

# Randomized Comparison of High-Flow versus Conventional Hemodialysis Catheters<sup>1</sup>

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Abbreviations: DOQI = Dialysis Outcomes Quality Initiative, Qb = pump settings, QbEff = effective flow rates

**PURPOSE:** To evaluate short-term flow rates achieved with a new split-tip polyurethane hemodialysis catheter.

**PATIENTS AND METHODS:** This was a prospective, randomized, nonblinded study. Patients referred for a tunneled-dialysis catheter received either a conventional silicone (Bard Hickman 13.5 F) if randomized to the control group, or a split-tip, high-flow polyurethane (MedComp AshSplit 14.5 F) catheter if randomized to the study group. Effective flow rates (QbEff) and recirculation were measured with use of ultrasonic dilution at pump settings (Qb) of 200, 300, 350 and 400 mL/min, as well as maximum Qb (QbMax, up to 500 mL/min) sustainable for at least 3 minutes. Measurements were repeated weekly for 6 weeks. Procedure times and initial and late complications were recorded.

**RESULTS:** Twelve patients were enrolled in each group, 11 and eight completed the study in the test and control groups, respectively. Insertion complications, limited to the split-tip group, included asymptomatic air embolus ( $n = 1$ ), prolonged tunnel bleeding ( $n = 2$ ), and kinking ( $n = 2$ ). Recirculation in both groups was low (mean < 6% at all flow rates). QbMax was 499 mL/min in the Ash group and 470 mL/min in the Hickman group. A repeated measures analysis of variance was used. Adjusted (for week) mean effective flow rates (Qbeff, mL/min) were as follows: at Qb = 200, Ash = 211, Bard = 211,  $P = .93$ ; at Qb = 300, Ash = 301, Bard = 292,  $P = .28$ ; at Qb = 350, Ash = 341, Bard = 314,  $P = .03$ ; at Qb = 400, Ash = 375, Bard = 329,  $P = .01$ ; at QbMax, Ash = 422, Bard = 359,  $P = .0005$ .

**CONCLUSION:** Both catheters delivered flows within the acceptable range indicated by the Dialysis Outcomes Quality Initiative. The split-tip catheter is capable of higher flow rates (Qb and QbEff) compared with the conventional catheter, which may allow more efficient dialysis. Insertion complications appear to be higher with the new design.

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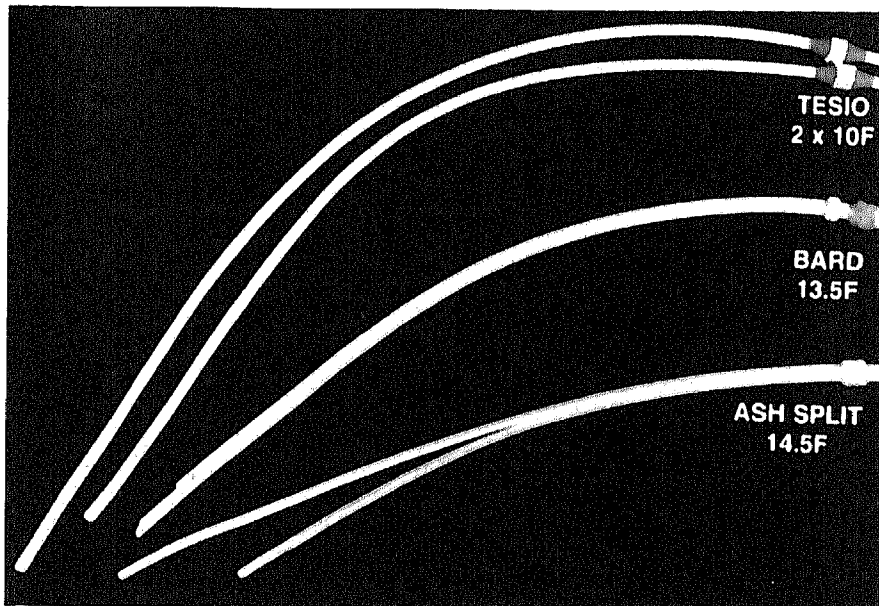
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APPROXIMATELY 200,000 patients currently undergo hemodialysis in the United States (1). While the majority of these patients have permanent forms of access, such as native fistulae or synthetic arteriovenous shunts, a large number of patients require temporary tunneled hemodialysis catheter placement during maturation of shunts

and fistulae, and a subset of patients use these catheters as their permanent form of access. In addition, temporary tunneled catheters for hemodialysis are used in the setting of renal transplantation, as well as intermittently in patients with complications of continuous ambulatory peritoneal dialysis.

