Chapter 5

Aneurysm sac pressure monitoring: Effect of technique on interpretation of measurements


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Abstract

Objective: The purpose of this study is to determine the accuracy of measuring pressure with a fluid filled pressure device (needle) and a non-fluid filled pressure device (catheter) inside a thromboased aneurysm sac after exclusion from circulation by endovascular grafting.

Methods: In a static environment, consisting of a syringe to which a pressure monitoring kit was connected, experiments were performed to study the influence of the type of device (either needle or catheter) and the effect of the characteristics of the medium on the accuracy and reproducibility of pressure measurements. The pressures obtained with the needle in the different kinds of media were compared with those obtained in blood. Similar experiments were performed using a pressure catheter. Subsequently, pressure measurements were performed in a dynamic and physiological environment. This environment consisted of an artificial circulation in which an aneurysm, constructed of porcine aorta and filled with human aortic thrombus, was mounted. The pressures were compared and analyzed by Bland-Altman plots.

Results: Under static pressure conditions the pressure levels obtained by a pressure needle in blood were not significantly different from those measured in starch solution with a viscosity comparable with blood viscosity and in blood with thrombus. ($p > 0.05$) In the other media the reproducibility was poor. Under identical conditions, pressures obtained by a pressure catheter in starch solution with a viscosity higher than blood were significant lower than the pressures measured in blood ($p < 0.05$). In the other media there was no significant difference in pressure levels ($p > 0.05$). Under dynamic pressure conditions the reproducibility of pressures obtained with the needle inserted in the human thrombus was very poor.

Conclusion: A needle pressure measuring device, inserted into media like human fibrin thrombus, does not yield accurate and reproducible results. A catheter with a tip-sensor rather than a needle is superior to study the pressure in the aneurysm sac after EVAR.
5.1 Introduction

The aim of EVAR is to reduce the risk of aneurysm rupture by excluding the aneurysm from the circulation and by reducing the pressure in the aneurysm sac. One of the problems of this technique is the occurrence of endoleaks because of pressurization of the aneurysm sac [1]. A pressurized aneurysm sac may result in rupture after EVAR [2]. Therefore, it is attractive to develop methods for aneurysm sac pressure monitoring. In clinical practice aneurysm sac pressure monitoring could be helpful to determine whether re-intervention is needed.

However, pressure monitoring is not possible non-invasively. The simplest method is puncturing the aneurysm sac with a needle and connecting the needle to a pressure transducer. There are several reports about pressure measurements in thrombus performed with needles [3–6]. Alternatively, AAA sac pressure can be measured with a catheter with a tip-sensor [7]. Thanks to the micro-sensor technology wireless pressure sensors have been developed and implanted [8].

One of the problems with pressure monitoring in the aneurysm sac is that we do not know the accuracy and reproducibility of the techniques. We hypothesized that the needle technique (fluid filled), which is commonly used to measure pressure in aneurysm sacs after EVAR is a less accurate technique than using a pressure catheter with a tip-sensor or a micro pressure sensor (non-fluid filled).

The purpose of this study is to determine the accuracy of measuring pressure inside aneurysm sac thrombus with a fluid filled pressure device (needle) and a non-fluid filled pressure device (catheter), respectively.

5.2 Methods

This study was divided into four different experiments. First pressure measurements were performed in a static model. Subsequently, experiments were performed in a dynamic model.

5.2.1 Set-up static experiments

The static model consisted of a 60 ml syringe. A 19-gauge needle, similar to those used for puncturing the sac, was inserted in the syringe. The needle was connected to a standard pressure monitoring kit, consisting of connecting tubes and a pressure sensor (Pressure monitoring kit, Baxter, Uden, The Netherlands) (Figure 5.1).

Needle pressure measurement devices are used to measure blood pressure and are able to record rapid changes in pressure. These devices have also been used to measure pressure in the aneurysm sac [3–6]. An electronic pressure transducer, connected to the pressure needle, converts the pressure into electrical signals. The transducer uses a very thin, highly stretched metal membrane that forms a wall to the fluid chamber. The fluid chamber is connected to a needle inserted in the
Figure 5.1: Schematic representation of the experimental set-up of experiment 1. The experimental set-up consists of a syringe (A), a 19 gauge needle (B), a small tube filled with NaCl 0.9% (C), infusion system with NaCl 0.9% (D), a flushing system with the electrical pressure transducer (E), an electrical connection to the measuring device (F) and a measuring device with electronic pressure display (G). \( \Delta x \) has been kept constant.

Substance in which the pressure has to be measured. When the pressure is high, the membrane bulges slightly and when it is low, it returns toward its resting position. A small iron slug rests on the membrane and this can be displaced upward into a center space inside an electrical wire coil. Movement of the iron slug changes the inductance of the coil, and this can be recorded electrically. Before introducing the needle in the syringe the pressure monitoring kit was flushed by NaCl 0.9%.

Subsequently a pressure catheter (MicroTransducer Catheter, Dräger Medical Electronics, Oss, The Netherlands) was used instead of a pressure needle (Figure 5.2).

