRT and PPT, respectively.
5. To describe any technical issues that HCPs encounter while performing the DRT versus PPT technique.

Figure 3 A randomised crossover trial design will be used. This design helps to reduce between group variability by having each participant perform each of the interventions under study. The order in which the interventions are performed is determined by randomisation, to control for any potential training or learning effect. A washout period is included between interventions to allow for participant recovery from any resulting fatigue.

METHODS AND ANALYSIS

Design

This study will use a randomised crossover design with two study arms (see figure 3).

Setting

The study will be carried out at the McMaster Children’s Hospital, an academic centre for tertiary paediatric care in Hamilton, Canada.

Recruitment and consent

Potential participants will be recruited via local study promotion by the investigators, poster advertisement and email invitation. Gift cards will be used as an incentive for participation. Written informed consent will be obtained from interested and eligible participants prior to participation (see online supplementary appendix 1).

Participant eligibility

HCPs at McMaster Children’s Hospital satisfying the following inclusion and exclusion criteria will be eligible to participate in this study.

Inclusion criteria

1. HCPs working or training at McMaster Children’s Hospital, which includes staff nurses, staff physicians, postgraduate medical trainees, nursing students and medical students.
2. HCPs who may be asked to perform manual fluid resuscitation as part of their clinical care activities.

Exclusion criteria

1. Inability to understand English.
2. Limited manual dexterity, specifically resulting in an inability to perform manual fluid resuscitation involving syringes.
3. Have acted in a physically strenuous capacity that may result in significant hand fatigue, in the 30 min immediately prior to performance of trial intervention (eg, resuscitative tasks such as manual fluid resuscitation or CPR). Where this is the only criteria limiting participation of a given subject, rescheduling of an alternate testing time will be permitted.

Randomisation

A third-party randomisation technique will be utilised to assign participants to one of the two study arms. This will determine the order in which the two interventions will be performed. Given the nature of the study and its small size, no stratification or blocking will be utilised.

Model and interventions

Model setup

The setup used for this study will consist of a model simulating a 15 kg child and include a peripheral IV catheter. A 22 gauge, 1.00 inch IV catheter will be affixed to the hand of the model in typical clinical fashion to simulate in vivo conditions. The distal end of the catheter will be secured in an unobstructed manner within conduit tubing leading to a graduated cylinder, in
which the accumulating fluid may be continuously visualised. The proximal end of the IV catheter will be connected to a 7-inch catheter extension set. See online supplementary appendix 2 for an illustration of the model. For the DRT setup the proximal end of the catheter extension set will be capped with a needleless syringe lock. An excess supply of 60 ml syringes will be provided when subjects are to perform fluid administration using the DRT method, along with needleless adapters to facilitate the safe preparation of syringes of fluid from the provided 1-litre bag of normal saline. For the PPT setup, the proximal end of the catheter extension set will be connected to a triple stopcock, with a 60 ml syringe at the second port, and standard IV tubing leading to a 1-litre bag of normal saline at the third port. Only one syringe will be required to perform the PPT manual fluid administration method. Online supplementary appendices 3 and 4 provide schematic representations of the DRT and PPT setups, respectively, including the specific parts to be used in our trial.

Interventions

The study intervention is the method of manual fluid administration that the HCP participant will use to administer 60 ml/kg (900 ml) of normal saline to the simulated patient. As this is a randomised crossover trial, each of the two interventions will be applied to an HCP participant on two separate occasions. The interventions are:

1. DRT: As DRT is a two-person technique, an assistant will be provided who will perform the role of fluid syringe preparation. It is important to note that when the DRT intervention is being performed, the HCP participant will not be permitted to switch roles with the assistant as, in our experience, this does not occur in the setting of a real resuscitation.

2. PPT: This is a single-provider technique and no assistant is required.

Trial flow

On the first day of participation, following consent, participants will undergo randomisation. HCP participants will be scheduled to attend the testing site in pairs. The reason for this is a practical one: when an HCP participant is randomised to the DRT, they will require an assistant, as this is a two-provider technique. We will engage the second study participant, who is in attendance at the same time also to be tested, to act as the assistant for the other participant in this instance. On each testing day, a coin toss will be used to determine which of the two participants in attendance is tested first.

Example:

Day 1: Participant A performs DRT (participant B assists) → 30 min break → participant B performs PPT.

Day 2: Participant A performs PPT → 30 min break → participant B performs DRT (participant A assists).

Standardisation procedure

Prior to undergoing formal testing, HCPs will watch a brief standardisation video that will provide an overview of the roles/techniques to be performed including a demonstration. Providers will be afforded the opportunity to practice each technique briefly prior to formal testing to account for and attempt to minimise any training or learning effect. Participants will be permitted up to 3 syringes/syringe volumes to practice the technique to be performed after which time formal testing will proceed. The practice period is limited so that this will not result in participant fatigue.

Participant testing

The research assistant will be responsible for verifying the integrity of all equipment prior to formal testing and for ensuring compliance with study procedures according to a checklist. The HCP participant will then be provided with a brief clinical vignette for the simulated clinical situation: child in decompensated shock with hypotension, fever and rash. Testing will begin on verbal prompt and cease at participants’ discretion when they believe that they have administered the required 900 ml of normal saline. All testing will be video-recorded.

Washout period

A 30 min washout period is selected to mitigate for any potential fatigue which may have occurred as a result of acting as an assistant prior to undergoing formal testing as a participant. We chose 30 min based on our experience with a currently enrolling trial in which participants also perform manual fluid resuscitation using syringes. In that study, a minimum 10 min rest period is required between evaluations with an opportunity to take a longer break if desired (this has been offered to all participants and none have requested). In our upcoming study, participants will manually administer a larger volume of fluid. We therefore conservatively selected a 30 min washout period.

Data collection

Upon completion of each intervention, a research assistant will record data of interest on a data collection form (see online supplementary appendix 5). Each participant will also complete a post-trial questionnaire to collect demographic data including information regarding prior experience with paediatric fluid resuscitation (see online supplementary appendix 6). Participants will also be asked to rate how fatiguing they found the intervention to be on a seven-point Likert scale. Following testing on the second occasion, participants will be asked to complete the remaining portion of the questionnaire, related to performance of the second intervention.

All testing trials will be video-recorded as was carried out in our recently conducted study with good results. In that study, we successfully focused the video camera on the IV cannula and extension tubing site and did not capture any participant identifiers. We found actually timing participant testing with a stopwatch proved difficult in practice and that this was inaccurate. Outcome
data was therefore obtained by independent and blinded dual review of trial video recordings using a specific data extraction protocol, which showed excellent interobserver reliability (ICC=0.9997). We intend to utilise a similar procedure in the planned trial with several notable differences. In our previous trial, we carefully prepared the fluid-filled syringes for the HCP participants and colour-coded them, which allowed us to determine the fluid administration time for each 300 ml bolus by observing the administration site. In this trial, however, a different method is required as HCPs will be preparing the syringes themselves, resulting in variable volume and no colour coding of the syringes. To determine the fluid volume administered (and resulting rates), we will therefore need to film the graduated cylinder in which the fluid administered to the model will be collected.

Blinding

The investigators will be blinded to the randomisation schedule. It will not be possible to blind the investigators to the allocation of participants. The research assistants involved in extracting outcome data from the trial video recordings will not be otherwise involved in the study and will be blinded to its purpose. It will, however, be obvious from the video-recordings which technique the provider is performing. Participants will be blinded to the amount of fluid being collected in the graduated cylinder as an indicator of how much fluid has been administered to the model. We plan to shield from view of the participant the graduated cylinder in which the administered fluid is being collected.

Outcome measures

Primary outcome measure

The primary outcome is a comparison of the overall fluid infusion rates achieved by the two studied techniques. This will be calculated from total volume (determined by research assistant at completion of intervention) and time data collected by the blinded assessors from the video recordings of each trial. Two separate assessors will review each intervention video, and their results will be averaged for consistency.

Secondary outcome measures

1. The accuracy of fluid volume delivery will be determined by the research assistant based on the amount of fluid collected in the graduated cylinder, and how this differs from the requested volume of 900 ml.
2. Self-reported fatigue will be measured through use of seven-point Likert scales on the post-trial questionnaire.
3. Catheter dislodgment events will be recorded by the research assistant on the data collection form.
4. Fluid infusion rates will be determined based on a video review of the time to administer the first, second and final 300 ml ‘boluses’, as determined by the two independent and blinded outcome assessors.
5. Observable technical difficulties related to performance of the interventions will be noted in real time by the research assistant and during the process of video review by the blinded outcome assessors.