While percutaneous imaging-



**Figure 1.** Intravascular portion of the two study catheters. The Tesio catheter is shown for comparison (see Discussion). Note that the Ash catheter has a split tip but single catheter shaft.

guided placement of these catheters is associated with a very low initial complication rate (2,3), these catheters are prone to long-term complications that include infection and poor flow, often due to thrombosis. Flow-related problems account for a significant percentage of unanticipated catheter removal (53% in one recent series [2]). To date, nearly all hemodialysis catheters have had approximately the same limitations in terms of flow rates, with average flow rates in the vicinity of 300 mL/min (4–16), with the possible exception of the Tesio Twin Catheter (Medcomp, Harleysville, PA), which has been reported to deliver higher blood flows in recent series (17,18).

A recently introduced catheter design, called the Ash Split catheter (Medcomp), is designed to deliver higher flow rates than existing catheters. This catheter design has a single tunnel, but split tips in its intravenous portion, effectively functioning as a twin catheter in its distal most aspect. The purpose of this study was to compare the new catheter design to an established conventional hemodialysis catheter (Hickman; Bard Access Systems, Salt Lake City, UT), with specific

attention to flow rate, as well as short-term catheter malfunction. The control catheter was chosen based on its established performance in previous series (2,3).

#### PATIENTS AND METHODS

This was a prospective, randomized, controlled study approved by our Institutional Review Board. All patients referred to the interventional radiology department for tunneled hemodialysis catheter placement were considered for the study. The study ran from January to May 1998. To be eligible, patients had to be undergoing hemodialysis using the catheter for a minimum of 6 weeks at one of two local dialysis units, both operated by the same nephrology group and both using identical catheter care protocols. Exclusion criteria included previous enrollment in the study, inability to sign informed consent, and right internal jugular vein occlusion. Only right internal jugular vein catheter placements were studied to minimize the number of variables, especially because there is evidence that left internal jugular catheters

may have lower flow rates than right internal jugular catheters (6). After signing informed consent, patients were randomly assigned to the treatment (Ash Split) or the control (Bard) group. Randomization was performed using random number generation. Catheter placement and follow-up care was performed, as previously described, using ultrasound guidance for the venipuncture and fluoroscopic guidance for catheter positioning (2). Lidocaine without epinephrine was used for local anesthesia and conscious sedation was used in all patients. In the treatment group, catheter insertion was identical to the control group except that, after passing the catheter through the subcutaneous tunnel, the tip was manually split according to the manufacturer's directions (Fig 1). A split of 10 cm was used. Because the difference between the two catheters was readily apparent, this was not a blinded study. At the time of catheter placement, data collection included demographics, complications, and two measures of procedure time. The first measure was room time, defined as the entire time the patient was in the procedure room. The second was catheter insertion time, defined as the time from local anesthesia to the last suture.

After catheter placement, catheter function was evaluated with use of ultrasonic dilution technique (Transonic HD01; Transonic Systems, Ithaca, NY). This technique has been validated as an accurate measure of flow during dialysis (18,19). Once per week for a total of 6 weeks, hemodynamic data were collected using this technique. Effective flow rates ( $Q_{\text{eff}}$ ) were determined at pump speed settings ( $Q_b$ ) of 200, 300, 350, and 400 mL/min. In addition, maximum sustainable flow rates were recorded, defined as the  $Q_{\text{eff}}$  when the  $Q_b$  was set to the highest setting on the dialysis pump that could be sustained for a minimum of 3 minutes. Recirculation was also measured using the same device. In addition, the mean flow rate for the entire dialysis session was determined with use

September 1999 JVIR

of the formula: total liters processed divided by time on dialysis (20,21). Flow rates and recirculation were determined at the beginning of each week.

