Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

Maciej Antkiewicz

Zmiany ciśnienia panującego w worku tętniaka aorty przed i po leczeniu wewnątrznaczyniowym jako kryterium oceny skuteczności leczenia oraz czynnik predykcyjny powikłań

ROZPRAWA DOKTORSKA

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Rozprawa doktorska

Katedra i Klinika Chirurgii Naczyniowej, Ogólnej i Transplantacyjnej

Promotor: Prof. dr hab. Dariusz Janczak

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Wstęp

Tętniaki aorty brzusznej (z ang. abdominal aortic aneurysm, AAA) to jedno z najpoważniejszych schorzeń, z którymi zmaga się współczesna chirurgia naczyniowa. Jest to odcinkowe poszerzenie aorty. O tętniaku mówimy, gdy średnica naczynia jest o 50% większa niż jego wartość prawidłowa. Najgroźniejszym powikłaniem tej choroby jest pęknięcie tętniaka. Wraz z wielkością tętniaka wykładniczo rośnie ryzyko jego pęknięcia. Dlatego wskazania do operacji AAA istnieją już przy średnicy 55mm, nawet jeśli tętniaki nie dają żadnych objawów. Pęknięcie tętniaka stanowi bezpośrednie zagrożenie życia i wymaga natychmiastowego leczenia. Ryzyko zgonu w takim przypadku sięga nawet 60%[1]. Szczególnie trudnym i wymagającym rodzajem tętniaków są tętniaki piersiowo-brzuszne (z ang. thoracoabdominal aortic aneurysm, TAAA). Wynika to z ich rozległości oraz obejmowania tętnic nerkowych i trzewnych. Technika operacyjna TAAA polega na jednoczesnym wyłączeniu worka tętniaka z krążenia przy zachowaniu napływu do jego odgałęzień.

Obecnie na świecie funkcjonują dwie metody zaopatrywania tętniaków aorty: klasyczna oraz wewnątrznaczyniowa (z ang. endovascular aneurysm repair, EVAR). To właśnie ta druga metoda staje się coraz popularniejszym sposobem leczenia AAA i stopniowo wypiera operacje klasyczne (otwarte). EVAR polega na implantacji stentgraftu – protezy wewnątrznaczyniowej z dostępu przez tętnice udowe wspólne. Stentgraft rozkładany wewnątrz AAA tworzy nowy kanał przepływu krwi, zamykając jej napływ do worka tętniaka i tym samym zabezpieczając go przed wysokim i pulsującym ciśnieniem. Plusem tej metody jest znacznie mniejszy niż w metodzie otwartej uraz operacyjny, szybszy powrót do pełnej sprawności, mniejsze ryzyko zakażeń okołooperacyjnych. W przypadku TAAA stentgraft posiada odgałęzienia dla tętnic trzewnych i nerkowych (z ang. branched endovascular aneurysm repair, BEVAR), a zabieg jest dużo bardziej wymagający[2]. Ryzyko zgonu okołooperacyjnego sięga 10%, ryzyko niedokrwienia rdzenia od 2,7-20%, a ryzyko niedrożności tętnic trzewnych i nerkowych 5%[3]. Wobec wysokiego ryzyka i trudności BEVAR pojawiły się metody, mające stanowić alternatywną metodę wewnątrznaczyniowego zaopatrywania TAAA. Jedną z takich technik jest implantacja wielowarstwowego modulatora przepływu (z ang. Multilayer Flow Modulator, MFM). MFM to rodzaj stentu wykonanego z wielu warstw stalowego drutu. Jego zadaniem jest zmiana przepływu wewnątrz aorty z turbulentnego na laminarny, a tym samym redukcja sił ścinających i naporu krwi na ścianę tętniaka. Ponieważ w przeciwieństwie do stentgraftów, MFM nie jest pokryty materiałem, zachowuje przepuszczalność, dzięki której krew napływa do odgałęzień trzewnych i nerkowych. Przepuszczalność MFM wynosi 65%, a poziom redukcji prędkości przepływu krwi w worku

tętniaka 90%[4]. Nadal jednak jest to metoda eksperymentalna, wymagająca dalszych badań nad jej skutecznością i bezpieczeństwem[5].

Zdecydowanym minusem EVAR i BEVAR jest występowanie charakterystycznych dla tych zabiegów powikłań, nazywanych przeciekami wewnątrznaczyniowymi. Jest to przepływ krwi pomiędzy stentgraftem, a workiem tętniaka. Takie powikłanie może grozić dalszym powiększaniem się AAA, a nawet jego pęknięciem [6]. Szacuje się, że przeciek występuje u 17-26% pacjentów po EVAR [7–10]. Badanie EUROSTAR obejmujące 6000 pacjentów poddanych EVAR, wykazało częstość występowania przecieków na poziomie 22%. U tych pacjentów ryzyko pęknięcia tętniaka po 4 latach znacząco wzrosło z <1% do 7,5-13,6% [6].

Zależnie od etiologii, wyróżnia się 5 typów przecieku:

- Typ I z powodu nieszczelności znad końca stentgraftu: proksymalnego Ia), dystalnego (Ib) lub okludera tętnicy biodrowej (Ic);
- Typ II od odgałęzień tętniaka: pojedynczego (IIa) lub kilku naczyń (IIb) – tętnicy krezkowej dolnej, tętnic lędźwiowych;
- Typ III z powodu defektu stentgraftu: między poszczególnymi modułami (IIIa) lub ubytkami w materiale (IIIb);
- Typ IV związany z przeciekiem przez mikroporowatości tworzywa, z którego wykonany jest stentgraft;
- Typ V związany z tzw. endotensją, czyli poszerzaniem się worka tętniaka, przy braku widocznego przecieku[11, 12].

Temat przecieków, mimo wielu przeprowadzonych badań nadal nie został wyczerpany. Szczególnie, jeśli chodzi o V typ przecieku, który praktycznie jest nie do wykazania w trakcie zabiegu. Poznanie patomechanizmu przecieków i opracowanie metod ich wczesnego wykrywania, jest więc jednym z kluczowych problemów, które powinny ukierunkowywać badania naukowe w dziedzinie EVAR. Jednym z pomyślnie rokujących jest pomiar ciśnienia panującego wewnątrz worka tętniaka (z ang. aneurysm sac pressure, ASP) po jego zaopatrzeniu. Dotychczasowe analizy wykazały, że wysokie ASP jest związane z powiększaniem się tętniaków zaopatrywanych metodą wewnątrznaczyniową[13, 14]. Skillern i wsp. udowodnili na modelu eksperymentalnym, że podwyższone ASP po EVAR, wiąże się z wysokim ryzykiem konieczności reinterwencji w przyszłości. ASP może zostać skutecznie zmierzone za pomocą cienkich cewników wprowadzanych małoinwazyjną metodą przezskórną [8, 15–17]. Jedno z pierwszych takich badań przeprowadzone u 8 pacjentach poddanych EVAR zostało opublikowane w 1997 roku przez Chutter i wsp. Wykazało istotny spadek ASP po zaopatrzeniu AAA[18]. Przydatnym wskaźnikiem

opisującym spadek ASP jest MPI (z ang. mean pressure index) opisywany jako ułamek średniego ASP do średniego ciśnienia panującego w aorcie (z ang. aortic pressure, AP). Dotychczasowe pomiary wykonywane w okresie roku po EVAR wykazały związek między podwyższonym MPI, a progresją AAA oraz występowaniem przecieków. MPI wynosiło odpowiednio: 19% dla tętniaków malejących po zaopatrzeniu, 59% dla tętniaków rosnących, 78% z obecnością przecieku typu II, 93% z obecnością przecieku typu Ia [13, 14]. Shawn i wsp. za pomocą eksperymentalnego modelu endotensji, doszli do wniosku, że wysokie wartości ASP po EVAR, mogą wiązać się z koniecznością reinterwencji w przyszłości [19].

Cele

Dotychczas wykazano, że ASP jest wskaźnikiem istotnym i przekłada się na ryzyko wystąpienia przecieku, jak i powiększania się AAA. Kluczowe pozostaje pytanie, czy już na etapie wykonania procedury endowaskularnej, wartość ASP i jej spadek może posłużyć do oceny skuteczności przeprowadzonej procedury. Co więcej, czy już na wczesnym etapie można za jego pomocą przewidzieć, które przypadki będą obciążone wysokim ryzykiem powikłań, a w szczególności przecieków.

Celem cyklu prac był pomiar wartości ASP za pomocą mikroprowadnika w takcie procedur EVAR, BEVAR i implantacji stentu MFM. Następnie zestawienie zebranych danych z cechami klinicznych i anatomią zaopatrywanych tętniaków oraz ocena ich dalszego wzrostu / regresji.

Materiał i Metody

Projekt

Jest to badanie eksperymentalne, prospektywne, opierające się na analizie wyników śródoperacyjnych badań inwazyjnych. Pomiary wykonywano podczas wewnątrznaczyniowego leczenia AAA oraz TAAA w Ponadregionalnym Centrum Chirurgii Endowaskularnej, należącym do Katedry i Kliniki Chirurgii Naczyniowej, Ogólnej i Transplantacyjnej, Uniwersyteckiego Szpitala Klinicznego im. Jana Mikulicza-Radeckiego we Wrocławiu. Pomiary anatomiczne tętniaków przeprowadzono na podstawie badań obrazowych (angiografia tomografii komputerowej), wykonanych przed zabiegiem i po 3 miesiącach. Uzyskano aprobatę Komisji Bioetycznej Uniwersytetu Medycznego we Wrocławiu (KB-51/2019). Wszyscy badani podpisali świadomą zgodę na udział w eksperymencie medycznym.