Statistical analysis and sample size rationale

The study is powered based on the primary outcome. Analysis and reporting of the results will follow the CONSORT guidelines for reporting randomised controlled trials as extended to follow accepted practices for crossover trials. We will adopt an intention-to-treat principle to analyse all outcomes (see table 1 below for details on study outcomes of interest and the corresponding statistical analysis plan).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Study outcomes and analysis plan</th>
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<tbody>
<tr>
<td><strong>Study outcome</strong></td>
<td><strong>Analysis plan</strong></td>
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</tbody>
</table>
| **Primary outcome** | **Two-tailed paired Student t test**  
α 0.05, β 0.20 |
| Comparison of the overall fluid infusion rates (ml/s) between the two techniques |  
α 0.05, β 0.20 |
| **Secondary outcomes** | **Two-tailed paired Student t test**  
α 0.05, β 0.20 |
| Comparison of fluid volume actually administered to the model between the two techniques |  
α 0.05, β 0.20 |
| Comparison of self-reported fatigue rating of individual healthcare providers between techniques | Wilcoxon test |
| Comparison of the proportion of trials where a catheter dislodgement event occurs between the two techniques | McNemar’s test |
| Comparison of infusion rate between the first, second, and third 300 ml volumes administered (separately for each technique)* | Repeated-measures ANOVA |
| Descriptive information regarding any technical issues that HCPs encounter while performing the DRT vs the PPT technique | Not applicable |

*The final ’300 ml’ rate will be calculated using the total time required and volume delivered after the first 600 ml. This will be near to but not exactly 300 ml, and the rate will be accurate based on the time required to give this exact volume. ANOVA, analysis of variance; DRT, disconnect-reconnect technique; HCP, healthcare providers; PPT, push-pull technique.
Sample size

Using the fluid infusion time and SD data from our previously conducted trial as nuisance parameters, Table 2 provides a summary of the range of required sample sizes depending on what is felt to be appropriate in terms of a clinically important difference to detect between the intervention group means for a standardised volume of 900 ml administered. Note that we base our sample size calculation on total fluid intervention time although our primary outcome in this trial will be fluid infusion rate. Rate, of course, is calculated using the total fluid intervention time. We plan to use fluid administration rate in this trial, because the total fluid volume administered will differ between HCPs according to how accurately they are able to administer the requested fluid volume.

Given what we know about fluid resuscitation and how restoration of adequate circulatory preload can mean the difference between life and death, we believe that a mean difference of 60 s between the two different techniques would be of clinical significance to detect. This equates to a difference in fluid administration rate of approximately 0.2 ml/s and would require 12 participants with paired data to achieve 80% power. Accounting for the possibility of participant dropouts or other unanticipated issues, we conservatively plan to enrol 16 HCPs in total. If all 16 HCPs complete testing, this would yield a power level of 90% based on the calculations of our statistician co-investigators. We believe that it is reasonable to power our sample size calculation at the 90% level, knowing that if we experience any dropouts that we will retain (in all likelihood) a minimum of 80% power.

Ethics and dissemination

Ethics approval for the conduct of this study was obtained from the Hamilton Health Sciences Research Ethics Board 23 October 2012 (Project no. 12–358), and all procedures will be conducted in accordance with the Tri-council Policy Statement: Ethical conduct for research involving humans.23 All participants will undergo a process of informed consent, and will be made aware that participation is strictly voluntary. Participants may withdraw from the study at any time. ETC and GH will function as student coprimary investigators for this trial and will work under the supervision of MP, faculty supervisor. MP will lead the steering committee, and be responsible for overall monitoring of the trial. GF and LT are statisticians and have assisted with trial planning, design and analytical considerations. GF performed the sample size calculations. All of the authors of this paper are coinvestigators on the planned study and members of the trial steering committee. Should any safety concerns arise during the conduct of the study these will be brought to the attention of the steering committee and carefully reviewed. We intend to present the results of our study at one or more major scientific conferences and we will publish our results in a peer-reviewed scientific journal.

Feasibility

Given that our investigator group successfully recruited, consented and tested 48 HCPs in a 7-week time frame in the initial Pediatric Fast Fluid Trial, we fully anticipate the successful completion of the study proposed within a 1-year time frame.

<table>
<thead>
<tr>
<th>Mean difference in total fluid intervention rates (ml/s)</th>
<th>Power</th>
<th>Required sample size—number of HCPs (N)</th>
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<tbody>
<tr>
<td>0.05</td>
<td>0.9</td>
<td>203</td>
</tr>
<tr>
<td>0.05</td>
<td>0.8</td>
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</tr>
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<td>0.1</td>
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<td>0.1</td>
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<tr>
<td>0.15</td>
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<tr>
<td>0.15</td>
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<td>19</td>
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<td>0.2</td>
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<td>16</td>
</tr>
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<td>0.2</td>
<td>0.8</td>
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HCP, healthcare providers.

REFERENCES

Study protocol for a randomised controlled trial comparing the efficiency of two provider-endorsed manual paediatric fluid resuscitation techniques

Evan T Cole, Greg Harvey, Gary Foster, et al.

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Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques in a Simulated Setting

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<td>Date Submitted by the Author:</td>
<td>13-Jun-2014</td>
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<td>Cole, Evan; McMaster University, Department of Pediatrics Harvey, Greg; McMaster University, Department of Pediatrics Urbanski, Sara; McMaster University, Department of Pediatrics Foster, Gary; McMaster University, Clinical Epidemiology and Biostatistics Thabane, Lehana; McMaster University, Department of Clinical Epidemiology &amp; Biostatistics Parker, Melissa; McMaster University, Department of Pediatrics; University of Toronto, Department of Pediatrics</td>
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</table>
Title: Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques in a Simulated Setting

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Key Words: Paediatrics, Shock, Resuscitation, Fluid Therapy

Abstract word count: 285  Manuscript word count: 3050
ABSTRACT

Objectives: Manual techniques of intravascular fluid administration are commonly used during paediatric resuscitation, though it is unclear which technique is most efficient in the hands of typical health care providers. We compared the rate of fluid administration achieved with the Disconnect-Reconnect and Push-Pull manual syringe techniques for paediatric fluid resuscitation in a simulated setting.

Methods: This study utilized a randomized crossover trial design and enrolled sixteen consenting Health Care Provider participants from a Canadian paediatric tertiary care center. The study was conducted in a non-clinical setting using a model simulating a 15 kg child in decompensated shock. Participants administered 900mL (60mL/kg) of normal saline to the simulated patient using each of the two techniques under study. The primary outcome was the rate of fluid administration, as determined by two blinded independent video reviewers. We also collected participant demographic data and evaluated other secondary outcomes including total volume administered, number of catheter dislodgements, number of technical errors, and subjective and objective measures of provider fatigue.

Results: All sixteen participants completed the trial. The mean (SD) rate of fluid administration (mL/s) was greater for the Disconnect-Reconnect technique at 1.77 (0.145) than it was for the Push-Pull technique at 1.62 (0.226), with a mean difference of 0.15 [95% CI 0.055 - 0.251] (p=0.005). There was no difference in mean volume administered (p=0.778) or participant self-reported fatigue (p=0.736) between techniques. No catheter dislodgement events occurred.

Conclusion: The Disconnect-Reconnect technique allowed for the fastest rate of fluid administration, suggesting that use of this technique may be preferable in situations requiring rapid resuscitation. These findings may help to inform future iterations of paediatric resuscitation guidelines.

Trial Registration: This trial was registered at ClinicalTrials.gov [NCT01774214] prior to enrolling the first participant.
ARTICLE SUMMARY

Key messages:

- There is little data available to guide healthcare providers in selecting a technique for rapid paediatric fluid administration where this is clinically required

- This randomized crossover trial compared two common manual techniques for rapid paediatric fluid administration in a simulated setting

- The Disconnect-Reconnect technique (DRT) yielded a faster rate of fluid administration (1.77 mL/sec, SD 0.145 mL/sec) than did the Push-Pull technique (PPT) (1.62 mL/sec, SD 0.226 mL/sec) (p=0.005), with fewer technical errors

- The total volume administered, number of catheter dislodgements, and subjective provider fatigue were the same for both techniques

Strengths and limitations of the study:

- A randomized crossover trial design was the most rigorous method to address the research question

- Findings provide objective data for clinicians who must select a method by which to perform rapid paediatric fluid administration, and may help inform future resuscitation guidelines

- Limitations of this research include use of a non-clinical model as a patient surrogate and that we did not evaluate set-up time for each technique

- The clinical significance of our findings are unknown
INTRODUCTION

Background:

Paediatric shock is a recognized medical emergency which, when left untreated, inevitably leads to further deterioration and cardiac arrest.[1] For children in particular, hypotension is a late clinical finding, which requires immediate action to avert disaster.[2] Current resuscitation guidelines recommend rapid intravascular administration of isotonic crystalloid and/or colloid as an essential component of the initial resuscitation and stabilization of paediatric shock.[3,4,5,6]

The American College of Critical Care Medicine (ACCM) guidelines for haemodynamic support in paediatric septic shock recommend that fluid boluses of 20 mL/kg be initiated immediately and repeated until perfusion is restored or signs of fluid overload develop.[7] Although the FEAST trial has led to questions regarding the role of fluid resuscitation in paediatric shock management, it is far from clear that these findings should be extrapolated to the European and North American clinical settings where anemia and malaria are comparatively rare.[8,9] Guidelines therefore continue to recommend prompt and rapid fluid administration for the treatment of paediatric shock in these settings,[10] as this has been linked with improved survival odds.[11-15]

Importance:

Although various paediatric resuscitation guidelines recommend rapid intravascular fluid administration, there is a paucity of evidence regarding how to best achieve this in the clinical setting. Recommended benchmarks for timely fluid administration are often not met in practice, suggesting that further research to improve knowledge translation is warranted.[12,13,16,17] Survey data from one Canadian paediatric academic center demonstrates that acute care providers utilize a number of techniques to perform fluid resuscitation for children, with manual syringe techniques being most common.[18]
There are two commonly used syringe techniques for manual fluid resuscitation: the Disconnect-Reconnect Technique (DRT, Figure 1) and the Push-Pull Technique (PPT, Figure 2). Though previous research has separately evaluated these two techniques,[19,20] their relative efficiency in the hands of typical health care providers has not been studied.

