

# EFFECTIVE CENTRAL VENOUS CATHETER HEMODIALYSIS WITH A NOVEL NEEDLEFREE CONNECTION DEVICE (TEGO™)

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## Background:

Ten percent (10%) of patients with permanent (long-term) central venous catheter (CVC) access undergoing chronic hemodialysis are known to develop catheter related blood stream infections (CRBSI) 1-8 while 25% of these catheters develop occlusions due to thrombosis.<sup>9-13,21</sup> To address these concerns, a novel needle-free microbiologically and mechanically closed connector device (TEGO, ICU Medical, San Clemente, California, USA) was evaluated in CVC patients undergoing chronic hemodialysis. The TEGO incorporates a normally closed, swabable female luer and a male luer which is then connected to the hub of a CVC. The TEGO supports a flow rate of more than 600cc/min using a Buchi oil bath heated to 37° Celsius used to simulate the Hemodialysis fluid circuit under pressure. The TEGO also produces reliable automatic positive fluid displacement into the catheter tip at the end of each catheter flush procedure. This positive fluid displacement into the CVC is known to reduce clot formation in de novo placed CVCs.<sup>14-15, 22-27</sup>

Twenty-three CVC accessed chronic hemodialysis patients underwent a total of 150 hemodialysis treatments to evaluate adequate flow rate<sup>1,16</sup> and possible clinical evidence of catheter thrombosis. A TEGO device was placed at the arterial and venous CVC hubs for one-week duration on each patient for a total of three consecutive hemodialysis sessions. Each TEGO device was then exchanged for a new TEGO prior to the fourth hemodialysis treatment on each patient. It was verified at each session that adequate flow rate was obtained and no clinical evidence of catheter thrombosis was found. Also, at the end of this trial, no clinical evidence of CRBSI was reported.

## Materials and Methods:

In twenty-three CVC accessed chronic hemodialysis patients, a TEGO device was aseptically attached to both the arterial and venous CVC hubs. Nine patients underwent three hemodialysis treatments weekly for a three-week period completing a total of 81 hemodialysis treatments. Nine additional patients underwent three hemodialysis treatments weekly for a two-week period completing 54 total hemodialysis treatments. Finally, five additional patients underwent three hemodialysis treatments for one week, completing 15 total hemodialysis treatments. The dialyzer units used in this study were: Gambro, Stockholm, Sweden; Hospal, Bologna, Italy; Nikkiso, Tokyo, Japan; Bellco, Mirandola, Italy; and B Braun, Meurenburg, Germany. Patient's initials, age, gender, and diagnoses were recorded. Arterial and venous pressures as well as flow rate measurements were taken during dialysis at different time intervals and documented. Long term hemodialysis CVCs used in this trial were either Tesio catheters (Medcomp, Harlesville, Pa., USA) or Opti-Flow dual lumen catheters (Bard, Salt Lake City, Utah, USA).

Prior to commencing each hemodialysis treatment standard procedures were completed. The TEGO is a closed, cap-less connector and was therefore disinfected with a standard swabbing procedure using a 70% isopropyl alcohol prep pad. The Normal Saline and Heparin solution

present in both venous and arterial CVC lumens adapted with the TEGO devices was then aspirated and discarded. Next, both venous and arterial CVC lumens were flushed with 5 to 10cc of Normal Saline depending on the clinical situation and CVC used. To perform the hemodialysis treatment each of the arterial and venous tubing sets were connected directly to the respective TEGO devices and the treatment completed. At the end of each hemodialysis treatment, the standard CVC flushing protocol was utilized. The procedure consisted of flushing both the arterial and venous CVC hub connections adapted with TEGO devices with 10cc of Normal Saline followed with a flush solution of 1cc of Normal Saline and 1cc of 5000 international units of Heparin respectively for the venous and arterial CVC lumens. After flushing, the CVCs were not clamped or capped as the TEGO provides a mechanically and microbiologically closed system.

## **Results:**

Arterial and venous pressures as well as corresponding flow rates taken at different time intervals during each of the 150 hemodialysis treatments using the TEGO devices are tabulated in Table 1. Patient demographics are also listed in Table 1. All of the hemodialysis treatments conducted in this study revealed adequate blood flow rate<sup>16</sup> (flow rates > 250cc/min) along with adequate corresponding arterial and venous pressures. No clinical evidence of thrombotic occlusions of the CVCs were noted. Also, no clinical observations of CRBSI were observed.