Pacjenci

52 pacjentów (42 mężczyzn, 10 kobiet, w wieku od 58 do 86 lat):

- 30 z podnerkowym AAA (zakwalifikowanych do EVAR);
- 22 z TAAA (14 pacjentów przeszło BEVAR, u 8 wszczepiono MFM).

Implantacja stentgraftu (EVAR)

Zabieg wykonywany jest na sali hybrydowej. Zaczyna się go od wykonania dostępu do naczyń udowych wspólnych. Pod kontrolą fluoroskopii i arteriografii wprowadza się i pozycjonuje główny – rozwidlony moduł stentgraftu, tak by umieścić go tuż poniżej odejścia tętnic nerkowych. Następnie dokłada się ipsi- i kontralateralną odnogę biodrową. Ostatnim etapem zabiegu jest doprężenie wszystkich elementów balonami niskociśnieniowymi i wykonanie kontrolnej arteriografii.

Implantacja stentgraftu z odgałęzieniami (BEVAR)

Po wykonaniu dostępu do naczyń udowych wspólnych, zwykle konieczny jest też dostęp do tętnicy pachowej. Jako pierwszy pozycjonuje się główny moduł stentgraftu, tak by jego odgałęzienia były na odpowiedniej wysokości i rotacji względem pnia trzewnego, tętnicy krezkowej górnej i tętnic nerkowych. Następnie wprowadza się element rozwidlony przedłużając stentgraft do podziału tętnic biodrowych i moduł biodrowy, po stronie ipsilateralnej. Kontralateralną odnogę stentgraftu zwykle implantuje się w późniejszym etapie (po 2-4 tygodniach), co zapewnia czasowy napływ do tętnic lędźwiowych, zmniejszając ryzyko niedokrwienia rdzenia kręgowego [20].

Kolejnym etapem zabiegu jest implantacja stentgraftów, łączących odgałęzienia głównego modułu z tętnicami trzewnymi i nerkowymi. Zabieg kończy się doprężeniem wszystkich elementów i kontrolną arteriografią.

Implantacja wielowarstwowego modulatora przepływu (MFM)

Do implantacji stentu MFM wystarczy jednostronny dostęp do tętnicy udowej wspólnej. Za pomocą arteriografii aorty identyfikuje się strefy lądowania, w obrębie których zostanie implantowany stent. Następnie umieszcza się system wprowadzający zawierający stent tak, by proksymalny i dystalny koniec MFM znalazły się w zdrowych odcinkach aorty powyżej i poniżej tętniaka. Uwalnianie stentu MFM wykonuje się powoli pod kontrolą fluoroskopii, poprzez ściąganie zewnętrznej osłony. Po implantacji wykonuje się kontrolną arteriografię.

Technika pomiaru

Pomiary ASP wykonywano podczas następujących procedur: EVAR, 2. etap BEVAR, implantacja MFM. Po znieczuleniu miejscowym lidokainą, zakładano port naczyniowy do lewej tętnicy promieniowej. Poprzez port wprowadzano 0.014-calowy prowadnik do pomiaru ciśnienia (Comet - Boston Scientific) wraz z cewnikiem. Pod kontrolą fluoroskopii, prowadnik umieszczano tak, by końcówka pomiarowa mieściła się wewnątrz tętniaka, zaś cewnik umieszczano jego końcem w aorcie powyżej tętniaka

Na poszczególnych etapach zabiegu wykonywano jednoczasowy pomiar ASP (aneurysm sac pressure) wewnątrz tętniaka i AP (aortic pressure) powyżej tętniaka z nagraniem wyników w formie elektronicznej. Zanotowano ciśnienia skurczowe, rozkurczowe, średnie oraz ciśnienie tętna zarówno dla ASP jak i AP. Obliczono ułamek ASP/AP dla każdego z tych ciśnień, tj. SPI (systolic pressure index), DPI (diastolic pressure index), MPI (mean pressure index) oraz PPI (pulse pressure index). Po zakończeniu zabiegu prowadnik pomiarowy wraz z cewnikiem, usuwano pod kontrolą fluoroskopii. Po operacji port z tętnicy promieniowej był usuwany, a w miejscu wkłucia zakładano opatrunek uciskowy.

Analiza statystyczna

Do analizy statystycznej wykorzystano program Statistica 13.3 (StatSoft Polska). Wykonano testy normalności Shapiro-Wilka, następnie t-Studenta porównując otrzymane współczynniki. Do analizy nieparametrycznej wykorzystano test Wilcoxona. Posłużono się również analizą wariancji ANOVA oraz testami korelacji. Poziom istotności ustalono na poziomie <0.05.

Wyniki

U wszystkich 52 pacjentów udało się przeprowadzić pomiary. Obecność cewnika pomiarowego wewnątrz tętniaka nie wpływała na sprawność przeprowadzenia procedury.
W kolejnych publikacjach z cyklu uzyskano następujące wyniki (tabele i wykresy znajdują się we właściwych publikacjach na końcu rozprawy):

1. Grupa 23 pacjentów z tętniakami aorty brzusznej poddana zabiegowi EVAR

Przed implantacją stentgraftu, ciśnienia ASP oraz AP były równe. Skórczowe, rozkurczowe i średnie ciśnienie w aorcie (AP) nie zmieniało się w trakcie zabiegu. Ciśnienie skurczowe w worku tętniaka (ASP) istotnie zmalało ($p < 0{,}001$): z 107,4 ±22,3 mmHg, przez 80,4 ±20,9 mmHg po implantacji wszystkich modułów, do 65,6 ±26,1 mmHg po doprężeniu modułów balonem. Podobnie istotnie ($p < 0{,}001$) zmalało średnie ASP: z 73,6 ±15,8 mmHg, przez 61,0 ±15,2 mmHg po implantacji, do 53,8 ±17,8 mmHg po doprężeniu. Rozkurczowe ASP również malało na kolejnych etapach zabiegu: z 56,8 ±14,0 mmHg, przez 51,3 ±13,5mmHg po implantacji ($p = 0.06$), do 48,0 ±14,6 mmHg po doprężeniu ($p < 0{,}05$).

Przeciek wewnątrznaczyniowy w kontrolnej arteriografii wykazano u 5 pacjentów: 1 przeciek typu I, 4 typu II. W grupie bez przecieków średnie ASP wynosiło 48,8 ±1,4 mmHg, podczas gdy w grupie z przeciekami 54,1 ±19,7 mmHg ($p = 0{,}06$). Średnie ASP w przecieku typu I wynosiło 70,0 mmHg.

2. Grupa 30 pacjentów poddana zabiegowi EVAR z uwzględnieniem analizy anatomii tętniaków przed zabiegiem i po 3 miesiącach.

Pacjenci otrzymali różne modele stentgraftów: Cook (9 pacjentów), Jotec (3), Gore (7), Medtronic (3), Terumo (8). Wykazano istotną statystycznie korelację dla spadku ciśnienia tętna (PPI) na korzyść dla modeli Gore i Terumo.

W przebiegu EVAR zarejestrowano następujący spadek współczynników ciśnienia: SPI z 98% do 61%, DPI z 100% do 87%, MPI z 99% do 74%, PPI z 97% do 34%. Po ich zestawieniu z danymi anatomicznymi, nie wykazano istotnej zależności względem średnicy tętniaka, jego objętości, kształtu, ilości drożnych tętnic lędźwiowych, długości i średnicy szyi tętniaka, średnicy tętnicy krezkowej dolnej, czy kątowi odejścia i szerokości tętnic biodrowych wspólnych. Jedyną istotną korelację wykazano między zagięciem szyi tętniaka, a wartością PPI (korelacja odwrotna, ($p < 0{,}05$). Przeciek w kontrolnej arteriografii wykazano u 7 pacjentów: 1 przeciek typu I, 6 przecieków typu II).

U 20 pacjentów przeprowadzono kontrolne badanie angiografii tomografii komputerowej. Przeciek typu II wykazano u 8 pacjentów. Wykazano dodatnią korelację między wartością PPI, a dalszym wzrostem tętniaka ($p < 0,05$).

3. Grupa 14 pacjentów z tętniakami aorty piersiowo-brzusznej poddanych BEVAR oraz 8, którym wszczepiono stent MFM

Współczynniki SPI, DPI, PPI u pacjentów poddanych BEVAR osiągnęły końcowe wartości: 60 ±13%, 95 ±16%, 33 ±17%. W grupie MFM te same współczynniki wynosiły kolejno: 100 ±3%, 98 ±12%, 104 ±4%. SPI oraz PPI były statystycznie wyższe w grupie MFM, co więcej nie zmieniały się istotnie w trakcie zabiegu ($p < 0,001$).

Wczesna ocena badań obrazowych po 30 dniach wykazała redukcję wielkości TAAA u pacjentów poddanych BEVAR: z 60,5 ±9,9mm, do 56,2 ±11,7mm. W grupie MFM wielość tętniaków pozostała podobna: 69,9 ±17,1mm przed zabiegiem, 70,9 ±17,4mm po 30 dniach).

Całkowite wykrzepienie worka tętniaka (zjawisko pożądane świadczące o skuteczności zabiegu), wystąpiło u 9 pacjentów grupy BEVAR. Pozostałych 5 miało przeciek. Tylko u 1 pacjenta po implantacji MFM tętniak całkowicie wykrzepił. Ilość wczesnych powikłań również była istotnie większa w grupie MFM.