Goals of This Investigation:

The primary objective of this study was to compare two commonly used manual fluid resuscitation techniques (DRT and PPT) to determine which facilitates a faster rate of fluid administration in a simulated paediatric resuscitation scenario. We also evaluated additional outcomes relevant to overall fluid resuscitation efficiency.

METHODS

Full trial protocol was published prior to trial commencement.[21] The following represents an abbreviated version of the trial protocol.

Study Design and Setting:

The study was a single-blind, non-clinical, randomized crossover trial with two study arms. The trial was conducted at McMaster Children’s Hospital, an academic tertiary paediatric care center in Hamilton, Canada. Approval for study conduct was obtained from the Hamilton Integrated Research Ethics Board, and trial registration with ClinicalTrials.gov (NCT01774214) was completed prior to enrolment of the first study participant. All participants provided written informed consent and participated voluntarily.

Selection of Participants:

Eligible participants included nursing staff, physicians and medical trainees at McMaster Children’s Hospital who would be expected to perform manual fluid resuscitation as part of their
clinical activities. Participants were to be excluded if they had poor English, physical limitations affecting performance of the required tasks, or had acted in a physically strenuous capacity (for example providing CPR) in the 30 minutes preceding participation. Coffee gift cards ($25 value) were offered to all subjects as a participation incentive, with a second coffee card available as a prize to the participant in each group with the best performance.

Model Setup:

The trial setup included a model simulating a 15 kg child with a 1 inch 22-gauge, IV catheter. The distal end of the catheter was secured in an unobstructed manner within conduit tubing leading to a graduated cylinder. The graduated cylinder, used to collect and measure fluid effectively delivered to the model, was kept hidden from the view of participants. The proximal end of the IV catheter was connected via a catheter extension set to the appropriate technique-dependent setup. For the DRT method an excess supply of empty 60 mL syringes was provided, as well as a 1-litre bag of normal saline attached appropriately to a needle-less syringe adaptor. For the PPT setup, the proximal end of the catheter extension set was connected to a triple stopcock, with an empty 60 ml syringe at the second port, and standard IV tubing leading to a 1-litre bag of normal saline at the third port.

Randomization:

A third party randomization technique was used to assign participants to one of the two study arms in a 1:1 ratio, determining the order in which the two interventions were performed. The allocation sequence was generated by the third party, who was also responsible for the randomization of participants, and for keeping the randomization schedule secret from and inaccessible to the study investigators. Simple randomization was utilized, with no blocking or stratification.
Blinding:

We undertook a number of measures to effect blinding and minimize the risk of bias. Participants were provided with trial details sufficient to allow for informed consent, but they were not advised of the study outcomes of interest or the hypotheses of the investigators. Participants were blinded to the amount of fluid accumulating in the graduated cylinder by physically shielding it during testing. The research assistant was provided limited detail regarding the purpose of the study as necessary to facilitate recruitment and consent of participants, set-up of required equipment, and coordination of testing. While the randomization schedule was concealed, the research assistant could not be blinded to participant assignment due to the nature of the intervention. The beginning and end of the intervention phase was defined by start and stop signals. The verbal start signal was an instruction given by the research assistant to the participant, while the verbal stop signal was given by the participant when they felt they had administered the required amount of fluid. It is conceivable that the research assistant was aware of the purpose of the trial, though there were no conflicts of interest with respect to study outcomes.

To minimize risk of bias in ascertainment of the primary outcome, we also utilized two independent outcome assessors who were blinded to the purpose of the study. The outcome assessors, who were non-clinicians, independently extracted the intervention time outcome data based on review of video footage displaying only the graduated cylinder and in which the start and stop announcements were audible. The outcome assessors also reviewed video footage of each intervention filmed from a second angle, extracting information on technical errors. As the videos were numbered by participant ID, and the outcome assessors reviewed all video footage, it is possible that they could have deduced the interventions under study and participant assignment. Outcome data was extracted independently and in duplicate to increase surety. With these measures, we considered our trial as single blind. Collected data was input by EC.
**Intervention and Participant Testing:**

The study intervention involved administration of 60mL/kg (900mL) of normal saline to the simulated patient as rapidly as possible using DRT or PPT. Pursuant to the crossover design, each of the two interventions was applied in turn to each participant, with a washout time of 30 minutes to mitigate any potential impact of fatigue on subsequent performance.

After obtaining informed consent, participants were randomized and underwent a standardization procedure to orient them to the study procedures and techniques to be performed.[21] The participant was then provided with a clinical vignette for the simulated scenario describing a hypotensive child with suspected septic shock. Formal evaluation was initiated upon verbal prompt from the research assistant. Participants were required to recall the volume of fluid that they had administered and completed the intervention when they believed 900mL had been given.

**Data Collection and Outcomes:**

All testing was directly observed by the research assistant and video recorded. Two video cameras captured video data during testing: Camera 1 filmed the catheter site where fluid was being administered by the participant, while Camera 2 filmed the graduated cylinder where fluid accumulated over the course of the intervention. Two outcome assessors who were not informed of the purpose of the trial independently reviewed the videos for specific outcome data (below). The primary outcome was fluid administration rate (total fluid administered/total time). Total intervention time was determined by the video assessors, based on the “start” and “stop” signals from the research assistant and participant respectively. The research assistant determined the total volume administered upon completion of the intervention.

Secondary outcomes included:

1. Total volume effectively administered as a measure of technique accuracy.
2. Interval rates of fluid administration for the first, second and third 20 mL/kg aliquots administered.

3. Self-reported fatigue as determined from a 7-point Likert scale on a post-intervention questionnaire.

4. The proportion of catheter dislodgement events that occurred.

5. Technical issues encountered during the intervention that resulted in a significant departure from intended procedural technique.

**Sample Size:**

For the purposes of sample size calculation, infusion time and standard deviation data from our previously completed DRT trial [19] were used as nuisance parameters. The POWER procedure in SAS(r) V9.2 statistical software was used to calculate a required sample size of 16 to detect a mean difference of 0.2mL/s (deemed significant based on clinical experience of investigators), with power 0.9 and alpha 0.05.

**Analysis:**

The reporting of the trial was done in accordance with the CONSORT criteria (www.consort-statement.org). We used a flow-diagram to summarize the flow of participants in the study. The baseline characteristics are analyzed using descriptive statistics reported as count (percent) for each categorical variable. We planned to perform all analyses according to an intention-to-treat basis. The primary outcome was analyzed by a two-tailed paired Student t-test. Differences in volume of fluid effectively administered were evaluated with a two-tailed paired Student t-test. Interval rates of fluid administration were analyzed with a repeated-measures analysis of variance (ANOVA). Self-reported fatigue comparisons were analyzed using a Wilcoxon signed-rank test. We planned to compare the proportion of catheter dislodgement events using McNemar’s test. The criterion for statistical
significance was set at alpha = 0.05. The results are reported as estimate of effect, 95% confidence
interval (CI) and associated p-value. All analyses were performed using IBM SPSS Statistics Version
20 (Chicago, IL).

RESULTS

Characteristics of Study Participants:

Sixteen eligible healthcare providers (Table 1) were consented for testing with no excluded
participants. All participants completed the assigned interventions and questionnaire as per protocol,
and were included in the final analysis (Figure 3). Enrolment and testing were completed between
April and June 2013.

Table 1: Participant demographic data from post-intervention trial questionnaire.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Responses (%)</th>
</tr>
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<tr>
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<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>0 (0)</td>
</tr>
<tr>
<td>20 – 29</td>
<td>5 (31.3)</td>
</tr>
<tr>
<td>30 – 39</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>40 – 49</td>
<td>4 (25)</td>
</tr>
<tr>
<td>≥50</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Participant profession</td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>13 (81.3)</td>
</tr>
<tr>
<td>Nursing Student</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Staff Physician</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Participant student status</td>
<td>Yes</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----</td>
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<tr>
<td></td>
<td>1 (6.3)</td>
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<table>
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<tr>
<th>Resuscitation experience</th>
<th>None</th>
<th>Minimal</th>
<th>Some Experience</th>
<th>Experienced</th>
<th>Very Experienced</th>
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<tr>
<td></td>
<td>1 (6.3)</td>
<td>1 (6.3)</td>
<td>5 (31.3)</td>
<td>6 (37.5)</td>
<td>3 (18.8)</td>
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<th>Use of syringes during a paediatric fluid resuscitation</th>
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<td>15 (93.8)</td>
<td>1 (6.3)</td>
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<table>
<thead>
<tr>
<th>Participant’s preferred bolus method in paediatric fluid resuscitation</th>
<th>Regular IV Pump</th>
<th>Syringe (DRT)</th>
<th>Syringe (PPT)</th>
<th>Rapid Infuser</th>
<th>Pressure Bag</th>
<th>Other</th>
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<tr>
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<td>1 (6.3)</td>
<td>14 (87.5)</td>
<td>1 (6.3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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</table>
Don’t Know 0 (0)

Legend for Table 1
DRT – Disconnect-Reconnect Technique
PPT – Push-Pull Technique

Main Results:

Outcome analysis results are summarized in Table 2. The primary outcome of total fluid administration rate (mL/s) significantly differed between the two techniques, with a mean difference of 0.15 [95% CI 0.05 - 0.25] (p=0.005). DRT was more efficient with a mean (SD) fluid administration rate (mL/s) of 1.77 (0.145) compared to 1.62 (0.226) for PPT. Of note, one participant’s administration rate was a significant outlier in the PPT group. Exclusion of this outlier from analysis did not significantly impact the primary outcome result.

