

Table 1. Baseline Characteristics of Patients, Minimal Inclusion Criteria, and Intravenous Immunoglobulin Regimen*

Author, Year (Reference)	Patients, n	Mean Age (SD), y		Inclusion Criteria	Reported Severity of Illness Measures		Treatment Regimens	Total Dose, g/kg of body weight	Duration of Therapy, d
		IVIG Group	Control Group		IVIG Group	Control Group			
Lindquist et al., 1981 (17)	67	48.3	39.2	Sepsis secondary to septicemia (Svanbom criteria) (reference 37)	NR	NR	Gamma-Venin (ZLB Behring, King of Prussia, Pennsylvania) (days 0–2, 0.15 g/kg; then every wk as needed) vs. no intervention	0.45	3 (+ as needed)
Just et al., 1986 (18)	104	40.2 (18.5)	40.2 (18.6)	Sepsis mainly after surgery or trauma (Center for Disease Control criteria) (reference 38)	NR	NR	Firma (Biotest Pharma, Frankfurt, Germany) (5 g every 12 h for 4 doses) vs. no intervention	0.30†	2
Jesdinsky et al., 1987 (19)	288	53.8 (17.5)	55.1 (19.0)	Sepsis from abdominal infections	NR	NR	Immunoglobulin 7S (Armour Pharma, Eschwege, Germany) (day 0, 10/g; days 1 to 4, 20.5 g) vs. no intervention	1.35†	5
Spannbrucker, 1987 (20), and Vogel et al., 1988 (21)	50	50.8 (15.5)	54.5 (12.0)	Septic shock	NR	NR	Pentaglobin (Biotest Pharma, Germany) (days 0 to 2, 0.15 g/kg) vs. no intervention	0.45	3
De Simone et al., 1988 (22)	24	45 (4)	34 (5)	Severe sepsis	NR	NR	Sandoglobulin (Sandoz Pharmaceutical, Milan, Italy) (day 1, 0.4 g/kg; day 2, 0.2 g/kg; day 7, 0.4 g/kg [as needed]) vs. no intervention	0.60	2 (+ as needed)
Grundmann and Hornung, 1988 (23)	46	46.9	52.8	Sepsis from gram-negative bacteriemia with positive endotoxin (sepsis score ≥ 12)	Mean sepsis score 17.0 (SD, 4.0)	Mean sepsis score 18.9 (SD, 4.8)	Intraglobin F (Biotest Pharma, Frankfurt, Germany) days 0 and 1, 0.25 g/kg, vs. no intervention	0.50	2
Wesoly et al., 1990 (24)	35	44.7 (19)	54.8 (17)	Sepsis after surgery (sepsis score ≥ 12)	Mean sepsis score 14.8 (SD, 2.5)	Mean sepsis score 16.3 (SD, 3.6)	Pentaglobin (Biotest Pharma, Germany) (days 0–2, 0.25 g/kg) vs. no intervention	0.75	3
Burns et al., 1991 (25)	38	61.5	59.8	Sepsis and thrombocytopenia	NR	NR	Sandoglobulin (Sandoz Pharmaceutical, Milan, Italy) (days 0–2, 0.4 g/kg) vs. albumin	1.2	3
Dominioni et al., 1991 (26)‡	62	67 (10)	68 (12)	Severe sepsis after surgery or trauma (sepsis score ≥ 20)	Mean sepsis score, 24 (SD, 4); mean APACHE II score, 17 (SD, 5)	Mean sepsis score, 24 (SD, 3); mean APACHE II score, 18 (SD, 5)	Sandoglobulin (Sandoz Pharmaceutical, Basel, Switzerland) (days 0 and 1, 0.4 g/kg, day 5; 0.2 g/kg) vs. human albumin in 5% dextrose in water	1	2 + 1§