Wnioski

1. Metoda pomiaru ASP za pomocą cienkiego prowadnika ciśnieniowego jest bezpieczna i łatwa do przeprowadzenia podczas wewnątrznaczyniowego leczenia tętniaków aorty.
2. W efekcie wykonania EVAR lub BEVAR dochodzi do istotnego spadku ASP.
3. Pomiar ASP może służyć do obiektywnej oceny skuteczności leczenia AAA oraz TAAA.
4. Zagięcie szyi tętniaka aorty brzusznej poprawia hemodynamiczny efekt zabiegu, redukując ciśnienie tętna (PPI) panujące wewnątrz tętniaka.
5. Podwyższone ciśnienie tętna (PPI) jest związane z dalszym wzrostem AAA mimo wykonania EVAR. Tym samym pomiar ASP może posłużyć jako metoda wczesnego wykrywania pacjentów podwyższonego ryzyka.
6. Metoda implantacji stentu MFM nie redukuje ASP w przeciwieństwie do zabiegu BEVAR, który istotnie obniża wartości SPI oraz PPI.

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Streszczenie

Wstęp

Nowoczesne techniki wewnątrznaczyniowe są obiecującymi metodami leczenia tętniaków aorty: implantacja stentgraftu rozwidlonego (z ang. endovascular aneurysm repair, EVAR) w przypadku tętniaka aorty brzusznej (z ang. abdominal aortic aneurysm, AAA) i implantacja stentgraftu z odgałęzieniami do tętnic trzewnych i nerkowych (z ang. branched endovascular aneurysm repair, BEVAR) lub implantacja wielowarstwowego modulatora przepływu (z ang. multilayer flow modulator, MFM) w przypadku tętniaka aorty piersiowo-brzusznej (z ang. thoracoabdominal aortic aneurysm, TAAA). Udokumentowano liczne przypadki powiększenia, a nawet pęknięcia tętniaka pomimo leczenia wewnątrznaczyniowego. Wiąże się to ze zwiększonym ciśnieniem wewnątrz worka tętniaka (z ang. aneurysm sac pressure, ASP).

Cel pracy

Celem pracy był pomiar i analiza ASP podczas EVAR, BEVAR, MFM. Następnie analiza korelacji między ASP, anatomią tętniaka i dalszym jego powiększaniem.

Materiał i metody

Badania objęły 52 pacjentów: 30 z podnerkowym AAA (zakwalifikowanych do EVAR), 22 z TAAA (14 pacjentów przeszło BEVAR, a u 8 wszczepiono MFM). Inwazyjne pomiary ASP wykonano za pomocą cienkiego prowadnika z sensorem ciśnienia, umieszczonego wewnątrz tętniaka. Ciśnienie w aorcie (AP) mierzono za pomocą cewnika umieszczonego na prowadniku. Wskaźnik ciśnienia skurczowego (z ang. systolic pressure index, SPI), wskaźnik ciśnienia rozkurczowego (z ang. diastolic pressure index, DPI), wskaźnik średniego ciśnienia (z ang. mean pressure index, MPI) oraz wskaźnik ciśnienia tętna (z ang. pulse pressure index, PPI) obliczono jako iloczyn ASP i AP. Wyniki kontrolnej angiografii tomografii komputerowej po 3 miesiącach porównano z wyjściowymi.

Wyniki

Pomiary zostały pomyślnie przeprowadzone u wszystkich uczestników bez komplikacji. Nie było istotnych różnic między wszystkimi ASP i AP przed zabiegiem. Po zabiegu ciśnienie istotnie obniżyło się w worku tętniaka, ale nie w aorcie. Podczas EVAR zaobserwowano znaczny spadek SPI (z 98% do 61%), DPI (z 100% do 87%), MPI (z 99% do 74%) i PPI (z 97% do 34%).

Nie stwierdzono istotnych korelacji wskaźników ciśnienia ze średnicą tętniaka, polem przekroju, objętością, kształtem i wielkością skrzepliny, liczbą drożnych tętnic lędźwiowych, długością i średnicą szyi tętniaka, średnicą tętnicy krezkowej dolnej oraz średnicą i kątem odejścia tętnic biodrowych wspólnych. Wykazano natomiast odwrotną korelację między kątem zagięcia szyi tętniaka, a PPI. Po połączeniu wyników tomografii z pomiarami ciśnienia zaobserwowano dodatnią korelację między PPI, a powiększeniem tętniaka. Porównując BEVAR i MFM, wartości SPI i PPI były istotnie niższe w grupie BEVAR. W trakcie zabiegu u pacjentów poddawanych BEVAR odnotowano spadek SPI i PPI, natomiast w grupie MFM nie stwierdzano istotnych zmian.

Wnioski

1. Pomiar ASP podczas EVAR, BEVAR i MFM za pomocą prowadnika z sensorem ciśnienia jest wykonalny i bezpieczny.
2. ASP stanowi potencjalny parametr pozwalający na ocenę skuteczności leczenia. W szczególności PPI może służyć jako czynnik prognostyczny powiększenia tętniaka po EVAR i pomóc w identyfikacji pacjentów wysokiego ryzyka, wymagających szczególnej obserwacji.
3. BEVAR w przeciwieństwie do MFM, wiąże się z redukcją SPI i PPI.

Abstract

Background

Modern endovascular techniques are promising methods of aortic aneurysm treatment: endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) and branched endovascular aneurysm repair (BEVAR) or implantation of the multilayer flow modulator (MFM) for thoracoabdominal aortic aneurysm (TAAA). Numerous cases of aneurysm enlargement, and even rupture, despite endovascular repair have been documented. This has been linked to increased aneurysm sac pressure (ASP).

Objectives

The aim of the studies was to measure and analyse ASP during EVAR, BEVAR, MFM such as to identify correlations between ASP, aneurysm anatomy and subsequent aneurysm enlargement.

Materials and methods

Studies included 52 patients: 30 with infrarenal AAA (undergoing EVAR), 22 with TAAA (14 patients underwent BEVAR, while 8 MFM implantation). Invasive ASP measurements were done using a thin pressure sensor wire, placed inside the aneurysm. Aortic pressure (AP) was measured using a catheter placed over the wire. Systolic pressure index (SPI), diastolic pressure index (DPI), mean pressure index (MPI) and pulse pressure index (PPI) were calculated as ASP and AP ratio. The results of follow-up computed tomography angiography at 3 months were compared with baseline findings.

Results

The measurements were successfully obtained in all participants without any complications. There were no significant differences between all ASP and AP before procedure. After the procedure, blood pressure significantly decreased in the aneurysm sac but not in the aorta. During EVAR, a significant reduction was observed for SPI (from 98% to 61%), DPI (from 100% to 87%), MPI (from 99% to 74%), and PPI (from 97% to 34%). There were no significant correlations of pressure indices with an aneurysm diameter, cross-sectional area, volume, thrombus shape and size, number of patent lumbar arteries, length and diameter of aneurysm neck, diameter of the inferior mesenteric artery, as well as diameter and angle of common iliac arteries. On the other hand, aneurysm neck angulation was significantly inversely correlated with reduced PPI.

After combining computed tomography findings with pressure measurements, we identified a positive correlation between PPI and aneurysm enlargement. While comparing BEVAR and MFM, SPI and PPI were lower in the BEVAR group. During a procedure, a drop in SPI and PPI was noted in patients undergoing BEVAR, while no changes were revealed in the MFM group.

Conclusions

1. Measurement of ASP during EVAR, BEVAR or MFM, using a thin pressure wire, is feasible and safe.
2. ASP can facilitate the assessment of treatment efficacy. In particular, PPI can serve as a prognostic factor of aneurysm enlargement after EVAR and can help identify high-risk patients who remain prior monitoring.
3. BEVAR, but not MFM, is associated with a reduction in SPI and PPI.

Intra-aneurysm sac pressure measurement using a thin pressure wire during endovascular aneurysm repair

Maciej Antkiewicz[1,A,C–F], Wiktor Kuliczkowski[2,A,C,E,F], Marcin Protasiewicz[2,A,C,E,F], Magdalena Kobielarz[3,C–F], Piotr Barć[1,B,E,F], Maciej Malinowski[1,B,E,F], Katarzyna Frączkowska[1,C,D,F], Katarzyna Kulikowska[1,B,E,F], Marcin Merenda[1,B,E,F], Krzysztof Jacyna[1,B,E,F], Tomasz Dawiskiba[1,A,E,F], Dariusz Janczak[1,A,C,E,F]

[1] Department and Clinic of Vascular, General and Transplantation Surgery, Wroclaw Medical University, Poland
[2] Department and Clinic of Cardiology, Wroclaw Medical University, Poland
[3] Department of Mechanics, Materials Science and Biomedical Engineering, Wrocław University of Science and Technology, Poland

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

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Address for correspondence
Marcin Protasiewicz
E-mail: mprot@poczta.onet.pl

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Abstract

Background. An endoleak is a typical complication of endovascular aneurysm repair (EVAR). It is characterized by persistent blood flow between a stent graft and the aneurysm sac. Usually, it can be visualized during primary EVAR, but in many cases, this remains impossible. Therefore, other methods of endoleak assessment are urgently needed. The measurement of aneurysm sac pressure (ASP) seems to be a promising direction of research in this area.

Objectives. We aimed to evaluate the safety and efficacy of a new method for invasive pressure measurement inside the abdominal aortic aneurysm (AAA) during EVAR. We also assessed a correlation between pressure values and early angiographic occurrence of an endoleak after the procedure.

Materials and methods. A total of 20 patients with AAA were included in this experimental prospective study. During EVAR, systolic, diastolic and mean pressure values were recorded both for ASP and aortic pressure (AP) before procedure, after stent graft opening and after final stent graft ballooning.