Other parameters recorded during the follow-up period included the need to instill urokinase in the catheter (dose, duration, and result), radiologic studies prompted by poor flow rates and their results, as well as the reason for any premature catheter removal. When necessary, catheter injections were performed and the appropriate management of thrombotic complications was done, as previously described (2). Patients were followed for 6 weeks or until catheter removal, whichever came first. Catheter removal was considered the study endpoint regardless of the reason.

#### • Data Analysis

Each individual had six flow measurements (once each week for 6 weeks). The two catheters were compared using a repeated measures analysis of variance model, with time being a repeated factor and catheter used being a fixed effect. The individuals were treated as random effects. Demographic data at baseline were compared by means of Student *t* test. Insertion times were compared using the Wilcoxon rank sum test. To verify that the results were not changed by dropouts, we performed a supplementary analysis in which all missing data were replaced by that subject's last nonmissing datum (last observation carried forward). The results of this supplementary analysis were not substantially different from the analysis using all of the nonmissing data and are not included in this article.

#### • Determination of Sample Size

The sample size (eight per group completing the 6-week study) was chosen to provide 90% power if the true difference in mean flow rates between the catheters was 100 mL/min (eg, 300 for Bard and 400 for Ash). This assumes that the stan-

dard deviation within a group is 50 mL/min and that all testing is done at the 5% level. This is described in more detail in the Appendix.

### RESULTS

Twelve patients were assigned to each group. Five patients did not complete the study. One patient in the Ash group experienced catheter malfunction, which required exchange. Eleven patients completed the study in the Ash group. In the Bard group, eight patients completed the study. One patient each was excluded because of death during liver transplantation, catheter severed by the patient resulting in near exsanguination, and death due to myocardial infarction during replacement, resumption of continuous ambulatory peritoneal dialysis, and unexpected transfer to a rehabilitation facility.

#### • Demographics

At baseline, the groups did not differ in age (mean, 52 years [Ash]; 54 years [Bard];  $P = .68$ ) or weight (mean, 84 kg [Ash]; 69 kg [Bard];  $P = .13$ ), but did differ slightly as to height (mean, 168 cm [Ash]; 160 cm [Bard];  $P < .03$ ). There were 12 women and no men in the Ash group, and eight women and four men in the Bard group.

#### • Insertion

Insertion time, but not room time, was shorter in the Bard group. In the Ash group, mean insertion time was  $22 \pm 15$  minutes (median, 17 minutes; range, 11–68 minutes). In the Bard group, mean insertion time was  $16 \pm 5$  minutes (median, 14 minutes; range, 10–26 minutes;  $P = .04$ ). Mean room time in the Ash group was  $56 \pm 25$  minutes (median, 45 minutes; range 36–107 minutes). In the Bard group, mean room time was  $49 \pm 15$  minutes (median, 45 minutes; range, 30–83 minutes;  $P = .66$ ).

Insertion complications were limited to the Ash group and included catheter kinking ( $n = 2, 17\%$ ; one

resolved with further manipulation, one incompletely resolved), asymptomatic air embolus ( $n = 1, 8\%$ ), and bleeding from the catheter exit site requiring return to the hospital ( $n = 2, 17\%$ ; resolved with prolonged compression over the tunnel).

#### • Delayed Complications

One Ash catheter was removed at day 7 because of poor flow. A large fibrin sheath was noted at catheter exchange. As noted previously, one patient who deliberately severed her (Bard) catheter at the exit site died of a myocardial infarction during attempts at replacing the catheter. One of 11 (9%) Ash subjects completing the study was treated successfully for *Staphylococcus aureus* bacteremia with antibiotics at week 4. Low-dose urokinase (Open-Cath; Abbott Laboratories, Abbott Park, IL) was instilled in three of eight (38%) Bard catheters at weeks 5, 6, and 6, respectively. No other delayed complications occurred during the study period.

#### • Flow Rates

The Table shows the adjusted mean effective  $Q_{bEff}$  at each  $Q_b$ . This is shown graphically in Figure 2. Note that at  $Q_b$  of 200 and 300 mL/min, the  $Q_{bEff}$  did not differ between groups, but at  $Q_b$  of 350 and 400 mL/min and  $Q_{bMax}$ , the Ash catheter delivered significantly higher  $Q_{bEff}$  (Table). Both catheters were capable of delivering the recommended minimum flow rate of 300 mL/min set by the Dialysis Outcomes Quality Initiative (DOQI) Vascular Access Guidelines (22) during this short-term study. Using a different measure of flow (mean flow rate calculated by dividing total liters processed by time), the study catheter delivered significantly higher flow rates.