Continued on following page

Table 1—Continued

Author, Year (Reference)	Patients, n	Mean Age (SD), y		Inclusion Criteria	Reported Severity of Illness Measures		Treatment Regimens	Total Dose, g/kg of body weight	Duration of Therapy, d
		IVIIG Group	Control Group		IVIIG Group	Control Group			
Schedel et al., 1991 (27)‡	69	46 (16)	37 (18)	Severe sepsis	APACHE II score, 30; unsure whether mean or median	APACHE II score, 24; unsure whether mean or median	Pentaglobin (Biotest Pharma, Dreieich, Germany) (day 0, 30 g; days 1 and 2, 15 g) vs. no intervention	0.85†	3
Behre et al., 1995 (28)‡	52	50	55§	Severe sepsis with hematologic malignant condition and neutropenia (ACCP/SCCM criteria) (reference 13)	NR	NR	Pentaglobin (Biotest Pharma Dreieich, Germany) (time 0, 10 g; then 5 g every 6 h for 72 h) vs. 5% human albumin	0.9†	3
Dominioni et al., 1996 (29)‡¶	55	55 (19)	57 (19)	Severe sepsis after surgery or trauma (sepsis score ≥ 16)	Mean sepsis score, 23 (SD, 4)	Mean sepsis score, 23 (SD, 4)	Sandoglobulin (Sandoz Pharmaceutical, Basel, Switzerland) (days 0 and 1, 0.4 g/kg; day 5, 0.2 g/kg) vs. human albumin in 5% dextrose in water and saline solution	1	2 + 1§
Werdan et al., 1997 (10)‡	652	NR	NR	APACHE II score of 20–35; sepsis, severe sepsis, or septic shock (sepsis score ≥ 12)	NR; inclusion criteria indicate a range of APACHE II scores of 20–35¶**	NR; inclusion criteria indicate a range of APACHE II scores of 20–35¶**	Polyglobin N (Bayer, Germany) (day 0, 0.6 g/kg; day 1, 0.3 g/kg) vs. 0.1% albumin in 10% maltose	0.9**	2**
Yakut et al., 1998 (30)	40	32 (16)	31 (16)	Severe sepsis postsurgery (sepsis score ≥ 16)	Mean sepsis score, 20 (SD, 4); mean APACHE II score, 16 (SD, 4)	Mean sepsis score, 20 (SD, 3); mean APACHE II score, 16 (SD, 5)	Gamumin N (Miles Inc., Pharmaceutical Division, Ekhart, Indiana) (days 0 and 1, 0.4 g/kg; days 2–4, 0.2 g/kg) vs. human albumin	1.4	5
Masaoka et al., 2000 (31)‡	682	<65 ††	<65 ††	Sepsis mainly with neutropenia after chemotherapy	NR	NR	IVIIG nonspecified (days 3–5, 5 g) vs. no intervention	0.2†	3
Tugrul et al., 2002 (32)	42	42.0 (18)	49.3 (20.6)	Severe sepsis (ACCP/SCCM criteria) (reference 13)	Mean APACHE II score, 10.5 (SD, 4.6); mean SOFA score 5.0 (SD, 2.7); mean GCS score, 14.2 (SD, 2.1)	Mean APACHE II score, 14.0 (SD, 8.5); mean SOFA score, 5.7 (SD, 4.0); mean GCS score 12.9 (SD, 4.0)	Pentaglobin (Biotest Pharma, Dreieich, Germany) (days 0–2, 0.25 g/kg) vs. standard sepsis therapy	0.75	3
Karatzas et al., 2002 (33)	82	50.5 (3.3)	50.7 (7.4)	Severe sepsis (ACCP/SCCM criteria) (reference 13)	Mean APACHE II score, 21.3 (SD, 7.2)	Mean APACHE II score, 23.5 (SD, 7.9)	Pentaglobin (Biotest Pharma, Dreieich, Germany) (days 0–2, 0.25 g/kg) vs. standard sepsis therapy	0.75	3

Table 1—Continued

Author, Year (Reference)	Patients, <i>n</i>	Mean Age (SD), y		Inclusion Criteria	Reported Severity of Illness Measures		Treatment Regimens	Total Dose, <i>g/kg of body weight</i>	Duration of Therapy, <i>d</i>
		IVIg Group	Control Group		IVIg Group	Control Group			
Darenberg et al., 2003 (34)‡	21	53 (NR)	51 (NR)	Septic shock from group A streptococci (ACCP/SCCM criteria) (reference 13)	SAPS II score, 53; SOFA score, 11	SAPS II score, 51; SOFA score, 11	Endoglobulin (Baxter) (day 0, 1 <i>g/kg</i> ; days 1 and 2, 0.5 <i>g/kg</i>) vs. 1% albumin	2	3
Rodríguez et al., 2005 (35)‡	56	61.3 (19.9)	65.9 (18.2)	Sepsis from abdominal infections (ACCP/SCCM criteria) (reference 13)	Mean APACHE II score, 16.1 (SD, 5.9); mean TISS score, 19.0 (SD, 6.5) (day 1)	Mean APACHE II score, 15.2 (SD, 6.1); mean TISS score, 21.3 (SD, 9.3) (day 1)	Pentaglobin (Biotest Pharma, Frankfurt, Germany) (days 0–4, 0.35 <i>g/kg</i>) vs. 5% human albumin	1.75	5
Hentrich et al., 2006 (36)†	206	48.8	51.0	Severe sepsis or septic shock (ACCP/SCCM criteria) (reference 13) with hematologic malignant condition and neutropenia	NR	NR	Pentaglobin (Biotest Pharma, Dreieich, Germany) (time 0, 10 <i>g</i> ; then 5 <i>g</i> every 6 h for 72 h) vs. 5% human albumin	0.9†	3

* All sepsis scores refer to reference 39. ACCP/SCCM = American College of Chest Physicians/Society of Critical Care Medicine; APACHE II = Acute Physiology and Chronic Health Evaluation II; GCS = Glasgow Coma Scale; IVIg = intravenous immunoglobulin; NR = not reported; SAPS II = Simplified Acute Physiologic Score II; SOFA = Sepsis-related Organ Failure Assessment; TISS = Therapeutic Intervention Scoring System.

† Based on a patient who weighs 70 kg.

‡ Multicenter trial.

§ Median age.

|| The added number represents an additional day of therapy after the first uninterrupted course.

¶ Patients from a previous study (*n* = 62) (26) were removed from the total sample size (*n* = 117). Raw data for age could not be extracted; mean age is representative of all 117 patients and includes patients from the previous study.

** Based on a protocol published before the study was performed (40).

†† Data are presented as age categories (80% of patients were in each age category).