Results. The measurements were successfully obtained in all participants without any complications. There were no significant differences between all ASP and AP before procedure. After the procedure, blood pressure significantly decreased in the aneurysm sac but not in the aorta. Systolic ASP was significantly lower than systolic AP both after stent graft opening (80.4 ±20.9 mm Hg compared to 110.7 ±21.6 mm Hg, $p < 0.01$) and after its balloon post-dilatation (65.6 ±26.1 mm Hg compared to 107.4 ±22.1 mm Hg, $p < 0.001$). Diastolic ASP decreased significantly in comparison to diastolic AP only after stent graft ballooning (48.0 ±14.6 mm Hg compared to 56.4 ±13.6 mm Hg, $p < 0.05$).

Conclusions. Our study confirmed that the novel method for the measurement of ASP during EVAR, using a thin pressure wire, is feasible and safe.

Key words: endoleak, endovascular aneurysm repair, abdominal aortic aneurysm, aneurysm sac pressure

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Background

One of the most serious conditions in current vascular surgery is abdominal aortic aneurysm (AAA), which is defined as an enlargement of the aortic diameter by at least 50%. The major complication of AAA is rupture, which is a life-threatening condition that requires emergency treatment. The risk of aneurysm rupture grows exponentially with an increase in aneurysm diameter. Therefore, aneurysms of 55 mm in diameter are an indication for surgical treatment, even if they are asymptomatic.

Currently, there are 2 methods of surgical treatment for AAA: a classic open surgery and endovascular aneurysm repair (EVAR). The latter is becoming increasingly popular and is gradually replacing classic open surgeries. Endovascular repair involves implantation of a stent graft, that is, endovascular prosthesis, using common femoral artery access. The stent graft, which is deployed in the aneurysm lumen, creates a new channel for blood flow and closes its way to the aneurysm sac, thereby protecting it from high pulsatile blood pressure. The advantages of this method include less extensive trauma, faster recovery and a lower risk of infection than with open aortic repair.

Despite its obvious benefits, EVAR is not without limitations. A typical complication of the procedure is the so-called endoleak, which involves the presence of blood flow between a stent graft and the aneurysm sac. It is estimated that endoleaks occur in 17–26% of patients after EVAR,[1–4] especially those who show aneurysm growth and rupture.[5]

Although endoleaks can typically be visualized during primary EVAR, in many cases, this remains impossible. Therefore, there is an urgent need to develop novel methods of endoleak assessment. The measurement of aneurysm sac pressure (ASP) seems to be a promising direction of research. We postulate that continuation of ASP and its systolic–diastolic amplitude after EVAR may suggest the presence of endoleak while the decrease of these parameters indicates a correct result of the procedure.

Objectives

In this study, we aimed to evaluate the efficacy and safety of a new method for the measurement of intra-aneurysm pressure during EVAR. We also assessed the correlation between ASP and early occurrence of an endoleak early after the procedure.

Materials and methods

Study design and population

This was a prospective study based on the analysis of invasive pressure measurements obtained during endovascular treatment of infrarenal AAAs. A total of 23 patients (18 men and 5 women) at a mean age of 71.8 ±6.6 years (range: 58–85 years) were enrolled. The inclusion criteria were as follows: 1) a referral for primary surgical treatment of an AAA using EVAR; 2) the presence of an asymptomatic AAA; and 3) the length of the aneurysm neck of at least 20 mm. The demographic and clinical data of patients is presented in Table 1.

Endovascular aneurysm repair

We performed a standard stent graft implantation in a hybrid operating room with a fixed C-arm system.[6] The procedure was carried out under local anesthesia of the inguinal region. Bilateral femoral artery access was used. The main body of the bifurcated stent graft was deployed, positioned and opened under angiographic guidance, just below the origin of the renal arteries. Then, the ipsilateral and contralateral arms of the stent graft were deployed. The EVAR outcome, including early endoleak, was monitored using angiography. Femoral punctures were sealed using an endovascular closure device. After the procedure, all patients received dual antiplatelet therapy (aspirin plus clopidogrel, both 75 mg daily) for 3 months, followed by lifelong 75 mg aspirin according to protocol.[7]

Pressure measurement

The pressure measurements were taken with a 0.014-inch wire (COMET II Pressure Guidewire; Boston Scientific, Marlborough, USA). A 6F Judkins right guiding catheter (Boston Scientifi) was inserted using percutaneous radial access and advanced proximally to the aneurysm. The guidewire was advanced through the catheter into the aneurysm sac before stent graft implantation to monitor the ASP (position of pressure guidewire is visible in Fig. 1). Aortic pressure (AP) was measured through the catheter. Pressure measurements were taken at each stage of the procedure – that is, before and after stent graft deployment – as well as after ballooning of the stent graft. Systolic, diastolic and mean pressure values were recorded both for ASP and AP. Once the stent graft implantation was completed, the guidewire and the catheter were removed.

Ethics

All patients gave their written informed consent to undergo treatment, and the study protocol was approved by the local ethics committee. The study was conducted in line with the principles of the Declaration of Helsinki.

Statistical analysis

The Shapiro–Wilk test for normality was performed, followed by the Student's t-test for comparison between the obtained coefficients (dependent samples).

Table 1. Patients enrolled in the study

Patient No.	Gender	Age [years]	BMI	Comorbidities	Model of implanted stent graft
1	F	71	25.3	HT, COPD	Gore Excluder
2	M	85	27.8	HT, CVD, DM	Gore Excluder
3	M	68	27.7	HT, NE	Terumo Aortic Treo
4	M	73	26.5	HT, KD, NE	Jotec E-tegra
5	M	69	21.8	HT	Terumo Aortic Treo
6	M	83	28.7	HT, CVD, NE	Terumo Aortic Treo
7	M	62	31.1	HT	Terumo Aortic Treo
8	F	72	31.1	HT	Terumo Aortic Treo
9	F	73	25.0	HT	Terumo Aortic Treo
10	M	66	38.1	HT	Terumo Aortic Treo
11	M	80	24.7	HT, CVD, COPD, DM	Jotec E-tegra
12	M	66	31.3	HT	Terumo Aortic Treo
13	M	80	29.4	HT, CVD	Gore Excluder
14	M	75	32.3	HT, CVD, DM	Gore Excluder
15	M	72	26.3	–	Cook Zenith Alpha
16	M	66	28.7	–	Gore Excluder
17	M	68	24.2	–	Gore Excluder
18	F	74	31.3	HT	Cook Zenith Alpha
19	M	58	34.7	HT	Medtronic Endurant
20	M	75	31.7	HT	Medtronic Endurant
21	F	72	23.5	HT, CVD	Cook Zenith Alpha
22	M	66	23.5	HT	Cook Zenith Alpha
23	M	78	30.9	HT, CVD	Cook Zenith Alpha

M – male; F – female; BMI – body mass index; COPD – chronic obstructive pulmonary disease; CVD – cardiovascular disease; DM – diabetes mellitus; HT – hypertension; KD – kidney disease; NE – neurologic events.

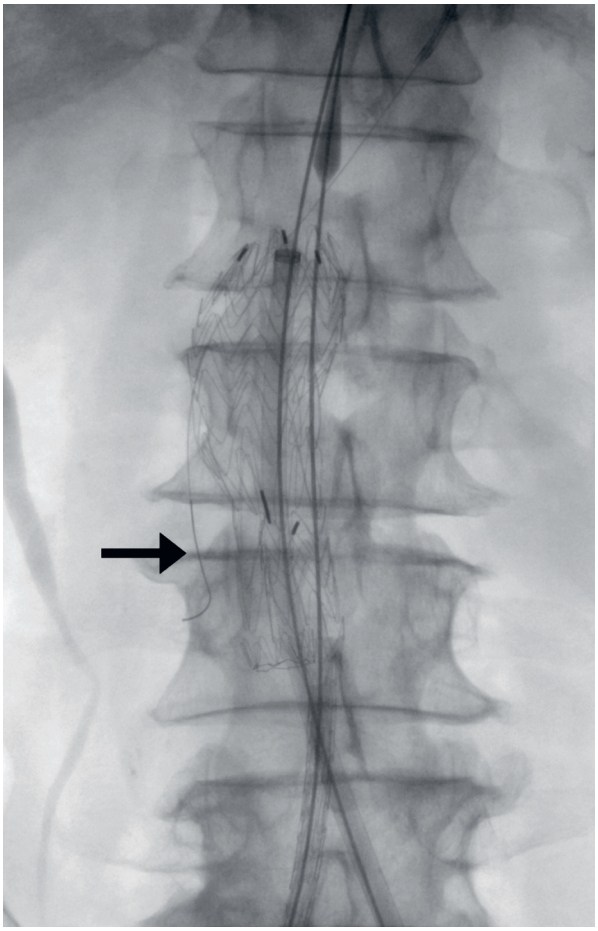

Fig. 1. Position of pressure guidewire during EVAR (black arrow)

The significance level was set at a p-value of less than 0.05. The analysis of correlation was performed using Pearson's correlation coefficient. STATISTICA v. 13.3 software (StatSoft Inc., Tulsa, USA) was used for analysis.

Results

The measurements were successfully obtained during EVAR in all patients without any complications.

