Comparison of a novel rapid fluid delivery device to traditional methods

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Executive summary

National guidelines recommend early and rapid fluid resuscitation as a key element of care in septic shock.[1,2] Adherence to these guidelines significantly improves patient outcomes, including mortality, hospital length of stay, and organ dysfunction. Common barriers to guideline adherence include difficulty with vascular access and the limitations of current fluid delivery techniques. This simulation-based study evaluated the LifeFlow Rapid Infuser, a novel device for rapid fluid infusion. When compared to current methods across a range of catheter sizes, the LifeFlow device resulted in significantly faster delivery of a 1 liter fluid bolus.

Introduction

The LifeFlow Rapid Infuser is a hand-operated device that enables healthcare providers to rapidly and accurately deliver intravenous (IV) fluids to critically ill patients. Early fluid resuscitation is particularly important in patients presenting with shock and hypotension, where delays in recognition and treatment may have a profound effect on morbidity, mortality, and hospital length of stay (LOS). [3-9] The American College of Critical Care Medicine/Pediatric Advance Life Support (ACCM/PALS) guidelines for septic shock specify that patients receive 20 mL/kg within five minutes of establishing vascular access, and up to 60 mL/kg in the first 15 minutes of care until perfusion improves.[1,10] The Surviving Sepsis Campaign guidelines and other adult protocols also support rapid fluid administration. Multiple studies have demonstrated decreased mortality, length of stay, cost, and organ dysfunction with early and rapid fluid delivery.[6,7,8,11] Current methods of fluid delivery are often slow and inefficient, limiting the ability of health care providers to achieve fluid delivery goals.

Standard methods of fluid resuscitation include gravity infusion, IV infusion pumps, pressure bags, and the use of the manual "push-pull" syringe technique (PPT), which is commonly used in pediatric emergency care. All of these techniques have drawbacks that limit the ability of providers to achieve fluid delivery goals. Infusion pumps deliver a maximum rate of 1000 mL/hr and can only achieve 60 mL/kg over 15 min in patients weighing less than 4 kg. Gravity flow is also universally inadequate when rapid fluid delivery is required to reverse shock and hypotension. The addition of a pressure bag (PB) has been shown to speed fluid delivery, but this technique requires constant re-inflation to achieve adequate flow.[12,13] With PPT, providers may be able to achieve ACCM/PALS guidelines, but the technique is complex, labor-intensive, and can result in syringe contamination.[12-15]

In contrast, LifeFlow provides a simple and intuitive method for rapid, controlled, and measured fluid bolus delivery. This technique enables healthcare professionals to respond immediately when a patient requires rapid fluid resuscitation. Prior studies comparing LifeFlow to standard fluid delivery alternatives have demonstrated that LifeFlow provides fluid volume faster than standard techniques and improves the accuracy of fluid bolus size administered compared to standard techniques.[16] Prior studies have not compared infusion rate across a comprehensive range of catheter sizes. The purpose of this study is to compare the rate of fluid delivery for LifeFlow, PB, and PPT across a range of typical catheter sizes.

Methods

Four critical care clinicians, each with more than five years of experience, participated in the study. Study participants were asked to infuse 1 L of saline into a patient simulator at the Center for Innovative Learning, a medical simulation center at WakeMed in Raleigh, NC. All clinicians had prior experience with LifeFlow, PPT, and PB methods. In each case, the participant was asked to follow hospital or manufacturer protocol to set up and deliver 1 L of saline to the patient simulator as quickly as possible. Prior to the study initiation, a testing plan was developed pairing venous catheter size (16 G, 18 G, 20 G, 22 G, and central venous catheter [CVC]) with resuscitation method (LifeFlow, PB, and PP) and randomizing across study participants.

IV catheter, alcohol wipes, gloves, and fluid bags were provided. The 1 L saline bag was weighed prior to and after infusion in order to confirm when 1 L was infused. To mimic typical clinical use, pressure bags were inflated at scenario start according to instructions but not re-pressurized during fluid delivery. Setup and infusion times were recorded for each infusion method and corresponding IV gauge. Flow rates of the three techniques were compared using Analysis of Variance (ANOVA) and pairwise comparisons correcting for multiple comparisons using the Tukey Method.

