ORIGINAL ARTICLE

Fluid resuscitation in severe sepsis and septic shock: systematic description of fluids used in randomized trials

Bram Rochwerg[1], Anna Władarczyk[2], Wojciech Szczeklik[2], Waleed Alhazzani[1,3], Anees Sindi[4], Fayez Alshamsi[1], Wang-chun Ip[1], Michael Wang[1], Sultan Altayyar[1], Guowei Li[5], Alison Fox-Robichaud[1], Gordon Guyatt[1,5], and the FISSH group*

1 Department of Medicine, McMaster University, Hamilton, Ontario, Canada
2 Department of Medicine, Jagiellonian University Medical College, Kraków, Poland
3 Department of Critical Care, Prince Sultan Military Medical City, Riyadh, Saudi Arabia
4 Department of Anaesthesia & Critical Care, King Abdulaziz University, Jeddah, Saudi Arabia
5 Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Ontario, Canada
6 Department of Medicine, University of Versailles, Versailles, France

KEY WORDS

buffer, colloid, crystalloid, fluids, sepsis

ABSTRACT

INTRODUCTION Fluid therapy is one of the cornerstones of initial management of sepsis, but the choice of fluids used for resuscitation is controversial.

OBJECTIVES While trying to determine the effects of alternative fluids used in sepsis resuscitation randomized controlled trials (RCTs), we found that the precise description of those fluids was frequently not available. This report presents the result of our efforts to provide the characteristics of those fluids to both researchers and clinicians.

METHODS We searched the following electronic databases: CENTRAL, MEDLINE, EMBASE, CINAHL, and ACPJC, and examined the reference lists of recently published meta-analyses of fluid therapies in critically ill patients. These databases were searched from inception until August 2013. The data abstraction stage included determination of fluid composition, pH, chloride concentration, and presence or absence of buffers. We relied on the original articles as well as on manufacturers' websites, contact with authors, and contact with experts in the field.

RESULTS Our original search yielded 7002 articles. In consecutive stages, we reduced it to 20. The types of fluids varied widely, including chloride content (110–154 mmol/l) and presence or absence of buffering substances in colloid solutions. Those characteristics were frequently not presented and rarely emphasized in the original articles.

CONCLUSIONS The basic characteristics of fluids used in fluid therapy trials are often not easily available, yet of increasingly recognized clinical importance. We provide the information concerning composition of fluids used in RCTs, which will be useful not only to future investigators and systematic reviewers but also to clinicians using those fluids in regular clinical practice.

Correspondence to:
Roman Jaeschke, MD, PhD, McMaster University, Hamilton, Ontario, 301 James Street South, Hamilton, ON, Canada, L8P3B6, phone: +1-905-522-1155, fax: +1-905-521-6068, e-mail: jaeschke@mcmaster.ca
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* All members of the FISSH group along with their affiliations are listed at the end of the manuscript.

INTRODUCTION Sepsis is a common health problem around the world with an annual incidence of approximately 200 to 300 cases per 100,000 inhabitants. It still carries a mortality rate of approximately 20% and even up to 40% in patients with septic shock.[1] Fluid therapy is one of the cornerstones of initial management of sepsis, and systemic blood pressure response to fluid therapy helps to discriminate patients with sepsis and severe sepsis from those with septic shock. The choice of fluids used for resuscitation (defined in principle as the administration of a bolus of intravenous fluid over and above that required for maintenance or replacement fluids) is both important and controversial.

TABLE Characteristics of fluids used in randomized clinical trials examining the resuscitation strategies of patients with sepsis syndromes

Type of fluid	Fluid name (generic)	Trade name/manufacturer	Osmolarity[a]	Tonicity[b]	Electrolytes, mEq/l	
					Na^+	Cl^-
high-molecular-weight HES (200,000–600,000 Da)	6% HES (200/0.5)	Haes Steril – Fresenius, Hemohes – B. Braun, HES – Baxter	308	iso	154	154
	10% HES (200/0.5)					
	6% HES (600/0.75)	Hespan – B. Braun	309	iso	154	154
	hypertonic saline HES	HyperHAES – Fresenius	2464	hyper	1232	1232
	pentastarch	Pentaspan – Bristol-Myers	326	iso	154	154
low-molecular-weight HES (130,000 Da)	6% HES (130/0.4)	Voluven – Fresenius, Venofundin – B.Braun	308	iso	154	154
	6% HES (130/0.42) in balanced solution	Tetraspan 60 mg/ml – B. Braun	297	iso	140	118
dextrans	6% dextran 70,000	Dextran 70 – Fresenius, B. Braun, Baxter	310	iso	154	154
gelatins	succinylated gelatin	Plasmagel – Fresenius	NA		120	NA
human albumins		Buminate 5% – Baxter	NA		145	NA
		4.5% Zenalb – Bio Products Laboratory UK	NA		100–160	NA
		4% Albumex – CSL	NA		140	128
		5% Albumin – Cutter	NA		154	154
crystaloids	normal saline	0.9% NaCl	308	iso	154	154
	hypertonic saline	3% NaCl	1030	hyper	513	513
	lactated ringer		275	iso	130	110
	modified ringer	Sterofundin ISO (Ringer's Acetate) – B.Braun	309	iso	145	127
		Sterofundin – B.Braun	299	iso	140	106
	half-strength Darrow's solution with 5% dextrose		NA	hypo	61	51

