BACKGROUND

The history of dialysis treatment in Japan spans over half a century, from the latter half of the 1950s until the present day with over 300,000 patients undergoing haemodialysis every week utilising plastic cannula for arteriovenous fistula (AVF) and arteriovenous graft (AVG) access. Plastic cannula are blunt and reduce the risk of intra dialysis infiltration. Reports indicate adoption of the technology ultimately for the benefit of patient safety without compromise to pump speed and arterial and venous pressures with these non-metal alternative. In accordance with the clinical adoption of this technology outside of Japan, further understanding of this technology is warranted around flow and pressure due to the varying clinical practices around the world. As discussed previously in the literature a sharp metal needle left inside an AVF/AVG places the patient at risk of infiltration if the sharp needle tip perforates the vessel wall intra dialysis. Whilst removing the risk of intra dialysis infiltration is an important consideration, maintaining effective blood flow rates and arterial and venous pressures is critical to ensure dialysis adequacy.

The objective of this investigation is to document the flow and pressure characteristics of the Argyle Safety Fistula Cannula with Clamping and Anti Reflux devices in deionised (DI) water and high viscous fluid (blood analog) media. The results of this investigation will better enable users of this technology to understand the comparative flow rates and pressures to that of the literature and expected outcomes of current technologies utilised.

PROJECT AIMS

One of the key properties of a fistula cannula needle is to provide adequate blood flow during a dialysis session. Pump speed and pressures parameter are in accordance to the FistulaFirst guideline created for and adopted by the USA.

Table 1 outlines the maximum blood flow rates through steel fistula needles per FistulaFirst.org. As reported in an Australian (Queensland) based clinical setting average pressure was achieved with the Argyle cannulas of 140mmHg on both arterial and venous insertions; with effective blood flows in excess of 300ml/minute with both haemodialysis and haemodiafiltration. It has been discussed in the literature that extrapolating results across sites is difficult due to the many varying factors within the clinical setting. This report aims to address a number of these questions.

METHOD

Testing performed was on the basis of recommendations per the Implanted Blood Access Devices for Hemodialysis Draft Guidance for Industry and Food and Drug Administration Staff 2013. This guidance document recommends that dynamic flow testing should be conducted from the minimum to the maximum flow rate in increments of at least 100 ml/min. It is preferred that this testing is conducted with a fluid that has a viscosity analogous to that of blood. In this study a glycerol/water mixture of 50/50 by weight was prepared to replicate the viscosity of blood at body temperature (37°C). A control baseline sample group was tested in DI water prior and after the high viscosity media dynamic flow test to ensure that the performance of the flow bench system returned back to baseline and the system contained no residual high viscosity fluid.

Samples

Four different types of fistula cannulas are tested. Both the Safety Fistula Cannula with Clamping (Length Configuration: 15G x 25mm and 17G x 38mm) and the Safety Fistula Cannula with Anti Reflex (Length Configuration: 15G x 30mm and 17G x 38mm) were tested in DI water and Blood Analog Fluid. Materials included Glycerol Anhydrous EMPLURA (Merk), with Dynamic Flow Tester, and U-tube viscometer. All equipment was in calibration during testing.

Test Procedure

All tests were conducted as described in the test protocol under study number 200136-243-MS-14 “Test Protocol for Dynamic Flow Test of Fistula Cannula with DI Water and High Viscosity Fluid”.

RESULTS

Viscosity measurement was analogous to blood viscosity during testing (3.4-3.6cP). Dynamic flow test for control baseline samples was acceptable. The average pressure measured at each flow rate and its graphical representation is below for all four types of fistula cannula. The 15G cannulas performed within the recommended parameters for flow and pressure (Figure 1). The 17G cannulas exceeded the pressure gradient after 250ml/min (Figure 2).

DISCUSSION AND CONCLUSION

The performance for flow and pressures for the Argyle Fistula Cannula were reviewed based on specifications from FistulaFirst.org. This study was performed to obtain the information on flow vs pressure characteristics of fistula cannulas when tested in a blood analogous fluid. Based on these results current clinical expectations on performance for both flow rates and pressures will be able to be achieved utilising the Argyle Fistula Cannula. Considering the specification as reference point only, all the 15G fistula cannulas are well within the specification limit, with the 17G fistula cannula exceeding specification limit for high viscous fluid (in excess of 250ml/min).

The Argyle fistula cannula has the potential to reduce patient vascular access complications compared to current technologies without compromising performance. The Argyle fistula cannula which enables removal of the steel needle prior to cannulation, coupled with acceptable flow and pressure rates certainly warrants further investigation.

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