Systolic, diastolic and mean pressure values for ASP and AP during the main stages of EVAR are shown in Fig. 2–4. Before stent graft deployment, all ASP and AP were almost equal. The systolic AP was maintained at the same level throughout the procedure (109.5 ±22.8 mm Hg before procedure compared to 110.7 ±21.6 mm Hg after opening compared to 107.4 ±22.1 mm Hg after ballooning, not significant (NS)). Similar observation was noted for diastolic AP (58.7 ±13.2 mm Hg compared to 55.2 ±13.5 mm Hg compared to 56.4 ±13.6 mm Hg, respectively, NS) and mean AP (74.2 ±14.8 mmHg compared to 74.8 ±14.1 mm Hg compared to 73.4 ±13.8 mm Hg, respectively, NS). However, after the main body and limbs

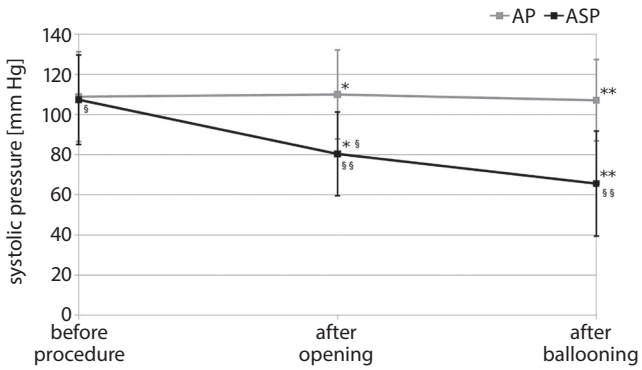

Fig. 2. ASP and AP values for systolic pressure on each stage of stent graft deployment. Data shown as means ± 95% confidence interval (95% CI); Student's t-test paired comparison

*ASP after opening compared to AP after opening, $p < 0.001$; **ASP after ballooning compared to AP after ballooning, $p < 0.001$; §ASP after opening compared to baseline ASP, $p < 0.001$; §§ASP after opening compared to ASP after ballooning, $p < 0.001$.

of the stent graft were opened, systolic ASP was reduced significantly from 107.4 ±22.3 mm Hg to 80.4 ±20.9 mm Hg ($p < 0.001$ compared to baseline systolic ASP and $p < 0.001$ compared to AP after opening) and after ballooning

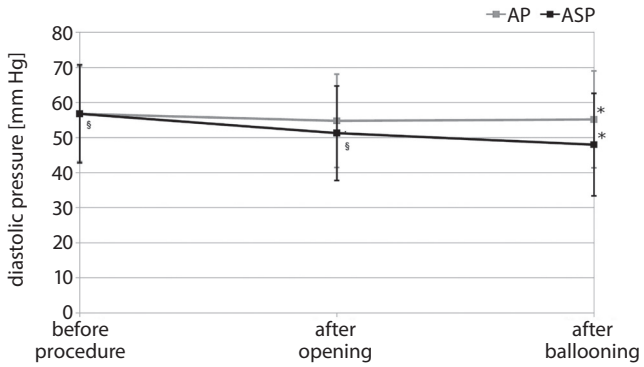

Fig. 3. ASP and AP values for diastolic pressure on each stage of stent graft deployment. Data shown as means ±95% CI; Student's t-test paired comparison

*ASP after ballooning compared to AP after ballooning, $p < 0.05$; §ASP after opening compared to baseline ASP, $p < 0.05$.

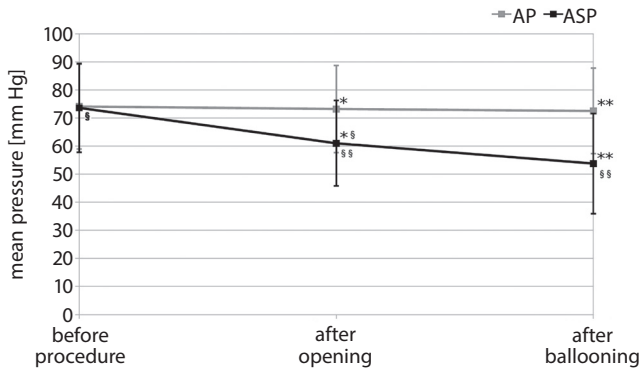

Fig. 4. ASP and AP values for mean pressure on each stage of stent graft deployment

Data shown as means ±95% CI; Student's t-test paired comparison *ASP after opening compared to AP after opening, $p < 0.001$; **ASP after ballooning compared to AP after ballooning, $p < 0.001$; §ASP after opening compared to baseline ASP, $p < 0.001$; §§ASP after opening compared to ASP after ballooning, $p < 0.01$.

to 65.6 ±26.1 mm Hg ($p < 0.001$ compared to ASP after opening and $p < 0.01$ compared to AP after ballooning) (Fig. 2). Diastolic ASP after opening dropped from 56.8 ±14.0 mm Hg to 51.3 ±13.5 mm Hg ($p < 0.05$ compared to baseline diastolic ASP) and after ballooning it decreased to 48.0 ±14.6 mm Hg ($p = 0.06$ compared to diastolic ASP after opening and $p < 0.05$ compared to AP after ballooning) (Fig. 3). Mean ASP after opening dropped from 73.6 ±15.8 mm Hg to 61.0 ±15.2 mm Hg ($p < 0.001$ compared to baseline mean ASP and $p < 0.001$ compared to AP after opening) and subsequently to 53.8 ±17.8 mm Hg ($p < 0.01$ compared to mean ASP after opening and $p < 0.001$ compared to AP after ballooning) (Fig. 4). The correlation results for AP and ASP are presented in Table 2.

Angiography performed after EVAR demonstrated the presence of an endoleak in 5 patients (1 endoleak type I and 4 endoleaks type II; please see the Discussion section for explanations of endoleak types). The ASP values for mean pressure in endoleak type II appeared to be

Table 2. Correlations between aneurysm sac pressure and aortic pressure

ASP and AP	r-value	p-value
Systolic baseline	0.98	<0.001
Systolic after stent graft opening	0.45	<0.05
Systolic after ballooning	0.47	<0.05
Diastolic baseline	0.99	<0.001
Diastolic after stent graft opening	0.74	<0.001
Diastolic after ballooning	0.64	<0.01

AP – aortic pressure; ASP – aneurysm sac pressure.

comparable with ASP mean pressure in group without endoleak (48.8 ±1.4 mm Hg compared to 54.1 ±19.7 mm Hg, respectively, $p = 0.06$). Mean ASP in 1 case of endoleak type I was higher (70.0 mm Hg) than in the other cases.

Discussion

Our study showed that pressure wire usage to measure ASP is feasible and safe. It was free of complications, including those associated with radial artery access. The presence of the pressure wire in the aneurysm lumen had no influence on the efficacy of the EVAR procedure. Moreover, the use of a 0.0014-inch pressure wire instead of a standard catheter allowed us to avoid leakage between the stent graft and the aneurysm neck. We observed a significant decrease in ASP during EVAR. The value of ASP diminished both after stent graft opening and its ballooning.

As the measurement of ASP is invasive and its clinical significance remains unclear, it is still rarely performed in the patients with AAA. When it is performed, it is usually done within 6 months from EVAR. Velazquez et al. performed ASP measurement in 76 patients, 17% of whom were shown to develop an endoleak (mostly associated with patent inferior mesenteric artery). Two-thirds of patients with endoleak had equal ASP and AP values.[2] A similar study was conducted by Baum et al. in 27 patients. Endoleak was present in 17 patients; ASP and AP values were comparable in 15 patients, while in 2 patients, ASP was half as low as AP.[8]

Depending on etiology, there are 5 types of endoleak: type I is caused by a leak at the end of prosthesis; type II is a leak from the branches of the aneurysm; type III is the leak connected with the defect of the stent graft; type IV is a leak through the fabric microporosity of stent graft; and type V is associated with so-called endotension, which means an enlargement of the aneurysmal sac with no visible endoleak.[9,10] Type I and III endoleaks are considered high-pressure endoleaks, with a high risk of aneurysm sac rupture because of direct exposure of the aneurysm wall to aortic pressure. Type II, IV and V endoleaks are considered lower risk and many of them may close spontaneously over time.[11,12]

A number of studies demonstrated a positive relationship between increased ASP and aneurysm growth or endoleak presence.[13,14] Using the experimental model of endotension, Shawn Skillern et al. concluded that high ASP after EVAR might be associated with a need for re-intervention in the future.[15] Chaudhuri et al. studied the impact of an endoleak on the experimental aneurysm model and revealed that only some types of endoleak were related to higher ASP.[16] A pending issue is ASP response to the different types of endoleak. Due to an insufficient sample size, this question could not be adjudicated in this study; however, it is of note that 1 case of endoleak type I presented high ASP values after the procedure, while cases with no endoleak or endoleak type II presented a decrease of ASP.

In contrast to the aforementioned studies, our measurements were performed during EVAR. Such a measurement is much less invasive and may be performed intraoperatively. Previous findings were long-term results that were frequently associated with EVAR-related changes inside the aneurysm sac, such as thrombus formation. This may suggest that the early outcome of EVAR may be less satisfactory than we expected.

We believe that potential clinical application of pressure measurements during the EVAR could be detection of early endoleaks that cannot be visualized by angiography, which may be very important in case of high-pressure endoleaks. These measurements may also facilitate the identification of patients at risk of endoleak and aneurysm growth, who thus require closer monitoring.

Limitations

Our study has several limitations. Most importantly, it was based on a small group of patients followed for a short time. However, we are planning to expand our study population and investigate the significance of correlations between the measured parameters and possible changes in aneurysm anatomy, the rate of re-interventions and the occurrence of endoleaks.

Conclusions

Our study proved that the novel method for the measurement of aneurysm sac pressure using a pressure wire during EVAR is safe and feasible. Our planned research will compare the current results with follow-up computed tomography angiography of our patients, which should provide further important insights, with possible implications for future research and clinical practice.