There was no difference in the volume (mL) of fluid effectively administered, -6.25 [95% CI -52.76 - 40.26] (p=0.778), with mean volumes for each group close to the 900 mL target [DRT (891, SD 36.6) and PPT (898, SD 58.1)].

A significant change in fluid administration rate occurred over the DRT intervention (p<0.001) and the PPT intervention (p=0.003). Pairwise comparisons of mean (SD) infusion rates (mL/s) were performed. DRT Rate 1, 1.63 (0.143) was significantly different from Rate 2, 1.83 (0.176) and Rate 3, 1.88 (0.180); (p<0.001), while Rates 2 and 3 did not differ (p=0.114). PPT Rate 1, 1.62 (0.223) did not differ from Rate 2, 1.58 (0.237); (p=0.356) or Rate 3, 1.67 (0.265); (p=0.197), but Rate 2 was significantly different from Rate 3 (p=0.003).

Participant self-reported fatigue (mean rank) did not differ between DRT (5) and PPT (5) (p=0.755). No catheter dislodgements occurred during the trial.

Three technical issues were noted during performance of PPT, however none occurred with DRT. One subject performing PPT accidentally drew air into the line, leading to a procedural delay of greater than 60s. Two additional subjects made technical errors while performing PPT: one drew back
on the syringe plunger while the stopcock was open to the simulated patient, while a second
incorrectly administered fluid to the bag of saline rather than the simulated patient.

Table 2: Outcome analysis results reported with statistical significance.

<table>
<thead>
<tr>
<th>Study Outcomes</th>
<th>Disconnect-Reconnect Technique (DRT) n=16</th>
<th>Push-Pull Technique (PPT) n=16</th>
<th>Effect Estimate</th>
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</thead>
<tbody>
<tr>
<td>Primary Outcome</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean Difference [95% CI]; p</td>
</tr>
<tr>
<td>Overall fluid infusion rate</td>
<td>1.77 (0.145)</td>
<td>1.62 (0.226)</td>
<td>0.153 [0.055, 0.251], p=0.005</td>
</tr>
<tr>
<td>(mL/s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid infusion rate by bolus</td>
<td>Bolus 1: 1.63 (0.143)</td>
<td>Bolus 1: 1.62 (0.223)</td>
<td>0.016 [-0.088, 0.121]; 0.744</td>
</tr>
<tr>
<td>(mL/s)†</td>
<td>Bolus 2: 1.83 (0.176)</td>
<td>Bolus 2: 1.58 (0.356)</td>
<td>0.246 [0.136, 0.357]; &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Bolus 3: 1.88 (0.180)</td>
<td>Bolus 3: 1.67 (0.265)</td>
<td>0.214 [0.087, 0.340]; 0.003</td>
</tr>
<tr>
<td>Total fluid volume infused</td>
<td>891.8 (36.60)</td>
<td>898.13 (58.11)</td>
<td>-6.250 [-52.760, 40.260],</td>
</tr>
<tr>
<td>(mL)</td>
<td></td>
<td></td>
<td>p=0.778</td>
</tr>
<tr>
<td>Subjective fatigue rank</td>
<td>5.75 (1.0)</td>
<td>5.63 (1.20)</td>
<td>0.125 [-0.650, 0.900]; 0.736</td>
</tr>
<tr>
<td>(mean rank)</td>
<td>Median (Q1, Q3)</td>
<td>6.0 (5.0, 6.5)</td>
<td>5.5 (5.0, 7.0)</td>
</tr>
<tr>
<td>Catheter Dislodgement Events (n)</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Issues Encountered (n)</td>
<td>0</td>
<td>3</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Legend for Table 2

† DRT infusion rates differ between bolus 1, 2, and 3; $p<0.001$
DRT infusion rates differ between bolus 1 and bolus 2; $p<0.001$
DRT infusion rates differ between bolus 1 and bolus 3; $p<0.001$
DRT infusion rates do not differ between bolus 2 and bolus 3; $p=0.114$
PPT infusion rates differ between bolus 1, 2, and 3; $p=0.003$
PPT infusion rates differ between bolus 2 and bolus 3; $p=0.003$
PPT infusion rates did not differ between bolus 1 and either bolus 2; $p=0.356$ or bolus 3; $p=0.197$

N/A – not applicable

DISCUSSION

This study demonstrates that use of the DRT technique allows for a faster rate of fluid administration than PPT. While fluid resuscitation speed was the primary outcome in this study, other measures of efficiency such as volume of fluid effectively delivered and catheter dislodgement events did not differ between the two techniques under study. Together these findings provide practical information for health care providers who must select a method of IV fluid administration when faced with a child who requires rapid intravascular volume expansion. While statistically significant, these findings are of unknown clinical importance suggesting a need for further research in this area.

Our previous work demonstrated that health care providers experience increasing fatigue with the ongoing performance of manual fluid resuscitation,[19] and so it was anticipated that a similar finding would be observed in the present study. Contrary to our hypothesis and opposite to our previous findings, fluid administration rate actually increased between the first and second 300mL boluses for DRT, and between the second and third boluses for PPT. This unexpected improvement in manual fluid resuscitation performance over the course of the intervention may have been due to a learning effect, despite our use of a standardization procedure. If a learning effect was indeed present, then it is also interesting that this was observed early on with DRT and later with PPT, suggesting that skill in performing PPT is more difficult to acquire.
The idea that PPT may be challenging for health care providers to perform under stressful conditions is further corroborated by our finding of multiple technical issues during performance of the intervention with PPT. In contrast, no technical issues were observed with DRT. We witnessed three technical errors when health care providers performed PPT: 1. air drawn into the IV line and inability of the provider to problem solve, 2. stopcock toggling error leading to an attempt to ‘pull’ from the patient instead of the bag, and 3. stopcock toggling error leading to an attempt to ‘push’ fluid back into the bag of saline rather than into the patient. We have in fact observed stopcock toggling errors with performance of PPT in the setting of real resuscitations, which is why we chose to evaluate this outcome in our study. Intravascular air injection can lead to pulmonary air embolism resulting in ventilation-perfusion mismatching, right-heart strain and total cardiovascular collapse.[22,23,24] In the setting of congenital heart disease systemic air embolism may occur, leading to serious sequelae including stroke.[22] Stopcock toggling errors are also problematic in that these may lead to delays in fluid administration or jeopardize the integrity of the IV catheter if blood is withdrawn. Together these findings would also favor selection of DRT when rapid manual fluid administration is required.

It is important to note that DRT is a two-provider technique. In situations where limited healthcare personnel are available to assist with resuscitation, the use of DRT instead of PPT may interfere with a second provider’s availability to perform other simultaneously required vital tasks. Fluid resuscitation is also often performed in the prehospital environment, and use of the DRT technique may be less practical than PPT in a moving ambulance or helicopter. There is also, theoretically, a greater risk of introducing infection with use of DRT, which requires repeated syringe connection and disconnection from the IV line. Studies of central line infection suggest that catheter hubs can be an important infectious source, and that aseptic technique (which may not occur in an urgent scenario) effectively reduces risk.[25] Since DRT requires the use of multiple syringes, the technique also entails a slightly increased cost and production of waste relative to PPT.
Administration of a 300 mL bolus requires five 60-mL syringes for DRT versus one syringe for PPT, though DRT does not require use of a triple stopcock. Table 3 provides a summary of the advantages and limitations to consider for the two manual fluid resuscitation techniques evaluated in this study.

Table 3. Advantages and limitations of two provider-endorsed manual paediatric fluid resuscitation techniques.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disconnect-Reconnect (DRT)</td>
<td>- Facilitates a faster rate of fluid administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Simple technique; likely easier to learn and possibly easier to recall and perform</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Requires two providers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Many syringes required which may increase cost and waste production</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Requires multiple connections to the IV line which may increase risk of contamination</td>
<td></td>
</tr>
<tr>
<td>Push-Pull (PPT)</td>
<td>- Can be performed by a single provider</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Likely better suited to space-limited environments i.e. out-of-hospital setting</td>
<td></td>
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<tr>
<td></td>
<td>- May require only a single connection to the IV line (closed system) which may decrease risk of contamination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Facilitates a slower rate of fluid administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- More complex task; requires greater dexterity and more practice may be needed for optimal recall and performance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Risk of adverse events as a result of stopcock toggling errors</td>
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</tbody>
</table>

The majority of participants in this study were staff nurses. Participant career stage ranged from trainee to experienced staff member, and all but one were familiar with the use of manual syringe techniques for performing fluid resuscitation. Our study population is therefore a good sample of the
healthcare providers who would be asked to perform fluid resuscitation in a paediatric tertiary care setting. We would expect healthcare providers working at smaller or non-specialized centers to have less experience with paediatric fluid resuscitation techniques compared to our subjects.