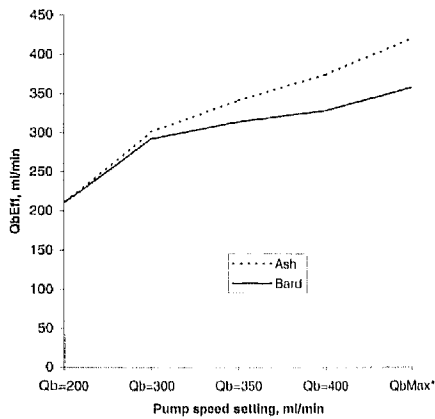
#### • Recirculation

While recirculation was low with both catheters, the study catheter had significantly lower recirculation at nearly all flow rates, as can be

**Blood Flow and Recirculation**

	QbEff (mL/min)			Recirculation (%)		
	Ash (n = 8)	Bard (n = 8)	P	Ash (n = 8)	Bard (n = 8)	P
Qb = 200	211 ± 4.6	211 ± 5.0	.94	0.8 ± 0.8	3.3 ± 0.8	.04
Qb = 300	301 ± 5.8	292 ± 6.3	.29	1 ± 1	4.4 ± 1.1	.03
Qb = 350	341 ± 7.9	314 ± 8.7	.03	1.2 ± 1.1	4.4 ± 1.2	.06
Qb = 400	375 ± 11.6	329 ± 13	.01	1.3 ± 1	5.2 ± 1.1	.01
QbMax	422 ± 12	359 ± 13	.0005	1.3 ± 1.3	5.6 ± 1.4	.03
Mean BF	353 ± 6.3*	309 ± 7.1*	.0001			

Note.—Values represent mean ± standard error. Qb = pump setting, QbEff = effective blood flow, QbMax = maximal pump setting (see text), BF = blood flow.



**Figure 2.** Effective flow rates (QbEff) at various pump speed settings (Qb).

seen in the **Table**. Mean recirculation did not exceed 6% with either catheter.

**DISCUSSION**

Hemodialysis catheters form an integral component of the delivery of hemodialysis. While it is possible that the use of such catheters for chronic hemodialysis access may decrease with time because of the recommendations of the DOQI (22), they will continue to be used as a bridge to permanent access or continuous ambulatory peritoneal dialysis and be the sole form of access for a subset of patients. Whether for short- or long-term use, current hemodialysis catheters are by no means perfect: problems associated with such catheters include infection, thrombosis, and poor flow. Refinements in catheter technology

that improve any or all of these problems are likely to be welcomed by the nephrology community.

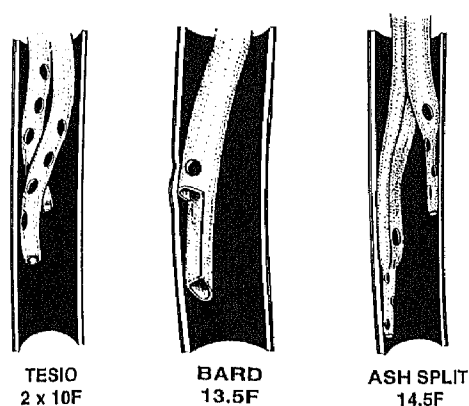
The demand for flow rates from hemodialysis catheters has increased in the era of high-flux dialysis. Previously, definitions of accepted mean flow rates for tunneled hemodialysis catheters were 150 to 200 mL/min (10,12); and published series reported mean flow rates of approximately 212–266 mL/min (4–6) for single catheters. Most series, even recently, have defined catheter failure as occurring when flow rates fall below 200 mL/min (12,21). However, the DOQI defines catheter failure as the inability to deliver 300 mL/min (22), ushering in a new age of demands on hemodialysis catheters. Most published series to date would not meet these criteria. One possible exception is the Tesio twin catheter design, which consists of two separate 10-F catheters and has been reported to deliver flow rates of 352–396 mL/min (17,18,20). However, Canaud et al, using similar twin catheters reported mean flow rates of only 276 mL/min (8).