The MicroTrandsducer Catheter was developed on the basis of an advanced semiconductor technology for accurate invasive blood pressure measurements. The catheter contained a pressure sensor at the tip. This sensor consisted of a pressure sensitive silicon chip, which generated an electrical signal in proportion to the pressure change. The pressure sensor had a pressure sensitivity of \( 9.58 \mu V/V/mmHg \) conferring an accuracy of 2 mmHg.

The pressure sensors were calibrated by measuring the pressure in a box. The pressure measured by the pressure sensors was verified by means of a regular mercury manometer which was connected to the box. The mercury manometer was calibrated by the technical department of the Leiden University Medical Center. Syringes A to G were filled with 31 ml blood (A), starch solution with viscosity 3.1 (B) (a liquid with the same viscosity as blood), starch solution with tealeaves (C) (an inhomogeneous liquid), gelatinous liquid (D) (a material like thrombus),
5.2 Methods

Figure 5.2: Schematic representation of the experimental set-up of experiment 2. The experimental set-up consists of a syringe (A), a pressure catheter (B), measuring device with electronic pressure display (C) and pressure catheter with tip-sensor. ∆x has been kept constant.

Blood with thrombus (E) (obtained during conventional aneurysm surgery), starch solution with viscosity 5.1 (F) (a liquid with a high viscosity) and water (G) (a liquid with a low viscosity), respectively.

Air with an atmospheric pressure was situated between the pistons of the syringes and their substances, so the total content (air and substance) was compressible. Pressure inside the syringe was generated by moving the piston.

5.2.2 Static experiments

The effect of the characteristics of the substance in the syringe on the pressure measurement was evaluated. Thus, during the experiments different kinds of media and suspensions were deposited in the syringe. The volume of the liquid was kept 31 ml in all experiments. The piston of the syringes were pushed by hand in the syringes over the same extent (∆x = 5 ml). Ten pressure measurements were performed in each syringe. The pressure measurements with syringe A (filled with blood) were considered as control measurements.
5.2.3 Statistical analysis static experiments

The pressures of the static experiments with various substances were compared with the pressure levels obtained in blood (syringe A), because the used pressure measuring devices were especially developed to measure pressure in full blood. Statistical analyses were performed by Mann-Whitney non-parametric test. Statistical significance was defined as a \( p \)-value of less than 0.05.

5.2.4 Set-up dynamic experiments

An artificial aneurysm, made of porcine aorta, was included in an improved in-vitro model of the human circulation as described previously (Figure 5.3) [9]. The system was filled with 5 liter starch solution with the same viscosity as blood. We proved in the static experiments of this study that starch solution with the same viscosity does not influence the pressure measurement. A cross-sectional segment of a human thrombus, obtained during open aneurysm surgery, was inserted in the aneurysm. Thrombi from eight different patients were used.

5.2.5 Dynamic experiments

First, the mean pressure in the thrombus was measured at various locations. Overall, sixty measurements were performed. A pressure needle was inserted in the aneurysm. After measuring the pressure with the needle, the needle was uncoupled from the connecting tube of the pressure monitoring kit. The needle was still situated in the thrombus. The catheter was inserted through the needle in the thrombus. Subsequently, pressure measurements were performed by the pressure catheter. By applying this method it was possible to perform the pressure measurements with a needle and catheter at the same place in the thrombus.

Finally, we performed pressure measurements in order to study the effect of possible obstructions inside a needle, on the accuracy of the measurements. Nine pressure measurements were performed by an unobstructed needle and subsequently by a needle, which was already obstructed with human thrombus. All pressure measurements were performed by various systolic/diastolic systemic pressures (range mean pressure 108 – 133 mmHg).

5.2.6 Statistical analysis dynamic experiments

Theoretically, the pressures measured by the different devices at the same location should be similar. The pressure needle measurements were compared with the pressure catheter measurements by means of a Bland and Altman-plot [10]. The pressure levels obtained with the unobstructed needle and the obstructed needle were compared by means of Mann-Whitney non-parametric testing. Statistical
Figure 5.3: Schematic representation of the in-vitro model of the human systemic circulation, which is used in experiment 3 and 4. The model consists of a pressure measuring device (A), an artificial heart driver (B), a valve (C), an open reservoir (D), a ball valve (E), left ventricle (F), two needle to measure pressure in circulation (G), a flow transducer (H), an air-chamber (I), blood pressure cuff (J) and an artificial saccular aneurysm made of pig’s aorta filled with human thrombus.

significance was defined as a $p$-value of less than 0.05. SPSS 11.0 for Windows (SPSS Inc, Chicago, USA) was used for statistical analysis

5.3 Results

5.3.1 Static experiment with needle

The pressures measured in syringe C (starch solution with tealeaves), D (gelatinous liquid), F (starch solution with viscosity 5.1) and G (water) were significant different from the pressures measured in syringe A (blood) ($p < 0.05$). The mean pressures in syringe A (blood), B (starch solution with viscosity 3.1) and E (blood with thrombus) were approximately of the same value. In syringe E (blood with thrombus) the range of the measured pressures varied from 204 to 230 mmHg (Figure 5.4).
5.3.2 Static experiment with catheter

The pressure levels measured in syringe F (starch solution with viscosity 5.1) were significant different from the pressures measured in syringe A (blood) ($p < 0.005$). However, this difference is acceptable in a clinical setting (Figure 5.5).