There are a number of limitations of our study that warrant mention. All materials were set up in a clinically appropriate fashion for the participants beforehand, unlike in a real resuscitation. While the setup time for each technique was similar, this was not specifically evaluated in our trial. Secondly, the testing environment was quiet with no interruptions. A lack of distractors may have allowed participants to focus more effectively than is possible in practice, leading to greater accuracy and fewer errors. No catheter dislodgments occurred during testing, raising the possibility that our model may have offered some protection from this. However, catheter dislodgement from the model was indeed possible and occurred during pilot testing. Evaluation of PPT in a previous clinical trial found catheter dislodgement events to be a rare occurrence, experienced by only 1/57 children.[20] Finally, although our study demonstrated a statistically significant difference between DRT and PPT fluid administration rates, with the 95% confidence interval [0.055mL/s, 0.251mL/s] including the 0.2mL/s mean difference this study was powered to detect, our findings are of unknown clinical significance. Notwithstanding this, our work provides new data for the resuscitation community to consider, in light of current paediatric resuscitation guidelines.[3,4,5,7,12]

CONCLUSION

This study demonstrates that DRT facilitates a faster rate of fluid administration than PPT, and that PPT is associated with more technical errors. It may therefore be appropriate to recommend DRT as the preferred method of manual paediatric fluid resuscitation using syringes, though factors such as the patient, environment, resources and availability of personnel will also affect provider choices. Further study in the clinical setting is required to support recommendations in future iterations of
paediatric resuscitation guidelines regarding the safest and most effective way to perform rapid fluid resuscitation for children.
AUTHORS’ CONTRIBUTIONS

EC developed the trial protocol including study objectives, under the mentorship of MP and with input from GH. EC prepared the REB submission and produced revisions as required. EC and GH trained the research assistants and assisted with subject recruitment. EC was responsible for input of results data to the study database. EC was involved with data analysis and interpretation of study results, and produced the first version of this manuscript. GH assisted in revision of the manuscript draft, and participated in all stages of trial planning, document production and analysis. SU was primarily responsible for participant recruitment and scheduling. She ensured all testing was conducted appropriately, with assistance from EC and MP. GF and LT participated in trial design and statistical analysis planning. GF performed the sample size calculations. LT was responsible for the analysis of the data. MP conceived of the research question, played a major role in development of study objectives, and was responsible for scientific oversight of the trial. She played a key role in protocol development, preliminary data analysis and interpretation. She also revised the first draft of the manuscript and played a supervisory role in overseeing the work of EC, GH and SU. All authors reviewed and contributed to the submitted version of the paper.
ACKNOWLEDGEMENTS

We thank participating healthcare providers from McMaster Children’s Hospital for their time and effort, without which this trial could not have been completed. Mark Duffett organised the randomisation schedule and assisted with randomisation of trial participants. Michael Chong and Zach Arnott volunteered their time and served as our blinded video reviewers. Dr. Lawrence Mbuagbaw (PhD) provided assistance with statistical analyses.

FUNDING

This work was supported by the following funding sources. A CIHR Health Professional Student Research Award supported Evan Cole for his work on this study. A Regional Medical Associates Research Scholarship supported Dr. Greg Harvey by providing operating funds for trial conduct. Dr. Melissa Parker is supported by a Hamilton Health Sciences Research Early Career Award. New Faculty Start-up Funding from McMaster University (held by MP) also supported conduct of this work. None of the funding sources were in any way involved with trial design, conduction or data analysis.

CONTRIBUTORSHIP STATEMENT

EC developed the trial protocol including study objectives, under the mentorship of MP and with input from GH. EC prepared the REB submission and produced revisions as required. EC and GH trained the research assistants and assisted with subject recruitment. EC was responsible for input of results data to the study database. EC was involved with data analysis and interpretation of study results, and produced the first version of this manuscript. GH assisted in revision of the manuscript draft, and participated in all stages of trial planning, document production and analysis. SU was primarily responsible for participant recruitment and scheduling. She ensured all testing was conducted appropriately, with assistance from EC and MP. GF and LT participated in trial design and statistical analysis planning, GF performed the sample size calculations. LT
was responsible for the analysis of the data. MP conceived of the research question, played a
major role in development of study objectives, and was responsible for scientific oversight of the
trial. She played a key role in protocol development, preliminary data analysis and
interpretation. She also revised the first draft of the manuscript and played a supervisory role in
overseeing the work of EC, GH and SU. All authors reviewed and contributed to the submitted
version of the paper.

CONFLICTS OF INTEREST

EC has no competing interests to declare.
GH has no competing interests to declare.
SU has no competing interests to declare.
GF has no competing interests to declare.
LT has no competing interests to declare.
MP has no competing interests to declare.

DATA SHARING STATEMENT

The data presented in this manuscript represent the analysis of all the available data related to
this work. The primary dataset for this study is available to the corresponding author, MP. Study
participants did not consent to the publication of the full dataset.
REFERENCES


5 Pediatric Trauma. In: Advanced trauma life support for doctors student course manual. 8th edn. Chicago, IL: American College of Surgeons Committee on Trauma 2008:225-246.


FIGURE CAPTIONS

Figure 1A-C: The ‘Disconnect–Reconnect’ technique (DRT) for fluid administration requires an assistant. The assistant prepares syringes of fluid while the provider repeatedly selects a syringe (A), attaches it to the IV line and depresses the plunger (B), then disconnects and discards the empty syringe (C).

Figure 2A-B: The ‘Push–Pull’ technique (PPT) for fluid administration requires the healthcare provider to repeatedly perform two steps. With the stopcock positioned “off” to the patient, the provider first pulls on the syringe plunger to fill the syringe with fluid (A). The provider must then toggle the stopcock “on” to the patient and depress the plunger to administer fluid to the patient (B).

Figure 3: CONSORT trial flow diagram.
Title: Rapid Paediatric Fluid Resuscitation: A Randomized Controlled Trial Comparing the Efficiency of Two Provider-Endorsed Manual Paediatric Fluid Resuscitation Techniques in a Simulated Setting

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Key Words: Paediatrics, Shock, Resuscitation, Fluid Therapy

Abstract word count: 285  Manuscript word count: 3050
ABSTRACT

Study Objective: Manual techniques of intravascular fluid administration are commonly used during paediatric resuscitation, though it is unclear which technique is most efficient in the hands of typical health care providers. We compared the rate of fluid administration achieved with the Disconnect-Reconnect and Push-Pull manual syringe techniques for paediatric fluid resuscitation in a simulated setting.

Methods: This study utilized a randomized crossover trial design and enrolled sixteen consenting Health Care Provider participants from a Canadian paediatric tertiary care center. The study was conducted in a non-clinical setting using a model simulating a 15 kg child in decompensated shock. Participants administered 900mL (60mL/kg) of normal saline to the simulated patient using each of the two techniques under study. The primary outcome was the rate of fluid administration, as determined by two blinded independent video reviewers. We also collected participant demographic data and evaluated other secondary outcomes including total volume administered, number of catheter dislodgements, number of technical errors, and subjective and objective measures of provider fatigue.

Results: All sixteen participants completed the trial. The mean (SD) rate of fluid administration (mL/s) was greater for the Disconnect-Reconnect technique at 1.77 (0.145) than it was for the Push-Pull technique at 1.62 (0.226), with a mean difference of 0.15 [95% CI 0.055 - 0.251] (p=0.005). There was no difference in mean volume administered (p=0.778) or participant self-reported fatigue (p=0.736) between techniques. No catheter dislodgement events occurred.

Conclusion: The Disconnect-Reconnect technique allowed for the fastest rate of fluid administration, suggesting that use of this technique may be preferable in situations requiring rapid resuscitation. These findings may help to inform future iterations of paediatric resuscitation guidelines.