Results

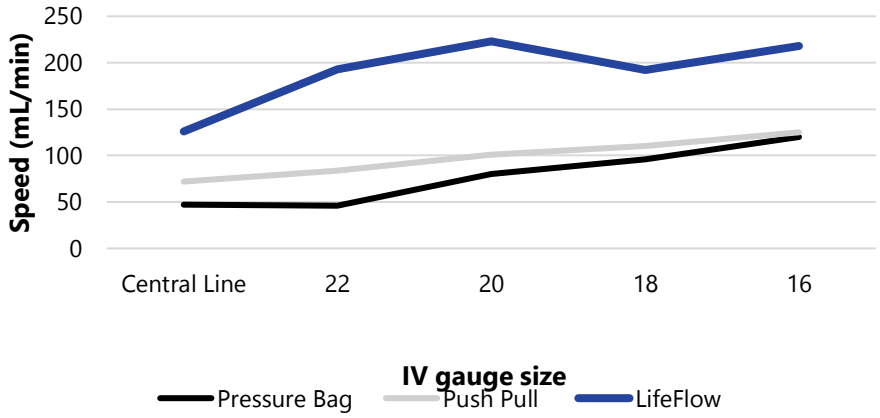
The average flow rate with LifeFlow was highest in the 20 G catheter (218 mL/min) and slowest in the CVC (126 mL/min) (**Table 1, Figure 1**). In all catheter sizes, the LifeFlow device significantly outperformed both PB and PPT ($p<0.01$).

Table 1. Speed comparisons for Pressure Bag, Push Pull, and LifeFlow methods in mL/min

	mL/min			
Gauge	Pressure Bag	Push Pull	LifeFlow	p-value
16	120	125	218	**0.003**
18	96	110	192	**<0.001**
20	80	101	223	**<0.001**
22	46	84	193	**<0.001**
CVC	47	72	126	**<0.001**

*CVC=central venous catheter

Figure 1. Speed (mL/min) comparison for various IV gauge sizes and rapid fluid infusion methods



Discussion

Early, rapid fluid resuscitation improves patient outcomes in hypotensive patients such as in septic shock. Yet fluid delivery guidelines are often not met due to the inefficiency of current methods.[14,17] Previous LifeFlow studies have demonstrated a speed advantage for LifeFlow compared to PB and PPT methods for a single catheter size.[16] In this study, LifeFlow was compared to PB and PPT across a comprehensive range of catheter sizes. For all catheter sizes, LifeFlow yielded faster infusion rates when compared to PB and PPT methods. The advantage is especially pronounced (up to 6 times faster) with CVC's and catheters 18 G or smaller, which are often required with patients in shock. This study suggests that LifeFlow offers clinicians a more rapid option for fluid resuscitation that may enable more consistent compliance with fluid delivery guidelines in ACCM/PALS, Surviving Sepsis, and other protocols.

While LifeFlow performs faster than PB and PPT with all gauge sizes, the rate of infusion through 16 G and 18 G catheters was slightly slower than with 20 G catheters. This may be attributed to the perception of greater ease of use through larger catheters, which prompts the user to relax and apply less force, resulting in modestly lower flow rates.

Limitations

This was a single center, simulation-based study using a small convenience sample of critical care providers. This simulated environment did not include the tasks, distractions, and stress of actual clinical care. These factors almost certainly further impact rates of fluid administration and may actually increase the difference between common techniques and LifeFlow. Further simulation and clinical studies with a larger and more diverse group of health care providers are warranted.

Conclusions

The LifeFlow Rapid Infuser delivers fluid significantly more rapidly compared to PB and PPT technique in a simulated patient. These findings support the use of the LifeFlow in patients requiring life-saving rapid and early fluid administration.

References

[1]Davis, AL, Carcillo JA, Aneja RK, Deymann AJ, Lin JC, Nguyen TC, et al. American College of Critical Care Medicine Clinical Practice Parameters for Hemodynamic Support of Pediatric and Neonatal Septic Shock. Crit Care Med 2017; 45(6):1061–1093.