We have shown that during the first 6 weeks after catheter placement that both catheter designs tested were capable of delivering the flow rates specified by the DOQI when placed with use of imaging guidance by interventional radiologists. However, the margin by which the conventional catheter exceeded this threshold was rather slim, while the split-tip catheter easily exceeded the DOQI threshold and was capable of delivering flow

rates well above prescribed rates. In fact, virtually every split-tip catheter functioned even at the maximal flow rate setting for the hemodialysis pump. This indicates that the split-tip catheter has a wider margin of functionality than the conventional catheter, which may become important in catheters that are suboptimally positioned or begin to develop fibrin sheaths. That is to say that a catheter that starts out being able to deliver > 400 mL/min can tolerate more reduction in flow from malposition or fibrin sheath than one that starts out with a maximum of 350 mL/min.

There are several reasons for the superior flow rates seen with the split-tip catheter; but the most important is probably luminal diameter. Because, according to the Poiseuille equation, flow is related to the fourth power of the radius, small increases in luminal diameter will result in relatively large changes in flow. The luminal diameter of the two catheters differs, although not dramatically, and this probably accounts for the majority of the observed differences in flow rates. However, the split-tip design also allows circumferential sideholes on the catheter tip, which is not possible with a step tip design. Similar sideholes are present in the Tesio twin catheter. Circumferential sideholes make a catheter less prone to subtle malpositioning problems in that, even if the arterial lumen is against a vessel wall, flow will not be as restricted as it is with a step tip design (**Fig 3**).

In addition to delivering superior



**Figure 3.** Tip configurations of the Ash, Bard, and Tesio catheters as might occur during hemodialysis. Note that circumferential sideholes on the Ash and Tesio catheters allow aspiration from the arterial (shorter) lumen, even when up against the vessel wall.

flow rates, the split-tip catheter had lower recirculation, although it was relatively low for both groups. This came as somewhat of a surprise because, intuitively, one might think that circumferential sideholes might predispose to increased recirculation. On the other hand, the venous lumen of the study catheter extends substantially further beyond the arterial lumen compared with the conventional catheter, which may account for the observed difference (Fig 1). Our results are consistent with previous series in which recirculation has been reported at 3.7%–12.6% for conventional catheters (5,9,13,20) and 3.9%–10.9% for twin catheters (18,20); if anything, the study catheter may be superior to both designs in this regard.

We chose to use the ultrasonic dilution technique for measurement of flow because it is a well validated, reproducible method (18,19), with little or no operator dependence. Most importantly, this technique allows measurement of the  $Q_{bEff}$  rather than the  $Q_b$ . As can be seen from our results and others using this technique (17,18), there are substantial differences between these two values at higher  $Q_b$ , and this must be kept in mind when comparing our results with those of previously published series, most of

which have reported flow rates based on  $Q_b$  (4–16,20,21). We are aware of only two series in which  $Q_{bEff}$  was reported (17,18), both for the Tesio catheter; in one series a nominal  $Q_b$  of  $388 \pm 6$  mL/min had a  $Q_{bEff}$  of  $352 \pm 8$  mL/min, and a recirculation average of  $4.6 \pm 0.5$  (17), whereas the other reported  $Q_{bEff}$  of  $372 \pm 26$  mL/min at  $Q_b$  of 400 mL/min, with a recirculation average of  $10.9 \pm 8.6\%$  (18). Those authors did not attempt to run the catheters at higher  $Q_b$ , so it is unclear whether higher  $Q_{bEff}$  might be obtainable with twin catheters. Because of the discrepancy between  $Q_b$  and  $Q_{bEff}$ , reports of “flow rates” based on  $Q_b$  must be viewed with some skepticism. It must be noted that, based on this study, there appears to be diminishing return in terms of  $Q_{bEff}$  as higher  $Q_b$  are set, with the curves flattening at higher  $Q_b$  (Fig 2). Therefore, estimated improvements in liters processed with increased  $Q_b$  will overestimate delivered dialysis.

As have some other authors, we also chose to measure mean blood flow in terms of total liters processed divided by time (20,21) with the thought that this might prove to be a valid measure of catheter performance. The argument that has been made in favor of this approach is that it is more reflective of the entire dialysis session rather than a single measurement point (21). This measure also showed the same pattern of higher flow in the Ash group.