Trial Registration: This trial was registered at ClinicalTrials.gov [NCT01774214] prior to enrolling the first participant.
ARTICLE SUMMARY

Key messages:

- There is little data available to guide healthcare providers in selecting a technique for rapid paediatric fluid administration where this is clinically required

- This randomized crossover trial compared two common manual techniques for rapid paediatric fluid administration in a simulated setting

- The Disconnect-Reconnect technique (DRT) yielded a faster rate of fluid administration (1.77 mL/sec, SD 0.145 mL/sec) than did the Push-Pull technique (PPT) (1.62 mL/sec, SD 0.226 mL/sec) (p=0.005), with fewer technical errors

- The total volume administered, number of catheter dislodgements, and subjective provider fatigue were the same for both techniques

Strengths and limitations of the study:

- A randomized crossover trial design was the most rigorous method to address the research question

- Findings provide objective data for clinicians who must select a method by which to perform rapid paediatric fluid administration, and may help inform future resuscitation guidelines

- Limitations of this research include use of a non-clinical model as a patient surrogate and that we did not evaluate set-up time for each technique

- The clinical significance of our findings are unknown
INTRODUCTION

Background:

Paediatric shock is a recognized medical emergency which, when left untreated, inevitably leads to further deterioration and cardiac arrest.[1] For children in particular, hypotension is a late clinical finding, which requires immediate action to avert disaster.[2] Current resuscitation guidelines recommend rapid intravascular administration of isotonic crystalloid and/or colloid as an essential component of the initial resuscitation and stabilization of paediatric shock.[3,4,5,6]

The American College of Critical Care Medicine (ACCM) guidelines for haemodynamic support in paediatric septic shock recommend that fluid boluses of 20 mL/kg be initiated immediately and repeated until perfusion is restored or signs of fluid overload develop.[7] Although the FEAST trial has led to questions regarding the role of fluid resuscitation in paediatric shock management, it is far from clear that these findings should be extrapolated to the European and North American clinical settings where anemia and malaria are comparatively rare.[8,9] Guidelines therefore continue to recommend prompt and rapid fluid administration for the treatment of paediatric shock in these settings,[10] as this has been linked with improved survival odds.[11-15]

Importance:

Although various paediatric resuscitation guidelines recommend rapid intravascular fluid administration, there is a paucity of evidence regarding how to best achieve this in the clinical setting. Recommended benchmarks for timely fluid administration are often not met in practice, suggesting that further research to improve knowledge translation is warranted.[12,13,16,17] Survey data from one Canadian paediatric academic center demonstrates that acute care providers utilize a number of techniques to perform fluid resuscitation for children, with manual syringe techniques being most common.[18]
There are two commonly used syringe techniques for manual fluid resuscitation: the Disconnect-Reconnect Technique (DRT, Figure 1) and the Push-Pull Technique (PPT, Figure 2). Though previous research has separately evaluated these two techniques,[19,20] their relative efficiency in the hands of typical health care providers has not been studied.

Goals of This Investigation:

The primary objective of this study was to compare two commonly used manual fluid resuscitation techniques (DRT and PPT) to determine which facilitates a faster rate of fluid administration in a simulated paediatric resuscitation scenario. We also evaluated additional outcomes relevant to overall fluid resuscitation efficiency.

METHODS

Full trial protocol was published prior to trial commencement.[21] The following represents an abbreviated version of the trial protocol.

Study Design and Setting:

The study was a single-blind, non-clinical, randomized crossover trial with two study arms. The trial was conducted at McMaster Children’s Hospital, an academic tertiary paediatric care center in Hamilton, Canada. Approval for study conduct was obtained from the Hamilton Integrated Research Ethics Board, and trial registration with ClinicalTrials.gov (NCT01774214) was completed prior to enrolment of the first study participant. All participants provided written informed consent and participated voluntarily.

Selection of Participants:

Eligible participants included nursing staff, physicians and medical trainees at McMaster Children’s Hospital who would be expected to perform manual fluid resuscitation as part of their
clinical activities. Participants were to be excluded if they had poor English, physical limitations affecting performance of the required tasks, or had acted in a physically strenuous capacity (for example providing CPR) in the 30 minutes preceding participation. Coffee gift cards ($25 value) were offered to all subjects as a participation incentive, with a second coffee card available as a prize to the participant in each group with the best performance.

**Model Setup:**

The trial setup included a model simulating a 15 kg child with a 1 inch 22-gauge, IV catheter. The distal end of the catheter was secured in an unobstructed manner within conduit tubing leading to a graduated cylinder. The graduated cylinder, used to collect and measure fluid effectively delivered to the model, was kept hidden from the view of participants. The proximal end of the IV catheter was connected via a catheter extension set to the appropriate technique-dependent setup. For the DRT method an excess supply of empty 60 mL syringes was provided, as well as a 1-litre bag of normal saline attached appropriately to a needle-less syringe adaptor. For the PPT setup, the proximal end of the catheter extension set was connected to a triple stopcock, with an empty 60 ml syringe at the second port, and standard IV tubing leading to a 1-litre bag of normal saline at the third port.

**Randomization:**

A third party randomization technique was used to assign participants to one of the two study arms in a 1:1 ratio, determining the order in which the two interventions were performed. The allocation sequence was generated by the third party, who was also responsible for the randomization of participants, and for keeping the randomization schedule secret from and inaccessible to the study investigators. Simple randomization was utilized, with no blocking or stratification.
Blinding:

We undertook a number of measures to effect blinding and minimize the risk of bias. Participants were provided with trial details sufficient to allow for informed consent, but they were not advised of the study outcomes of interest or the hypotheses of the investigators. Participants were blinded to the amount of fluid accumulating in the graduated cylinder by physically shielding it during testing. The research assistant was provided limited detail regarding the purpose of the study as necessary to facilitate recruitment and consent of participants, set-up of required equipment, and coordination of testing. While the randomization schedule was concealed, the research assistant could not be blinded to participant assignment due to the nature of the intervention. The beginning and end of the intervention phase was defined by start and stop signals. The verbal start signal was an instruction given by the research assistant to the participant, while the verbal stop signal was given by the participant when they felt they had administered the required amount of fluid. It is conceivable that the research assistant was aware of the purpose of the trial, though there were no conflicts of interest with respect to study outcomes.

To minimize risk of bias in ascertainment of the primary outcome, we also utilized two independent outcome assessors who were blinded to the purpose of the study. The outcome assessors, who were non-clinicians, independently extracted the intervention time outcome data based on review of video footage displaying only the graduated cylinder and in which the start and stop announcements were audible. The outcome assessors also reviewed video footage of each intervention filmed from a second angle, extracting information on technical errors. As the videos were numbered by participant ID, and the outcome assessors reviewed all video footage, it is possible that they could have deduced the interventions under study and participant assignment. Outcome data was extracted independently and in duplicate to increase surety. With these measures, we considered our trial as single blind.

Collected data was input by EC.
Intervention and Participant Testing:

The study intervention involved administration of 60mL/kg (900mL) of normal saline to the simulated patient as rapidly as possible using DRT or PPT. Pursuant to the crossover design, each of the two interventions was applied in turn to each participant, with a washout time of 30 minutes to mitigate any potential impact of fatigue on subsequent performance.

After obtaining informed consent, participants were randomized and underwent a standardization procedure to orient them to the study procedures and techniques to be performed.[21] The participant was then provided with a clinical vignette for the simulated scenario describing a hypotensive child with suspected septic shock. Formal evaluation was initiated upon verbal prompt from the research assistant. Participants were required to recall the volume of fluid that they had administered and completed the intervention when they believed 900mL had been given.

Data Collection and Outcomes:

All testing was directly observed by the research assistant and video recorded. Two video cameras captured video data during testing: Camera 1 filmed the catheter site where fluid was being administered by the participant, while Camera 2 filmed the graduated cylinder where fluid accumulated over the course of the intervention. Two outcome assessors who were not informed of the purpose of the trial independently reviewed the videos for specific outcome data (below). The primary outcome was fluid administration rate (total fluid administered/total time). Total intervention time was determined by the video assessors, based on the “start” and “stop” signals from the research assistant and participant respectively. The research assistant determined the total volume administered upon completion of the intervention.

Secondary outcomes included:

1. Total volume effectively administered as a measure of technique accuracy.
2. Interval rates of fluid administration for the first, second and third 20 mL/kg aliquots administered.

3. Self-reported fatigue as determined from a 7-point Likert scale on a post-intervention questionnaire.

4. The proportion of catheter dislodgement events that occurred.

5. Technical issues encountered during the intervention that resulted in a significant departure from intended procedural technique.

Sample Size:

For the purposes of sample size calculation, infusion time and standard deviation data from our previously completed DRT trial [19] were used as nuisance parameters. The POWER procedure in SAS(r) V9.2 statistical software was used to calculate a required sample size of 16 to detect a mean difference of 0.2mL/s (deemed significant based on clinical experience of investigators), with power 0.9 and alpha 0.05.

Analysis:

The reporting of the trial was done in accordance with the CONSORT criteria (www.consort-statement.org). We used a flow-diagram to summarize the flow of participants in the study. The baseline characteristics are analyzed using descriptive statistics reported as count (percent) for each categorical variable. We planned to perform all analyses according to an intention-to-treat basis. The primary outcome was analyzed by a two-tailed paired Student t-test. Differences in volume of fluid effectively administered were evaluated with a two-tailed paired Student t-test. Interval rates of fluid administration were analyzed with a repeated-measures analysis of variance (ANOVA). Self-reported fatigue comparisons were analyzed using a Wilcoxon signed-rank test. We planned to compare the proportion of catheter dislodgement events using McNemar’s test. The criterion for statistical
significance was set at alpha = 0.05. The results are reported as estimate of effect, 95% confidence interval (CI) and associated p-value. All analyses were performed using IBM SPSS Statistics Version 20 (Chicago, IL).

RESULTS

Characteristics of Study Participants:

Sixteen eligible healthcare providers (Table 1) were consented for testing with no excluded participants. All participants completed the assigned interventions and questionnaire as per protocol, and were included in the final analysis (Figure 3). Enrolment and testing were completed between April and June 2013.