a osmolarity of a solution is the number of osmoles of solute per liter of solution – independent of any membrane

b tonicity – effective osmolality – equal to the sum of the concentrations of the solutes which have the capacity to exert the osmotic force across a particular membrane (those which do not travel easily through the membrane). For the purpose of our report, we assumed a fluid is isotonic when its osmolarity was close to plasma (270–310 mOsm/l) in case of the absence of additional glucose and with Na close to plasma level (130–155 mEq/l)

c balanced fluid – we have defined it as any solution containing buffer (such as lactate, acetate, gluconate, pyruvate, malate, etc.) and with Cl ion concentration of no more than 128 mmol/l[29]

d no exact name of the fluid used in the study given, but described content is similar to this presented in the table

Abbreviations: hyper – hyper-osmolar, HES – hydroxyethyl starch, iso – iso-osmolar, NA – not available

Multiple large-scale randomized controlled trials (RCTs)[2-6] as well as meta-analyses[7-10] have compared different types of crystalloid and colloid solutions in the resuscitation of critically ill patients. Taking into account newly emerging evidence, as well as some suggestions of the importance of chloride content in the fluids,[11] we decided to perform a multiple-comparison meta-analysis (network meta-analysis)[12] examining both direct and indirect comparisons. Our question was: What are the comparative effects (in terms of mortality and need for renal replacement therapy) of different resuscitation fluids for patients with severe sepsis and septic shock?

While addressing this question we had to characterize and classify a variety of fluids. This included the division of crystalloids versus colloids, but also the subdivision of different types of colloids (i.e., hydroxyethyl starch, albumin, gelatins, dextrans), and fluids of varying chloride content and buffering substances (i.e., lactate or acetate). We found significant knowledge gaps regarding fluid chloride content and buffering potential and, therefore, set about to collect the relevant information. Obtaining the information proved challenging and time-consuming. The goal of this work was to characterize fluids used in randomized controlled trials (RCTs) on sepsis resuscitation over the course of the last few decades.

METHODS We examined parallel-group randomized controlled trials including patients with sepsis syndromes undergoing fluid resuscitation. Studies examining postoperative elective surgical patients

Electrolytes, mEq/l			Buffer (mEq/l)			Balanced[c]	pH	Study
K^+	Ca^{2+}	Mg^{2+}	lactate	acetate	other			
0	0	0	0	0		no	3.5–7.0	[6,26][d] [e1-3]
								[2,19][d] [e1-3]
0	0	0	0	0		no	5.9	[16,20] [e3]
0	0	0	0	0		no	3.5–6.0	[17][d] [e1]
0	0	0	0	0		no	5	[20] [e4]
0	0	0	0	0		no	4.0–5.5	[4,14,15,18][d] [e1,e3]
4	5	2	0	24	malate	yes	5.6–6.4	[5] [e3]
0	0	0	0	0		no	NA	[26][d] [e2]
0	0	0	0	0		no	NA	[6]
NA	0	0	0	0	caprylate, 4 mmol/l; tryptohanate, 4; bicarbonate (concentration not clear)	yes	NA	[24] [e2]
0	0	0	0	0		no	NA	[22,25,26] [e5]
0	0	0	0	0	octanoate, 6.4 mmol/l	yes	NA	[3] [e6]
0	0	0	0	0		no	NA	[16,20]
0	0	0	0	0		no	4.5–7. 0	[e7]
0	0	0	0	0		no	4.5–7. 0	[23] [e2]
4	3	0	28	0		yes	6. 0–7. 5	[27] [e7]
4	5	2	0	24	malate	yes	5.1–5.9	[5] [e3]
4	5	2	45	0		yes	4.5–7.5	[2] [e3]
18	0	0	27	0	possible: bicarbonate	yes	NA	[21] [e8]

e1 http://www.fresenius-kabi.com/, http://www.fresenius-kabi.pl/
e2 http://www.baxter.com/ ; http://www.baxter.com.pl
e3 http://www.bbraun.com/; http://www.bbraun.co.uk/
e4 http://www.bmscanada.ca
e5 http://www.bpl.co.uk/
e6 http://www.csl.com.au/
e7 http://dailymed.nlm.nih.gov/dailymed/; http:// www.who.int

were excluded and the minimum duration of observation was the length of intensive care unit or hospital stay. We compared any fluid (or fluid strategy) used for resuscitation against another fluid (fluid strategy). Our outcomes were mortality and the need for renal replacement therapy.