ORCID iDs

Maciej Antkiewicz https://orcid.org/ 0000-0003-1227-7720
Wiktor Kuliczkowski https://orcid.org/ 0000-0001-6284-0820
Marcin Protasiewicz https://orcid.org/ 0000-0003-0253-0585
Magdalena Kobielarz https://orcid.org/ 0000-0002-0191-6390
Piotr Barć https://orcid.org/ 0000-0003-1080-227X
Maciej Malinowski https://orcid.org/ 0000-0002-8443-0125
Katarzyna Frączkowska https://orcid.org/ 0000-0002-1395-348X
Katarzyna Kulikowska https://orcid.org/ 0000-0003-2427-4471
Marcin Merenda https://orcid.org/ 0000-0003-2282-6228
Krzysztof Jacyna https://orcid.org/ 0000-0001-6665-1402
Tomasz Dawiskiba https://orcid.org/ 0000-0003-2329-2918
Dariusz Janczak https://orcid.org/ 0000-0003-4671-9128

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ORIGINAL RESEARCH

Preliminary Assessment of Intra-Aneurysm Sac Pressure During Endovascular Aneurysm Repair as an Early Prognostic Factor of Aneurysm Enlargement

Maciej Antkiewicz[1], Marcin Protasiewicz[2], Wiktor Kuliczkowski[2], Tomasz Zubilewicz[3], Piotr Terlecki[3], Magdalena Kobielarz[4], Dariusz Janczak[1]

[1]Department and Clinic of Vascular, General and Transplantation Surgery, Wrocław Medical University, Wrocław, Poland; [2]Department and Clinic of Cardiology, Wrocław Medical University, Wrocław, Poland; [3]Department and Clinic of Vascular Surgery and Angiology, Medical University of Lublin, Lublin, Poland; [4]Department of Mechanics, Materials Science and Biomedical Engineering, Wrocław University of Science and Technology, Wrocław, Poland

Correspondence: Maciej Antkiewicz, Department and Clinic of Vascular, General and Transplantation Surgery, Wrocław Medical University, Borowska 213, Wrocław, 50-556, Poland, Tel +48 71 733 2003, Fax +48 71 733 2009, Email maciej.antkiewicz@gmail.com

Purpose: Numerous cases of abdominal aortic aneurysm (AAA) enlargement, and even rupture, despite endovascular aneurysm repair (EVAR), have been documented. This has been linked to increased aneurysm sac pressure (ASP). We decided to conduct further research with the aim to identify correlations between ASP during EVAR and subsequent aneurysm enlargement.

Patients and Methods: This experimental prospective study included 30 patients undergoing EVAR of infrarenal AAAs. Invasive ASP measurements were done using a thin pressure wire. Aortic pressure (AP) was measured using a catheter placed over the wire. Systolic pressure index (SPI), diastolic pressure index (DPI), mean pressure index (MPI), and pulse pressure index (PPI) were calculated both for ASP and AP. The results of follow-up computed tomography angiography (CTA) at 3 months were compared with baseline CTA findings.

Results: During EVAR, a significant reduction was observed for SPI (from 98% to 61%), DPI (from 100% to 87%), MPI (from 99% to 74%), and PPI (from 97% to 34%). There were no significant correlations of pressure indices with an aneurysm diameter, cross-sectional area, velocity, thrombus shape and size, number of patent lumbar arteries, length and diameter of aneurysm neck, diameter of the inferior mesenteric artery, as well as diameter and angle of common iliac arteries. On the other hand, aneurysm neck angulation was significantly inversely correlated with reduced PPI. After combining CTA findings with pressure measurements, we identified a positive correlation between PPI and aneurysm enlargement (ratio of the cross-sectional area at the widest spot at baseline and at 3 months after EVAR).

Conclusion: The study showed that ASP can be successfully measured during EVAR and can facilitate the assessment of treatment efficacy. In particular, PPI can serve as a prognostic factor of aneurysm enlargement and can help identify high-risk patients who remain prior monitoring.

Keywords: abdominal aortic aneurysm, aneurysm sac pressure, endovascular surgery, endoleak

Introduction

Endovascular aneurysm repair (EVAR) is a common modern technique for the treatment of abdominal aortic aneurysm (AAA). It involves implantation of a bifurcated stentgraft to create a new lumen for blood flow within the abdominal aorta and common iliac arteries. In some cases, unibody grafts are used instead of bifurcated ones, especially when one-sided common iliac artery is occluded or other technical issues make it impossible to implant contralateral iliac graft. As a result of EVAR, the pulsatile blood pressure no longer affects the aneurysm sac.

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Despite stentgraft implantation, numerous cases of aneurysm enlargement, and even rupture, after EVAR have been documented. The failure is usually linked to endoleak (EL), that is, blood leakage into the aneurysm sack. Depending on ethology there are 5 types of EL: type I the leak at the end of prosthesis: proximal end (Ia), distal end (Ib) or the leak at the iliac occluder (Ic); type II is the leak from aneurysm's branches: single (IIa) or multiple branches (IIb); type III is the leak connected with the defect of stentgraft: the leak between modules of prosthesis (IIIa) or the defect in the material of prosthesis (IIIb); type IV is the leak through fabric microporosity of stentgraft; type V (also called endotension), is an aneurysm enlargement with no visible leakage on computed tomography angiography (CTA).[1,2] EL occurs in 17% to 26% of patients undergoing EVAR,[3–6] especially in cases with aneurysm growth and rupture.[7] The EUROSTAR registry including 6000 patients after EVAR reported an EL frequency of 22%. Interestingly, the registry also showed that 5.3% of AAAs with no visible EL were still growing. At 4 years, the risk of aneurysm rupture increased abruptly from <1% to 7.5%–13.6%.[7] It was shown that those cases were linked to increased aneurysm sac pressure (ASP).[8,9]

Our previous research confirmed the efficacy and safety of ASP measurement by pressure wire during EVAR. While we generally observed a significant reduction in ASP during the procedure, there were some patients with only a small decrease or even no changes in ASP.[10] Therefore, we decided to conduct further research with follow-up CTA at 3 months. The aim of the study was to identify correlations between ASP during EVAR and subsequent aneurysm enlargement.

Materials and Methods

Study Design

This experimental prospective study was based on the analysis of intraoperative measurements and CTA findings. Invasive ASP measurements were performed during EVAR of infrarenal AAAs. Follow-up CTA was done at 3 months (which is our standard practice for EVAR patients), and the findings were compared with those obtained at baseline.

Population

The study included 30 patients (6 women and 24 men) at a mean age of 71.69 ±6.92 years (range, 58–86 years). Patients with an asymptomatic AAA who were referred for EVAR were considered eligible for the study. Morphology of AAAs was infrarenal, fusiform with dimensions as follows: aneurysm length 83.13 ± 27.50 mm, aneurysm diameter 58.51 ± 12.30 mm, volume of thrombus 54.02 ± 23.50%, neck length 4.04 ± 1.70 mm, neck diameter 2.48 ± 0.39 mm, neck angulation 36.02 ± 14.60 degree, IMA diameter 1.82 ± 1.53mm, amount of lumbar arteries >2.5 mm: 2.61 ± 1.58. All cases were in the Instructions For Use (IFU) of EVAR, including aneurysm neck length of at least 20 mm.

Endovascular Aneurysm Repair

Standard EVAR[11] was performed in a hybrid operating room. The whole procedure was carried out under local anaesthesia in the inguinal region. Bilateral femoral artery access was performed using a pre-close technique. The main bifurcated body of the abdominal stentgraft was deployed, positioned, and expanded under angiographic guidance, just below the origin of the lower renal artery. Next, the iliac parts of the stentgraft were deployed and expanded. Final angiography was performed to confirm proper graft implantation and detect possible EL.

Pressure Measurement

A 0.014-inch wire (COMET II Pressure Guidewire, Boston Scientific) was used for ASP measurements, as described previously.[10] A 6F Judkins right catheter was inserted by left radial access and introduced proximally to the aneurysm. The pressure wire was advanced through the catheter into the aneurysm sac at the beginning of the EVAR procedure to monitor the ASP. Aortic pressure (AP) was measured using a catheter placed over the wire. Pressure measurements were done at each stage of the EVAR: before stentgraft deployment, after deployment, and, finally, after ballooning of the stentgraft parts. Systolic, diastolic, mean, and pulse pressures were recorded for both ASP and AP. When the EVAR was completed, the wire and the catheter were removed.

Statistical Analysis

To obtain unified results, we used the following pressure indices for both ASP and AP: systolic pressure index (SPI), diastolic pressure index (DPI), mean pressure index (MPI), and pulse pressure index (PPI). The normality of data distribution was assessed by the Shapiro–Wilk test. The Student's *t*-test was used for a comparison between the obtained coefficients. The Wilcoxon test was applied for a non-parametric analysis. The analysis of variance and correlation tests were also performed. The significance level was set at a P value of less than 0.05. The Statistica 13.3 software (StatSoft, Poland) was used for analysis.

Ethics

The approval of the Bioethics Committee of Medical University in Wroclaw was obtained (KB-51/2019). All procedures performed in studies involving human participants were in accordance with the ethical standards of the Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

Consent for publication was obtained for every individual person's data included in the study.

Results

All patients underwent EVAR without any intraoperative complications. We implanted variable models of bifurcated stentgrafts: Cook (9 cases), Jotec (3 cases), Gore (7 cases), Medtronic (3 cases), Terumo (8 cases). The only significant correlation was on PPI, with the best results for Gore and Terumo (Figure 1), however it was not connected with EL presence or results after 3-months.

During EVAR, all pressure indices decreased significantly: SPI from 98% to 61%, DPI from 100% to 87%, MPI from 99% to 74%, and PPI from 97% to 34%.