Table 1: Participant demographic data from post-intervention trial questionnaire.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Responses (%)</th>
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<tbody>
<tr>
<td>Participant age range (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>0 (0)</td>
</tr>
<tr>
<td>20 – 29</td>
<td>5 (31.3)</td>
</tr>
<tr>
<td>30 – 39</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>40 – 49</td>
<td>4 (25)</td>
</tr>
<tr>
<td>≥50</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Participant profession</td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>13 (81.3)</td>
</tr>
<tr>
<td>Nursing Student</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Staff Physician</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>--------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Resident/Fellow</td>
<td>2 (15.5)</td>
</tr>
<tr>
<td>Medical Student</td>
<td>0 (0)</td>
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</tbody>
</table>

### Participant student status

<p>| | |</p>
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<tr>
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<tbody>
<tr>
<td>Yes</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>No</td>
<td>15 (93.8)</td>
</tr>
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</table>

### Resuscitation experience

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<tbody>
<tr>
<td>None</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Minimal</td>
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</tr>
<tr>
<td>Some Experience</td>
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</tr>
<tr>
<td>Experienced</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>Very Experienced</td>
<td>3 (18.8)</td>
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</table>

### Use of syringes during a paediatric fluid resuscitation

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<tr>
<td>Yes</td>
<td>15 (93.8)</td>
</tr>
<tr>
<td>No</td>
<td>1 (6.3)</td>
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</table>

### Participant’s preferred bolus method in paediatric fluid resuscitation

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<tbody>
<tr>
<td>Regular IV Pump</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Syringe (DRT)</td>
<td>14 (87.5)</td>
</tr>
<tr>
<td>Syringe (PPT)</td>
<td>1 (6.3)</td>
</tr>
<tr>
<td>Rapid Infuser</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pressure Bag</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
</tr>
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</table>
Main Results:

Outcome analysis results are summarized in Table 2. The primary outcome of total fluid administration rate (mL/s) significantly differed between the two techniques, with a mean difference of 0.15 [95% CI 0.05 - 0.25] (p=0.005). DRT was more efficient with a mean (SD) fluid administration rate (mL/s) of 1.77 (0.145) compared to 1.62 (0.226) for PPT. Of note, one participant’s administration rate was a significant outlier in the PPT group. Exclusion of this outlier from analysis did not significantly impact the primary outcome result.

There was no difference in the volume (mL) of fluid effectively administered, -6.25 [95% CI -52.76 - 40.26] (p=0.778), with mean volumes for each group close to the 900 mL target [DRT (891, SD 36.6) and PPT (898, SD 58.1)].

A significant change in fluid administration rate occurred over the DRT intervention (p<0.001) and the PPT intervention (p=0.003). Pairwise comparisons of mean (SD) infusion rates (mL/s) were performed. DRT Rate 1, 1.63 (0.143) was significantly different from Rate 2, 1.83 (0.176) and Rate 3, 1.88 (0.180); (p<0.001), while Rates 2 and 3 did not differ (p=0.114). PPT Rate 1, 1.62 (0.223) did not differ from Rate 2, 1.58 (0.237); (p=0.356) or Rate 3, 1.67 (0.265); (p=0.197), but Rate 2 was significantly different from Rate 3 (p=0.003).

Participant self-reported fatigue (mean rank) did not differ between DRT (5) and PPT (5) (p=0.755). No catheter dislodgements occurred during the trial.

Three technical issues were noted during performance of PPT, however none occurred with DRT. One subject performing PPT accidentally drew air into the line, leading to a procedural delay of greater than 60s. Two additional subjects made technical errors while performing PPT: one drew back...
on the syringe plunger while the stopcock was open to the simulated patient, while a second incorrectly administered fluid to the bag of saline rather than the simulated patient.

Table 2: Outcome analysis results reported with statistical significance.

<table>
<thead>
<tr>
<th>Study Outcomes</th>
<th>Disconnect-Reconnect Technique (DRT)</th>
<th>Push-Pull Technique (PPT)</th>
<th>Effect Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=16</td>
<td>n=16</td>
<td></td>
</tr>
<tr>
<td>Primary Outcome</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean Difference [95% CI]; p</td>
</tr>
<tr>
<td>Overall fluid infusion rate (mL/s)</td>
<td>1.77 (0.145)</td>
<td>1.62 (0.226)</td>
<td>0.153 [0.055, 0.251], p=0.005</td>
</tr>
<tr>
<td>Secondary Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid infusion rate by bolus (mL/s)†</td>
<td>Bolus 1: 1.63 (0.143)</td>
<td>Bolus 1: 1.62 (0.223)</td>
<td>0.016 [-0.088, 0.121]; 0.744</td>
</tr>
<tr>
<td></td>
<td>Bolus 2: 1.83 (0.176)</td>
<td>Bolus 2: 1.58 (0.356)</td>
<td>0.246 [0.136, 0.357]; &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Bolus 3: 1.88 (0.180)</td>
<td>Bolus 3: 1.67 (0.265)</td>
<td>0.214 [0.087, 0.340]; 0.003</td>
</tr>
<tr>
<td>Total fluid volume infused (mL)</td>
<td>891.8 (36.60)</td>
<td>898.13 (58.11)</td>
<td>-6.250 [-52.760, 40.260], p=0.778</td>
</tr>
<tr>
<td>Subjective fatigue rank</td>
<td>5.75 (1.0)</td>
<td>5.63 (1.20)</td>
<td>0.125 [-0.650, 0.900]; 0.736</td>
</tr>
<tr>
<td>(mean rank)</td>
<td>Median (Q1, Q3)</td>
<td>Median (Q1, Q3)</td>
<td>p=0.836</td>
</tr>
<tr>
<td></td>
<td>6.0 (5.0, 6.5)</td>
<td>5.5 (5.0, 7.0)</td>
<td></td>
</tr>
<tr>
<td>Catheter Dislodgement Events (n)</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Issues</td>
<td>0</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td>Encountered (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Legend for Table 2

† DRT infusion rates differ between bolus 1, 2, and 3; p<0.001
DRT infusion rates differ between bolus 1 and bolus 2; p<0.001
DRT infusion rates differ between bolus 1 and bolus 3; p<0.001
DRT infusion rates do not differ between bolus 2 and bolus 3; p=0.114
PPT infusion rates differ between bolus 1, 2, and 3; p=0.003
PPT infusion rates differ between bolus 2 and bolus 3; p=0.003
PPT infusion rates did not differ between bolus 1 and either bolus 2; p=0.356 or bolus 3; p=0.197

N/A – not applicable

DISCUSSION

This study demonstrates that use of the DRT technique allows for a faster rate of fluid administration than PPT. While fluid resuscitation speed was the primary outcome in this study, other measures of efficiency such as volume of fluid effectively delivered and catheter dislodgement events did not differ between the two techniques under study. Together these findings provide practical information for health care providers who must select a method of IV fluid administration when faced with a child who requires rapid intravascular volume expansion. While statistically significant, these findings are of unknown clinical importance suggesting a need for further research in this area.

Our previous work demonstrated that health care providers experience increasing fatigue with the ongoing performance of manual fluid resuscitation,[19] and so it was anticipated that a similar finding would be observed in the present study. Contrary to our hypothesis and opposite to our previous findings, fluid administration rate actually increased between the first and second 300mL boluses for DRT, and between the second and third boluses for PPT. This unexpected improvement in manual fluid resuscitation performance over the course of the intervention may have been due to a learning effect, despite our use of a standardization procedure. If a learning effect was indeed present, then it is also interesting that this was observed early on with DRT and later with PPT, suggesting that skill in performing PPT is more difficult to acquire.
The idea that PPT may be challenging for health care providers to perform under stressful conditions is further corroborated by our finding of multiple technical issues during performance of the intervention with PPT. In contrast, no technical issues were observed with DRT. We witnessed three technical errors when health care providers performed PPT: 1. air drawn into the IV line and inability of the provider to problem solve, 2. stopcock toggling error leading to an attempt to ‘pull’ from the patient instead of the bag, and 3. stopcock toggling error leading to an attempt to ‘push’ fluid back into the bag of saline rather than into the patient. We have in fact observed stopcock toggling errors with performance of PPT in the setting of real resuscitations, which is why we chose to evaluate this outcome in our study. Intravascular air injection can lead to pulmonary air embolism resulting in ventilation-perfusion mismatching, right-heart strain and total cardiovascular collapse.[22,23,24] In the setting of congenital heart disease systemic air embolism may occur, leading to serious sequelae including stroke.[22] Stopcock toggling errors are also problematic in that these may lead to delays in fluid administration or jeopardize the integrity of the IV catheter if blood is withdrawn. Together these findings would also favor selection of DRT when rapid manual fluid administration is required.