There is a potential drawback to thinner-walled catheters: they are more prone to kinking, and this was seen in two instances (17%) in this series. The additional time required to reduce kinking may have contributed to the slightly longer procedure time in the Ash group. Careful attention to the course of the catheter is essential at the time of placement to ensure kinking does not occur; we found that if kinking did occur, turning the catheter so that the septum was parallel to the radius of the curve helped overcome this problem. While this may result in tip orientation that we would consider suboptimal with a step tip

catheter (°), this did not appear to affect flow rates in this series. In addition to difficulty with kinking, two patients (17%) developed tunnel bleeding, which required their return to the hospital. We hypothesize that this may be due to the groove that is present along the entire length of the Ash catheter, which may allow “wicking” of blood along the catheter. In both patients, this bleeding responded to prolonged compression, but clearly any design improvement that might eliminate this problem would enhance the value of this catheter. A final consideration when comparing the two catheters is cost: the Ash catheter costs \$285 (\$375 for a complete kit) compared with \$160 for the control catheter. Because both catheters delivered flow rates that are acceptable, according to DOQI definitions, one could argue the cost-effectiveness of the Ash catheter. This question may be answered with further, long-term studies.

There are several limitations to this study. First, the sample size is small, however, the sample size calculation and result clearly show that this number of patients and observations are all that are needed to detect the large difference in flow rates between catheters at higher  $Q_b$ . Second, this short-term series does not address whether there are any long-term differences in catheter complications, such as fibrin sheaths or infections, and we are currently performing a long-term study to address these questions. Third, our group has extensive experience with the Bard catheter, while relatively less experience with the Ash catheter. The relatively high initial complication rate could be a result of a learning curve. Nonetheless, all operators (only fellowship trained staff interventional radiologists) had placed multiple Ash Split catheters before the study was initiated, and, in addition, we continue to see similar rates of these problems (none insurmountable) despite the fact that we have placed more than 150 of these catheters. Our current long-term trial will hopefully address this issue. Finally, it could be argued that the

control catheter should have been the Tesio catheter rather than the Bard catheter. The Bard catheter was chosen because it has been established to deliver satisfactory flow rates (2) and was our standard hemodialysis catheter at the time of the study. In the past, we have had some experience with the Tesio catheter and had abandoned it because of multiple problems, including greater time and difficulty of placement, catheter and hub breakage, high cost, initial malfunction, and poor flow rates. After an initial trial of using the Tesio catheter, we resorted to the Bard catheter as our standard catheter for these reasons. We believe our choice of the Bard catheter as control was appropriate given these considerations. Perhaps other investigators with more interest in the Tesio catheter will repeat this trial using it as the control.

In conclusion, we found that the Ash catheter delivered higher flows and lower recirculation compared with the control catheter, however, this was at the expense of higher initial complications and slightly longer operator time. Both catheters delivered flows acceptable according to DOQI definitions.

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#### APPENDIX

##### • Sample Size Determination

The measurements within an individual were assumed to be serially correlated over time. As an approximation, we assumed that the correlation between any two measurements in a fixed individual was  $\rho$ . If the variance of an individual measurement was  $\sigma^2$ , the variance of the average of  $n$  measurements for an individual would then be  $[1+(n-1)\rho]\sigma^2/n$ . The power for the repeated measures analysis of variance test of the catheter type was exactly the same as the power for a one-way analysis of variance test of the catheter type when using the mean of the individual's measurements as the response. Therefore, all power was calculated using one-way analysis of variance with the mean of the six measurements as the response.

A conservative assumption was

September 1999 JVIR

that all six measurements would be perfectly correlated. If this were true, then the variance of the mean of the six measurements would be exactly  $\sigma^2$ . From pilot studies (unpublished data, 1998) the mean flow rates were 280 mL/min with the control catheter with standard deviation from 67 subjects of 49

mL/min and for another 49 subjects 45 mL/min. We used a standard deviation of 50 mL/min as a (slightly) conservative estimate. The test catheter was introduced relatively recently and flow rates approaching 400 mL/min were observed in a small series (unpublished data, 1998).

If the true mean flow rates in the two catheter groups were 300 and 400 mL/min respectively, there would be greater than 90% power to reject the null hypothesis of equal means using a test at the 5% level if there were at least eight subjects completing the study in each of the two groups.