5.3.3 Dynamic experiments with needle and catheter

The pressure measurements inside a human thrombus were carried out with a pressure catheter and with a pressure needle on the same location. Figure 5.6 illustrates level of agreement between these measurements. All the depicted points in Figure 5.6, with the exception of five measurements, are in the range of mean + 2SD and mean - 2SD, which implies that there is not a significant difference. A range of mean + 2 SD and mean - 2 SD means a range of more than 80 mmHg. This is not acceptable in clinical setting. However, we decided that in clinical setting a difference of not exceeding 20 mmHg between the measured pressure by needle and the measured pressure by catheter is acceptable. This implies that a difference of mean + or - 10 mmHg is the threshold for acceptance. When this range is ap-
Figure 5.5: Pressure in the syringe measured in, respectively, blood (A), starch solution viscosity 3.1 (B), starch solution viscosity 3.1 with tealeaves (C), gelatin (D), blood with thrombus (E), starch solution viscosity 5.5 (F) and water (G). Median, 10th, 25th, 75th, 90th, percentiles are shown.

plied, a lot of measurements are out of this range, which implies that a substantial difference between the pressure measured by a needle and the pressure measured by a catheter exists.

The mean standard deviation of the pressure measurements by means of the pressure needle was 20.9 mmHg. The mean standard deviation of the pressure measurements by means of the pressure catheter was 9.1 mmHg.

5.3.4 Dynamic experiments with unobstructed and obstructed needle

Not surprisingly, the pressures measured with the unobstructed needle were significantly different from the pressures as measured with the obstructed needle ($p < 0.05$) (Figure 5.7).

5.4 Discussion

Successful EVAR is associated with a significant reduction of the intra-aneurysm pressure and pulsatility [7]. Pressure measurements are relevant for an early detec-
Figure 5.6: Agreement between the pressures measured by the pressure needle (N) and the pressures measured by the pressure catheter (C) is illustrated by plotting the average of the needle pressure and catheter pressure against the difference between both pressures. When the difference is negative, the catheter pressure exceeds the needle pressure. The mean and mean +/- twice the standard deviation of the difference between both pressures are depicted.

This study clearly demonstrates that the commercially available pressure needles are only accurate for use in liquid blood. The pressure catheter with a sensor at the tip proved to be superior to the needle in other substances than blood.

The major problem with the needle pressure measurement device is the possible obstruction of the needle by particles suspended in the liquid. If there are large particles in a liquid, as for example a thrombus in blood, the opening or canal of the needle can be obstructed which can result in impeding the liquid flow required to generate the changes in the pressure transducer. Cleaning the opening by flushing with NaCl 0.9% is not effective, because other particles will soon obstruct the opening of the needle again. Flushing the needle in situ may result in an inaccurate
and falsely increased pressure level. The problem is that in spite of blocking the entrance of the needle the electrical system will always translate even a false signal in an electrical signal.

We determined that the pressure catheter is much more accurate to measure pressures in different kind of liquids. The pressure catheter, tested in this study, in contrast to a pressure needle does not make use of a free liquid flow through a connecting tube between the matter in which the pressure is measured and the membrane of the pressure sensor. A silicon chip at the tip of the catheter translates a mechanical signal into an electrical one. The sensor is in free direct contact with the liquid in which the pressure needs to be measured.

Although, the aneurysm cavity is most likely never a static environment, pressure measurements were performed in a static model during the first experiments. In our opinion a static model is more suitable to investigate a possible difference in accuracy between the pressure needle and the pressure catheter in a controlled way.

A possible shortcoming of our experiment set-up of the static experiments is that we moved the piston in the syringe by hand. Theoretically, a difference in

Figure 5.7: Pressure measurements by a clean pressure needle and by an obstructed pressure needle in a human thrombus. The experiment has been performed during three different systemic mean pressure (108 mmHg, 121 mmHg, 133 mmHg). Median, 10th, 25th, 75th and 90th percentiles are shown.
piston movement could cause a difference in measured pressure. We used a syringe with an accurate calibration of milliliters, so a very precise movement was possible by hand. The velocity of the piston did not influence the measurement, because measurements were performed in a static condition. Pressure measurements were performed after the movement of the piston when the pressure in the syringe was stabilized.

It will be clear from our observations that pressure measurements in thrombosed aneurysms by a non-fluid filled pressure device (catheter with tip-sensor) is more accurate than by a fluid filled pressure device (needle). An unobstructed pressure needle will occasionally measure pressure accurately, but the operator can never be sure that the entrance of the needle after insertion will be unobstructed. When the needle is obstructed the measured pressure values will be incorrect and will be usually too low.

We did not include new wireless pressure sensors in our evaluation. We assume that these sensors are appropriate to measure accurately pressure in thrombosed aneurysms, because the wireless sensors are as well as the pressure catheter non-fluid filled devices [12]. Further research will be necessary to develop a proper method for aneurysm sac pressure monitoring as follow-up after EVAR.
References