[2]Rhodes, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Critical Care Medicine. 2017; 45(3): 486-552.

[3]Balamuth F, Weiss SL, Fitzgerald JC, Hayes K, Centkowski S, Chillutti M, et al. Protocolized treatment is associated with decreased organ dysfunction in pediatric severe sepsis. Pediatr Crit Care Med. 2016;17(9):817-22.

[4]Han, Y. Y., Carcillo, J. A., Dragotta, M. A., Bills, D. M., Watson, R. S., Westerman, M.E., & Orr, R. A. (2003). Early reversal of pediatric-neonatal septic shock by community physicians is associated with improved outcome. *Pediatrics*, 112(4), 793-799

[5]Lane RD, Funai T, Reeder R, Larsen GY. High Reliability Pediatric Septic Shock Quality Improvement Initiative and Decreasing Mortality. *Pediatrics*, 2016; 138(4):e20154153.

[6]Lee S, Ramar K, Park J, Gajic O, Li G, Kashyap R. Increased Fluid Administration in the First Three Hours of Sepsis Resuscitation Is Associated With Reduced Mortality. Chest. 2014, 146(4): 908-915.

[7]Leisman D, Doerfler M, Ward MF, Masick K, Wie B, Gribben J, Hamilton E, Klein Z, Bianchulli A, Akerman M, D'Angelo J, D'A,ore J. Survival Benefit and Cost Savings From Compliance With a Simplified 3-hour Sepsis Bundle in a Series of Prospective and Observational Cohorts. Crit Care Med. 2016. DOI: 10.1097/CCM.0000000000002184.

[8]Leisman, D, Wie B, Doerfler M, Bianculli A, Akerman M, D'Angela JK, et al. Association of fluid resuscitation initiation within 30 minutes of severe sepsis and septic shock recognition with reduced mortality and length of stay. Ann Emerg Med. 2016;68(3):298-311.

[9]Paul R, Neuman M, Monuteaux MC, Melendez E. Adherence to PALS sepsis guidelines and hospital length of stay. Pediatrics. 2012;130(2):e273-e280.

[10]Brierley J, Carcillo JA, Choong K, Cornell T, Decaen A, Deymann A, et al. Clinical practice parameters for hemodynamic support of pediatric and neonatal septic shock: 2007 update from the American College of Critical Care Medicine. Crit Care

Med. 2009; 37(2):666–688.

[11]Burrell AR, McLaws ML, Fullick M, Sullivan RB and Sindhusake D. Sepsis Kills: Early intervention saves lives. Med J Aust 2016; 204 (2): 73. || doi: 10.5694/mja15.00657

[12]Reddick AD, Ronald J, Morrison WG. Intravenous fluid resuscitation: was Poiseulle right? Emerg Med J. 2011;28(3):201-202.

[13]Stoner MJ, Goodman DG, Cohen DM, Fernandez SA, Hall MW. Rapid fluid resuscitation in pediatrics: testing the American College of Critical Care Medicine Guideline. Ann Emerg Med. 2007;50(5):601-607.

[14]Auerbach M, Whitfill T, Gawel M, Kessler D, Walsh B, Gangadharan S, Hamilton MF, Schultz B, Nishisaki A, Tay KY, Lavoie M, Katznelson J, Dudas R, Baird J, Nadkarni V, Brown L. Differences in the Quality of Pediatric Resuscitative Care Across a Spectrum of Emergency Departments. JAMA Pediatr. 2016 Oct 1;170(10):987-994.

[15] Heid, Florian, et al. "Microbial contamination of anesthetic syringes in relation to different handling habits." American journal of infection control 44.3 (2016):e15-e17.

[16] Piehl MD. A novel rapid infusion device for pediatric resuscitation. PICC 2016 abstract, PICC-0838

[17] Kessler D, Walsh B, Whitfill T, Gangadharan S, Gawel M, Brown L, Auerbach M. Disparities in Adherence to Pediatric Sepsis Guidelines across a Spectrum of Emergency Departments: a Multicenter, Cross-sectional Observational Study. *J Emerg Med* 50(3):403-415.e3. 2016 doi: 10.1016/j.jemermed.2015.08.004.