We have searched the following electronic databases: CENTRAL (Cochrane Central Register of Controlled Trials), MEDLINE, EMBASE (Excerpta Medica Database), CINAHL (Cumulative Index to Nursing and Allied Health Literature), and ACPJC (American College Physicians Journal Club) and examined the reference lists of the recently published meta-analyses of fluid therapies in critically ill patients. The search was performed in December 2012 and then updated in August 2013. Working in pairs, the number of reports identified during original wide searches was reduced in 2 stages: by reviewing titles and, as required, abstracts to delete records that were obviously not relevant (stage 1), and then by reviewing full texts of publications selected in stage 1 to determine eligibility and abstract the data (stage 2).

The data-abstraction stage included determination of fluid composition, including its pH, chloride concentration, and presence or absence of buffers. This information was frequently not provided in the original publications. To find it, we used data available publicly on-line, contacted manufacturers, or contacted the authors of the original studies. On occasion, we relied on input from expert researchers in this field.

RESULTS Our original search yielded 7002 articles; in consecutive stages, we reduced it to 185 (through title and abstract review) and finally to 20 articles (through full-text review). Fourteen studies, including 1 unpublished (BaSES) involved adults (>15 years of age)[2-6,13-20] and 6 involved a pediatric population.[21-26] We then embarked on the process of characterizing the fluids used in identified studies.

The main findings of this process are presented in the **TABLE**. It lists studies fulfilling our criteria and describes the main characteristics of the fluids used, including their mineral content with attention to the presence of buffering solutions and chloride level. The chloride content in fluids considered isotonic ranged from 110 to 154 mmol/l, and its content in buffered Ringer's solutions varied from 110 to 127 mmol/l (in un-buffered Ringer's solution up to 156 mmol/l; however, this was not used in RCTs). Such differences are probably clinically relevant,[11] although they were usually not considered of major importance by the authors of the original papers. The presence or absence of buffering substances was also not a major consideration in most reports. The source of the included information was presented; some of the additional data were extracted from manufacturers or government websites (www.bbraun.com, www.fresenius-kabi.com, www.baxter.com, www.dailymed.nlm.nih.gov, www.csl.com.au, www.medicines.org.uk) or obtained through personal communication from authors of original studies or experts in the field (see Acknowledgments).

DISCUSSION Our ultimate goal was to investigate the effects of different fluids used in resuscitation of patients with severe sepsis and septic shock, and this is the subject of a separate manuscript. However, categorizing these fluids according to their composition proved to be a critical first step. We hypothesized that their effects may be influenced by some of their properties: crystalloid versus colloid structure, higher versus lower molecular weight for hydroxyethyl starches, or the presence of buffering solutions. In a number of cases, the information concerning pH, chloride concentration, or presence of buffers was not readily available in relevant papers or publically available product descriptions. We believe this is likely related to a low degree of importance ascribed to these characteristics at the time of original publications and mirrors generally low awareness of those properties among practicing physicians. This manuscript provides the relevant information we were able to collect from a variety of sources and which could be of use for investigators and systematic reviewers involved in future research on this topic as well as for clinicians currently using those fluids.

The strength of this manuscript includes a careful search for and evaluation of studies that examined fluids used in septic shock trials. In our attempts to characterize fluids, we contacted a number of authors and manufacturers. We provide a number of resources which may be used by those interested to obtain more information. The weaknesses include not only the fact that, on occasion, we were unsuccessful in fully identifying a specific fluid used, but mostly the fact that the clinical relevance of identified fluid differences is not clear. The presence of buffering or stabilizing substances, pH, and especially chloride content of commonly used fluids is recognized as potentially important,[11] but high-quality patient-important evidence in this respect is still missing.

Until such evidence is available, we encourage readers to review the values in the **TABLE**, especially those describing chloride content. Even though, as seen in the recently published CRISTAL study,[27] normal saline is by far the most commonly used crystalloid for resuscitation, we believe this practice needs to be reassessed or at least formally investigated.[28] A similar comment applies to colloid solutions suspended in fluids with high chloride concentration. In our own practice, an increasing awareness of observational evidence suggesting the harmful effect of chloride rich solutions[11] has led some of us to limit their high-volume use.