We examined the calculated indices in relation to the anatomical features of AAAs. The correlations are presented in Table 1. There were no significant correlations between the pressure indices and aneurysm diameter, cross sectional-area, velocity, thrombus shape and size, number of patent lumbar arteries, neck length, neck diameter, diameter of inferior

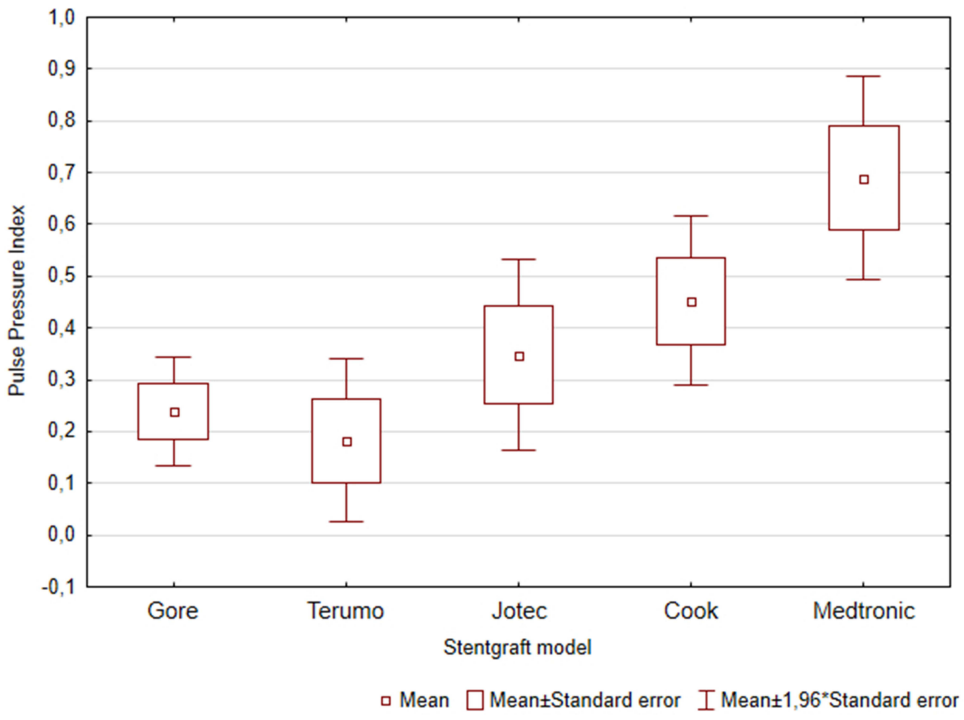

Figure 1 PPI results after EVAR for different types of implanted stentgrafts models.

Table 1 Correlations Between Anatomical Features of Abdominal Aortic Aneurysm and Pressure Indices After Endovascular Aneurysm Repair

Parameter	SPI	DPI	MPI	PPI
Cross-sectional area of the aneurysm	0.11	0.26	0.21	−0.11
Cross-sectional area of lumen	−0.07	0.04	0.01	−0.24
Cross-sectional area of thrombus	0.21	0.32	0.28	0.07
Ratio of thrombus to aneurysm area	0.19	0.31	0.25	0.15
Thrombus shape	0.30	0.34	0.32	0.29
Aneurysm length	−0.18	0.07	−0.05	−0.34
Aneurysm neck length	−0.13	−0.2	−0.17	−0.11
Aneurysm neck diameter	−0.12	−0.27	−0.19	−0.05
Aneurysm neck angle	−0.34	−0.2	−0.27	−0.46[a]
Aneurysm velocity	0.00	0.14	0.09	−0.20
Right common iliac artery diameter	0.25	0.05	0.18	0.23
Left common iliac artery diameter	0.10	0.06	0.10	0.06
Angle between common iliac arteries	0.05	0.00	0.00	0.16
Inferior mesentheric artery diameter	−0.12	−0.28	−0.19	−0.02
Number of wide lumbar arteries (>2.5 mm)	0.06	−0.01	0.04	0.03

Notes: [a]Statistically significant (P <0.05).
Abbreviations: DPI, diastolic pressure index; MPI, mean pressure index; PPI, pulse pressure index; SPI, systolic pressure index.

mesenteric artery, as well as diameter and angle of common iliac arteries. On the other hand, there was a significant inverse correlation between aneurysm neck angulation and a reduction in PPI. Directly after stentgraft implantation, EL was revealed in 7 of 30 cases: 6 type II EL and 1 type I (this case required an adjuvant procedure). There was no significant correlation between EL and pressure indices.

Only 20 of the 30 patients completed the 3-month follow-up. The results of CTA at baseline and at 3 months are compared in Table 2. The EL was present in 8 cases. It was slightly type 2 EL. There was no correlation between EL and other anatomical features like aneurysm size.

The aneurysm lumen was significantly reduced due to thrombus formation, while the overall aneurysm size was not changed or even enlarged in some cases (Figure 2). However, after combining CTA findings with pressure

Table 2 Anatomical Features of Abdominal Aortic Aneurysm at Baseline and at 3 Months After Endovascular Aneurysm Repair

Parameter	At Baseline	At 3 Months	P value
Cross-sectional area of the aneurysm, cm^2	99.41±49.49	95.07±50.97	0.0662
Cross-sectional area of the lumen, cm^2	41.56±24.95	22.31±7.67	0.0016[a]
Cross-sectional area of thrombus, cm^2	57.84±38.37	72.76±47.74	0.0221[a]
Aneurysm length, mm	82.68±28.26	81.90±26.24	0.7456
Aneurysm velocity, cm^3	1202.13±1083.13	1135.18±1076.82	0.1075

Notes: Data are presented as mean ± standard deviation; [a]Statistically significant (P <0.05).

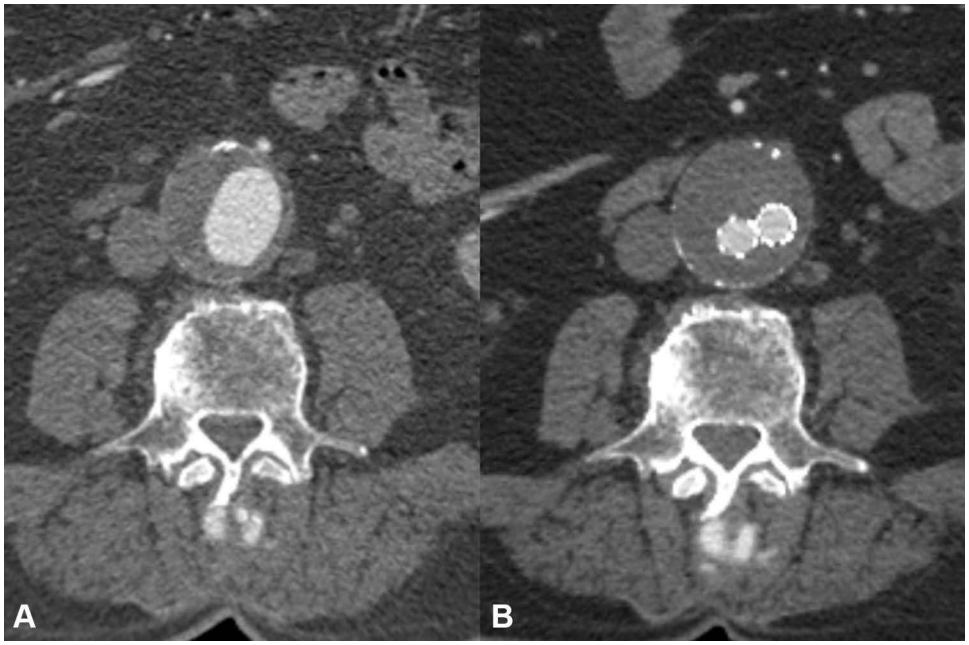

Figure 2 CTA scans showing abdominal aortic aneurysm before treatment (**A**) and after three months (**B**). An aneurysm sac enlargement is visible despite there was no EL.

measurements, we observed a positive correlation between PPI and aneurysm enlargement (the ratio of the cross-sectional area at the widest spot at baseline and at 3 months after EVAR). The correlation is shown in Figure 3.

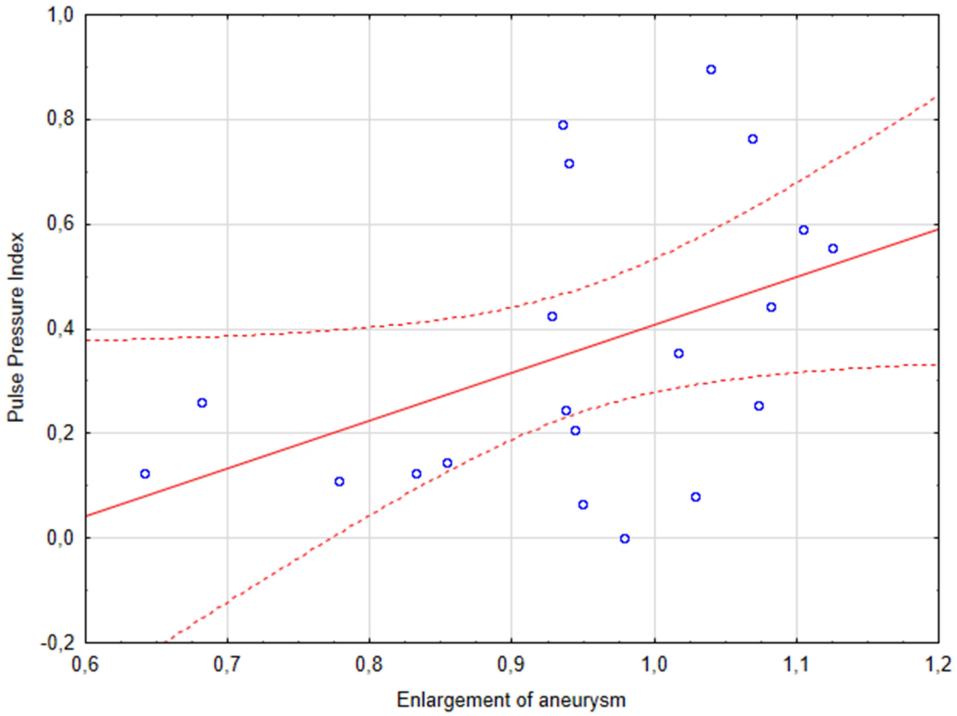

Figure 3 Correlation between pulse pressure index and aneurysm enlargement (ratio of the cross-sectional area at the widest spot at baseline and at 3 months; 1.0 indicates the same size at 3 months). The equation of the slope: PPI = −0.51 + 0.91 *Enlargement of aneurysm. Correlation coefficient 0.44; P<0.05.