It is important to note that DRT is a two-provider technique. In situations where limited healthcare personnel are available to assist with resuscitation, the use of DRT instead of PPT may interfere with a second provider’s availability to perform other simultaneously required vital tasks. Fluid resuscitation is also often performed in the prehospital environment, and use of the DRT technique may be less practical than PPT in a moving ambulance or helicopter. There is also, theoretically, a greater risk of introducing infection with use of DRT, which requires repeated syringe connection and disconnection from the IV line. Studies of central line infection suggest that catheter hubs can be an important infectious source, and that aseptic technique (which may not occur in an urgent scenario) effectively reduces risk.[25] Since DRT requires the use of multiple syringes, the technique also entails a slightly increased cost and production of waste relative to PPT.
Administration of a 300 mL bolus requires five 60-mL syringes for DRT versus one syringe for PPT, though DRT does not require use of a triple stopcock. Table 3 provides a summary of the advantages and limitations to consider for the two manual fluid resuscitation techniques evaluated in this study.

Table 3. Advantages and limitations of two provider-endorsed manual paediatric fluid resuscitation techniques.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disconnect-Reconnect (DRT)</td>
<td>- Facilitates a faster rate of fluid administration</td>
<td>- Requires two providers</td>
</tr>
<tr>
<td></td>
<td>- Simple technique; likely easier to learn and possibly easier to recall and perform</td>
<td>- Many syringes required which may increase cost and waste production</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Requires multiple connections to the IV line which may increase risk of contamination</td>
</tr>
<tr>
<td>Push-Pull (PPT)</td>
<td>- Can be performed by a single provider</td>
<td>- Facilitates a slower rate of fluid administration</td>
</tr>
<tr>
<td></td>
<td>- Likely better suited to space-limited environments i.e. out-of-hospital setting</td>
<td>- More complex task; requires greater dexterity and more practice may be needed for optimal recall and performance</td>
</tr>
<tr>
<td></td>
<td>- May require only a single connection to the IV line (closed system) which may decrease risk of contamination</td>
<td>-Risk of adverse events as a result of stopcock toggling errors</td>
</tr>
</tbody>
</table>

The majority of participants in this study were staff nurses. Participant career stage ranged from trainee to experienced staff member, and all but one were familiar with the use of manual syringe techniques for performing fluid resuscitation. Our study population is therefore a good sample of the
healthcare providers who would be asked to perform fluid resuscitation in a paediatric tertiary care setting. We would expect health care providers working at smaller or non-specialized centers to have less experience with paediatric fluid resuscitation techniques compared to our subjects.

There are a number of limitations of our study that warrant mention. All materials were set up in a clinically appropriate fashion for the participants beforehand, unlike in a real resuscitation. While the setup time for each technique was similar, this was not specifically evaluated in our trial. Secondly, the testing environment was quiet with no interruptions. A lack of distractors may have allowed participants to focus more effectively than is possible in practice, leading to greater accuracy and fewer errors. No catheter dislodgments occurred during testing, raising the possibility that our model may have offered some protection from this. However, catheter dislodgement from the model was indeed possible and occurred during pilot testing. Evaluation of PPT in a previous clinical trial found catheter dislodgement events to be a rare occurrence, experienced by only 1/57 children.[20] Finally, although our study demonstrated a statistically significant difference between DRT and PPT fluid administration rates, with the 95% confidence interval [0.055mL/s, 0.251mL/s] including the 0.2mL/s mean difference this study was powered to detect, our findings are of unknown clinical significance. Notwithstanding this, our work provides new data for the resuscitation community to consider, in light of current paediatric resuscitation guidelines.[3,4,5,7,12]

CONCLUSION

This study demonstrates that DRT facilitates a faster rate of fluid administration than PPT, and that PPT is associated with more technical errors. It may therefore be appropriate to recommend DRT as the preferred method of manual paediatric fluid resuscitation using syringes, though factors such as the patient, environment, resources and availability of personnel will also affect provider choices. Further study in the clinical setting is required to support recommendations in future iterations of
paediatric resuscitation guidelines regarding the safest and most effective way to perform rapid fluid resuscitation for children.
AUTHORS’ CONTRIBUTIONS

EC developed the trial protocol including study objectives, under the mentorship of MP and with input from GH. EC prepared the REB submission and produced revisions as required. EC and GH trained the research assistants and assisted with subject recruitment. EC was responsible for input of results data to the study database. EC was involved with data analysis and interpretation of study results, and produced the first version of this manuscript. GH assisted in revision of the manuscript draft, and participated in all stages of trial planning, document production and analysis. SU was primarily responsible for participant recruitment and scheduling. She ensured all testing was conducted appropriately, with assistance from EC and MP. GF and LT participated in trial design and statistical analysis planning. GF performed the sample size calculations. LT was responsible for the analysis of the data. MP conceived of the research question, played a major role in development of study objectives, and was responsible for scientific oversight of the trial. She played a key role in protocol development, preliminary data analysis and interpretation. She also revised the first draft of the manuscript and played a supervisory role in overseeing the work of EC, GH and SU. All authors reviewed and contributed to the submitted version of the paper.

ACKNOWLEDGEMENTS

We thank participating healthcare providers from McMaster Children’s Hospital for their time and effort, without which this trial could not have been completed. Mark Duffett organised the randomisation schedule and assisted with randomisation of trial participants. Michael Chong and Zach Arnott volunteered their time and served as our blinded video reviewers. Dr. Lawrence Mbuagbaw (PhD) provided assistance with statistical analyses. Figure 1 and Figure 2 are reproduced in this paper, from the original source article, with the permission of MP.
CONFLICTS OF INTEREST

EC has no competing interests to declare.

GH has no competing interests to declare.

SU has no competing interests to declare.

GF has no competing interests to declare.

LT has no competing interests to declare.

MP has no competing interests to declare.

FUNDING

This work was supported by the following funding sources. A CIHR Health Professional Student Research Award supported Evan Cole for his work on this study. A Regional Medical Associates Research Scholarship supported Dr. Greg Harvey by providing operating funds for trial conduct. Dr. Melissa Parker is supported by a Hamilton Health Sciences Research Early Career Award. New Faculty Start-up Funding from McMaster University (held by MP) also supported conduct of this work. None of the funding sources were in any way involved with trial design, conduction or data analysis.
REFERENCES


FIGURE CAPTIONS

Figure 1 A-C: The ‘Disconnect–Reconnect’ technique (DRT) for fluid administration requires an assistant. The assistant prepares syringes of fluid while the provider repeatedly selects a syringe (A), attaches it to the IV line and depresses the plunger (B), then disconnects and discards the empty syringe (C).

Figure 2 A-B: The ‘Push–Pull’ technique (PPT) for fluid administration requires the healthcare provider to repeatedly perform two steps. With the stopcock positioned “off” to the patient, the provider first pulls on the syringe plunger to fill the syringe with fluid (A). The provider must then toggle the stopcock “on” to the patient and depress the plunger to administer fluid to the patient (B).

Figure 3: CONSORT trial flow diagram.
The ‘Disconnect–Reconnect’ technique (DRT) for fluid administration requires an assistant. The assistant prepares syringes of fluid while the provider repeatedly selects a syringe (A).

90x60mm (300 x 300 DPI)
attaches it to the IV line and depresses the plunger (B)
then disconnects and discards the empty syringe (C).
90x60mm (300 x 300 DPI)
The ‘Push–Pull’ technique (PPT) for fluid administration requires the healthcare provider to repeatedly perform two steps. With the stopcock positioned "off" to the patient, the provider first pulls on the syringe plunger to fill the syringe with fluid (A).

90x60mm (300 x 300 DPI)
The provider must then toggle the stopcock "on" to the patient and depress the plunger to administer fluid to the patient (B).

90x60mm (300 x 300 DPI)
CONSORT Flow Diagram
210x227mm (300 x 300 DPI)
<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
<td>Title page + 1</td>
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<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td>1</td>
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<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td>3-4</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td>4</td>
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<tr>
<td><strong>Methods</strong></td>
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<tr>
<td>Trial design</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
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<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
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<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td>4-5</td>
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<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td>4</td>
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<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td>6-7</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td>6-7</td>
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<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
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<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td>7</td>
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<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
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<td>Randomisation:</td>
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<tr>
<td>Sequence</td>
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<td>Method used to generate the random allocation sequence</td>
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<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
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<tr>
<td>Allocation</td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td>5</td>
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<td>concealment mechanism</td>
<td></td>
<td></td>
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<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td>5</td>
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<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those</td>
<td>6</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td></td>
<td></td>
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<td>-------------</td>
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<tr>
<td>Participant flow (an diagram is strongly recommended)</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
<td></td>
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<td>Recruiment</td>
<td>Dates defining the periods of recruitment and follow-up</td>
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<tr>
<td>Baseline data</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
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<tr>
<td>Numbers analysed</td>
<td>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td></td>
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<tr>
<td>Ancillary analyses</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harms</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th><strong>Discussion</strong></th>
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<tr>
<td>Limitations</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td>Generalisability</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other information</strong></th>
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<tr>
<td>Registration</td>
<td>Registration number and name of trial registry</td>
</tr>
<tr>
<td>Protocol</td>
<td>Where the full trial protocol can be accessed, if available</td>
</tr>
<tr>
<td>Funding</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
</tr>
</tbody>
</table>

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).*
Rapid paediatric fluid resuscitation: a randomised controlled trial comparing the efficiency of two provider-endorsed manual paediatric fluid resuscitation techniques in a simulated setting

Evan T Cole, Greg Harvey, Sara Urbanski, Gary Foster, Lehana Thabane and Melissa J Parker

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