FISSH (Fluids in Sepsis and Septic Shock) Group
Waleed Alhazzani, Fayez Alshamsi, Sultan Altayyar, Djillali Annane, Deborah. J. Cook, Alison Fox-Robichaud, Gordon Guyatt, Diane Heels-Ansdell, Wang-chun Ip, Roman Jaeschke, Guowei Li, Lawrence Mbuagbaw, Bram Rochwerg, Anees Sindi, Wojciech Szczeklik, Lehana Thabane, Michael Wang, Anna Władarczyk, Qi Zhou (W.A., F.A., S.A., D.J.C., A.F.R., G.G., W.I., R.J., B.R., M.W.: Department of Medicine, McMaster University, Hamilton, Ontario, Canada; W.S., A.W.: Department of Medicine, Jagiellonian University Medical College, Kraków, Poland; W.A.: Department of Critical Care, Prince Sultan Military Medical City, Riyadh, Saudi Arabia; A.S.: Department of Anaesthesia & Critical Care, King Abdulaziz University, Jeddah, Saudi Arabia; D.J.C., G.G., D.H.A., R.J., G.L., L.M., L.T., Q.Z.: Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Ontario; D.A.: Department of Medicine, University of Versailles, Versailles, France)

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ARTYKUŁ ORYGINALNY

Resuscytacja płynowa w ciężkiej sepsie i wstrząsie septycznym: charakterystyka płynów dożylnych użytych w randomizowanych badaniach klinicznych

Bram Rochwerg[1], Anna Władarczyk[2], Wojciech Szczeklik[2], Waleed Alhazzani[1,3], Anees Sindi[4], Fayez Alshamsi[1], Wang-chun Ip[1], Michael Wang[1], Sultan Altayyar[1], Guowei Li[5], Alison Fox-Robichaud[1], Gordon Guyatt[1,5] oraz grupa FISSH*

1 Department of Medicine, McMaster University, Hamilton, Ontario, Kanada
2 II Katedra Chorób Wewnętrznych, Uniwersytet Jagielloński, Collegium Medicum, Kraków
3 Department of Critical Care, Prince Sultan Military Medical City, Riyadh, Arabia Saudyjska
4 Department of Anaesthesia & Critical Care, King Abdulaziz University, Jeddah, Arabia Saudyjska
5 Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Ontario, Kanada
6 Department of Medicine, University of Versailles, Versailles, Francja

SŁOWA KLUCZOWE

bufor, koloidy, krystaloidy, płyny infuzyjne, sepsa

STRESZCZENIE

WPROWADZENIE Terapia płynowa jest jedną z podstawowych metod wstępnego leczenia sepsy, niemniej jednak wybór płynów podczas resuscytacji płynowej pozostaje kwestią kontrowersyjną.

CELE W czasie analizy randomizowanych badań klinicznych dotyczących resuscytacji płynowej w sepsie zauważono, że dokładne opisy stosowanych płynów są często niedostępne. W artykule przedstawiono charakterystykę podstawowych płynów, co może być przydatne zarówno naukowcom jak i praktykującym klinicystom.

METODY Przeszukano następujące elektroniczne bazy danych: CENTRAL, MEDLINE, EMBASE, CINAHL i ACPJC oraz przeanalizowano literaturę źródłową ostatnio opublikowanych meta-analiz dotyczących terapii płynowej u pacjentów w stanie krytycznym. Bazy zostały przeszukane od najwcześniejszych pozycji do sierpnia 2013. Etap gromadzenia danych obejmował określenie składu chemicznego płynu, pH, stężenia jonów chlorkowych oraz obecności związku buforującego. Informacje uzyskano z prac oryginalnych, materiałów dostępnych na stronach internetowych producentów oraz bezpośrednio od autorów artykułów, jak i ekspertów z tej dziedziny.

WYNIKI W wyniku pierwszego przeszukania baz danych uzyskano 7002 artykułów. W kolejnych etapach liczbę zredukowano do 20. Stosowane płyny znacznie się od siebie różniły, w tym zarówno zawartością jonów chlorkowych (110–154 mmol/l) jak i obecnością substancji buforujących. W analizowanych artykułach powyższe informacje nigdy nie były wyeksponowane, a wręcz były one często nieobecne.

WNIOSKI Podstawowe cechy płynów stosowanych w badaniach dotyczących terapii płynowych nie są łatwo dostępne, a jednocześnie coraz częściej podkreśla się ich znaczenie kliniczne. Przedstawiamy zebrane informacje na temat składu płynów stosowanych w badaniach z randomizacją, które będą przydatne nie tylko dla przyszłych badaczy i recenzentów, ale także dla lekarzy wykorzystujących te płyny w codziennej praktyce klinicznej.

Adres do korespondencji: Roman Jaeschke, MD, PhD, McMaster University, Hamilton, Ontario, 301 James Street South, Hamilton, ON, Kanada, L8P3B6, tel.: +1-905-521-6077, fax: +1-905-521-6068, e-mail: jaeschke@mcmaster.ca
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