## **Discussion:**

CRBSI and thrombotic occlusion of long term CVCs are a major cause of morbidity and mortality in chronic hemodialysis<sup>13,19</sup> accounting also for a major and prohibitive expenditure in the medical budget.<sup>17,20</sup> It is also known that multiple manipulations of the CVC at its hub by health care professionals increases the risk for intraluminal contamination and resulting CRBSI.<sup>18</sup> Also, Bouza and colleagues<sup>18</sup> have shown that using a microbiologically and mechanically closed and swabable device (Clave) decreases contamination and possible CRBSI at the hub as well as at the catheter insertion site. In addition, CVC thrombosis is an independent variable in CRBSI. Experimental<sup>14</sup> and clinical experience<sup>15,22-27</sup> have shown that using a microbiologically and mechanically closed device that produces automatic positive fluid displacement during catheter flushing decreases the incidence of CVC thrombosis. Given evidence that such devices can decrease the incidence of both CVC hub and insertion site contamination, resultant CRBSI, as well as CVC thrombosis, this study trialed a novel microbiologically and mechanically closed device (TEGO). The TEGO supports a flow rate of more than 600cc/min under pressure and produces reliable automatic positive fluid displacement into the catheter tip at the end of each flushing procedure. In this trial, TEGO devices were aseptically placed at the arterial and venous CVC hubs of twenty-three patients with long-term CVCs. These patients then underwent a total of 150 hemodialysis treatments using the TEGO adapted catheters for three consecutive hemodialysis treatments for an average duration of one week. At the end of the one-week period, each TEGO was then exchanged for a new one. Adequate blood flow and acceptable arterial and venous pressures were documented during this study (Table 1). In addition, no clinical evidence of CVC thrombosis or CRBSI were observed during this trial. This TEGO experience suggests that using such a device delivers adequate hemodialysis with the possibility of decreasing both clinical CVC infection rates as well as CVC thrombosis. Additional and more extensive clinical trials with TEGO devices are in progress to further evaluate this challenge.

**TABLE 1**

Patient	Age / Gender	Diagnosis	Number of Treatments	CVC Access Device	Average Arterial Pressure mmHg	Average Venous Pressure mmHg	Average Flow Rate cc/min
P1	81-F	Analgesic Nephropathy	9	Tesio	-209	185	303
P2	61-M	Glomerulonephritis	9	Opti-Flow	-167	151	324
P3	71-F	Adult Polycystic Kidneys	9	Tesio	-203	191	321
P4	42-F	S-P Failed Renal Transplant	9	Opti-Flow	-163	103	296
P5	73-M	Ig A Nephropathy	9	Tesio	-198	151	309
P6	83-M	Hypertensive Nephroangiosclerosis	9	Tesio	-204	136	332
P7	72-F	Chronic Renal Failure, ? Etiology	9	Tesio	-210	212	300
P8	56-F	Renal Vascular Nephropathy	9	Opti-Flow	-219	219	297
P9	78-M	Adult Polycystic Kidneys	9	Tesio	-200	158	310
P10	82-M	Chronic Renal Failure, ? Etiology	6	Opti-Flow	-209	117	296
P11	78-F	Adult Polycystic Kidneys	6	Opti-Flow	-201	165	289
P12	73-F	Pyelonephritis & Interstitial Nephritis	6	Opti-Flow	-216	198	281
P13	69-F	Pyelonephritis & Interstitial Nephritis	6	Opti-Flow	-177	156	325
P14	76-F	Interstitial Pyelonephritis - Renal Calculi	6	Tesio	-207	178	300
P15	73-F	Analgesic Nephropathy	6	Tesio	-201	161	278
P16	64-F	Scleroderma	6	Opti-Flow	-193	203	300
P17	89-M	Chronic Renal Failure, ? Etiology	6	Opti-Flow	-196	147	330
P18	81-M	Chronic Renal Failure, ? Etiology	6	Opti-Flow	-224	172	337
P19	71-F	Chronic Renal Failure, ? Etiology	3	Tesio	-181	131	330
P20	45-F	Glomerulonephritis	3	Tesio	-189	128	300
P21	79-F	DM TYPE I	3	Tesio	-190	182	330
P22	80-M	DM TYPE I	3	Opti-Flow	-196	150	327
P23	74-F	Hypertensive Renal Vascular Disease	3	Opti-Flow	-204	120	289
<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>6.5</b>	<b>N/A</b>	<b>-199</b>	<b>164</b>	<b>308</b>

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