Discussion

One of the first studies reporting ASP measurement in 8 patients after EVAR was published in 1997 by Chuter et al.[12] Pressure measurements were performed through a catheter adjacent to the stentgraft implanted in the aneurysm using a simple aorto-uniiliac method. A significant reduction in ASP was noted.

Numerous investigators showed that some patients had elevated ASP despite treatment, even when there was no visible EL. Baum et al measured ASP in 27 patients after EVAR. EL was present in 17 patients; however, of the 10 patients without a visible EL, 4 patients were shown to have equal ASP and AP.[13] This may suggest that type V EL or endotension is associated with aneurysm enlargement and a high risk of rupture. Dias et al assessed ASP in 37 patients after EVAR. They reported a median MPI of 19% in shrinking AAAs, of 30% in unchanged AAAs, and of 59% in expanding aneurysms without EL.[8,9] Therefore, it is clear that ASP is significantly correlated with aneurysm enlargement.

Parsa et al summarized the causes of endotension, including pressure transmission through a thrombus or endograft fabric, the presence of microleak or ultrafiltration, and possible hyperfibrinolysis, infection and anticoagulation. The literature has highlighted that endotension is in fact the type II or III EL below the sensitivity limits of current imaging modalities.[14] Either way, an ASP measurement can detect EL, whatever its cause, so the diagnosis and proper treatment may be initiated.[8,15]

In contrast to investigators who assessed ASP a few months after treatment, we performed perioperative measurements. Thanks to advances in endovascular techniques, pressure measurements can be done with greater precision and with much less invasive tools, typically using thin-pressure wires for fractional flow reserve measurement in coronary arteries. A thin pressure wire was also used by Milnerowicz et al to assess the pressure in the renal arteries after chimney EVAR.[16]

Although our results differed from those reported by Dias et al, we also showed a significant correlation between ASP and aneurysm enlargement. Sonesson et al measured ASP in 10 patients who showed a reduction in the AAA diameter of at least 6 mm within a year after EVAR. They showed a significant drop in pressure, with a complete reduction in pulse pressure (PPI = 0%).[15] In our study, pulse pressure showed the most significant correlation with aneurysm enlargement; therefore, we hypothesize that it could be used to assess the efficacy of EVAR. Furthermore, we believe that the method described herein could facilitate the identification of patients at risk of aneurysm enlargement. Such patients could remain prior monitoring.

We found a significant inverse correlation between aneurysm neck angulation and a reduction in PPI. While most recent studies generally demonstrate angulation as a significant risk of EL, there are some works that describe it as a much more complicated relation.[17,18] Xenos et al performed a parametric study of AAA CTA results. They found that growing neck angulation reduced the peak fluid pressure in the aneurysm sac. This led to a reduced wall shear stress. While the peak von Mises stress initially increased as a result of the angulation, after exceeding 20 degrees a decrease in the peak stress was observed. At the same time, a substantial decrease in the mean von Mises stress was observed too.[19]

Silveira et al proposed a method that involves regular monitoring of ASP. They implanted a wireless sensor into the aneurysm sac during EVAR in a group of 25 patients. They confirmed that this type of measurement is reliable and effective. They also showed that MPI decreases over time along with thrombus maturation.[20] However, long-term results of this study are lacking. In our opinion, such a detector, perhaps integrated in stentgraft construction, would be a valuable and innovative device to collect long-term real-time ASP data after EVAR.

It should be mentioned, that evolution of EVAR took place to improve sealing accuracy. First, stentgrafts were covered with polytetrafluoroethylene (PTFE) or polyester fabric. In the course of further progress, stentgrafts include a second layer of low permeability PTFE to decrease the risk of type IV EL.[14] The next invention was polimer (polyethylene Glycol) coverage. Over time, polymer has been used in two techniques: the first one uses the polymer-filled endobags, the so-called Endovascular Aneurysm Sealing (EVAS) with Nellix stentgraft, while the second uses the O-ring polymer-based proximal neck sealing device, the so-called Ovation stentgraft. However, further studies showed therapeutic failure after Nelix implantation at a surprising and alarming rate of 33.2%. The most common failure mechanism was the stentgraft migration associated with type IA EL and sac expansion. On the other hand, Ovation stentgraft offers a customized sealing of the aneurysm, which remains stable over the years without influencing neck dilatation. The possibility of using polymer characteristics to create a customized sealing of the aneurysm has been a great revolution in EVAR procedures.[21]

Our study has several limitations. First, the study group was relatively small. Second, not all patients completed follow-up and underwent control CTA. Third, ASP was measured only once during EVAR, so long-term data are lacking.

Conclusion

Our study confirmed that ASP can be successfully measured during EVAR and might be used in the assessment of treatment efficacy. In particular, PPI was significantly correlated with subsequent aneurysm enlargement. Therefore, it might serve as a prognostic factor and help identify high-risk patients, who remain prior monitoring.

Abbreviations

AAA, abdominal aorta aneurysm; AP, aortic pressure; ASP, aneurysm sack pressure; CTA, computed tomography angiography; DPI, diastolic pressure index; EL, endoleak; EVAR, endovascular aneurysm repair; IFU, instructions for use; MPI, mean pressure index; PPI, pulse pressure index; SPI, systolic pressure index.

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Disclosure

The authors report no conflicts of interest in this work.

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Article

Aneurysm Sac Pressure during Branched Endovascular Aneurysm Repair versus Multilayer Flow Modulator Implantation in Patients with Thoracoabdominal Aortic Aneurysm

Maciej Antkiewicz [1,*], Wiktor Kuliczkowski [2], Marcin Protasiewicz [2], Tomasz Zubilewicz [3], Piotr Terlecki [3], Magdalena Kobielarz [4] and Dariusz Janczak [1]

[1] Department of Vascular, General and Transplantation Surgery, Wroclaw Medical University, 50-367 Wroclaw, Poland
[2] Department of Cardiology, Wroclaw Medical University, 50-367 Wroclaw, Poland
[3] Department of Vascular Surgery and Angiology, Medical University of Lublin, 20-059 Lublin, Poland
[4] Department of Mechanics, Materials Science and Biomedical Engineering, Wroclaw University of Science and Technology, 50-370 Wroclaw, Poland
* Correspondence: maciej.antkiewicz@gmail.com; Tel.: +48-71-733-2003

Abstract: Open thoracoabdominal repair is the gold standard in the TAAA treatment. However, there are endovascular techniques, that sometimes may be an alternative, such as branched endovascular aneurysm repair (BEVAR) or implantation of the multilayer flow modulator (MFM). In this study, we aimed to assess differences in the aneurysm sac pressure (ASP) between patients undergoing BEVAR and MFM implantation. The study included 22 patients with TAAA (14 patients underwent BEVAR, while eight MFM implantation). The pressure sensor wire was placed inside the aneurysm. A measurement of ASP and aortic pressure (AP) was performed during the procedure. The systolic pressure index (SPI), diastolic pressure index (DPI), and pulse pressure index (PPI) were calculated as a quotient of the ASP and AP values. After the procedure, SPI and PPI were lower in the BEVAR group than in the MFM group. During a procedure, a drop in SPI and PPI was noted in patients undergoing BEVAR, while no changes were revealed in the MFM group. This indicates that BEVAR, but not MFM, is associated with a reduction in systolic and pulse pressure in the aneurysm sac in patients with TAAA.

Keywords: thoracoabdominal aneurysm; aneurysm sac pressure; endovascular aneurysm repair; multilayer flow modulator

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1. Introduction

A thoracoabdominal aortic aneurysm (TAAA) is a type of aneurysm that is particularly difficult to treat due to its size and involvement of the renal and visceral arteries. TAAA repair requires a technique that will exclude the aneurysm from the circulation, while maintaining perfusion in the visceral and renal arteries. Open thoracoabdominal repair with the implantation of a branched graft is the gold standard in the TAAA treatment. However, the endovascular approach is a promising and modern alternative [1]. The stent-grafts used for TAAA repair have branches for extension into the visceral and renal vessel ostia, a technique called branched endovascular aneurysm repair (BEVAR) [2]. BEVAR was reported to be associated with complications including perioperative mortality in 10% of cases, spinal cord ischemia in 2.7–20% of cases, and occlusion of the target vessels (including renal arteries, celiac arteries, and superior mesenteric artery) in 5% of cases [3]. The implantation of the multilayer flow modulator (MFM) constitutes an alternative to endovascular TAAA repair. Compared with BEVAR, it is time effective and

easier to perform. The MFM stents are permeable mesh constructs of cobalt alloy wires interconnected in multiple layers.

After implantation in the aorta, the MFM modulates blood flow by reducing local wall shear stress, while maintaining branch patency. The porosity rate of the stent for optimal flow modulation was determined at 65%, and stent implantation was reported to cause 90% reduction in flow velocity outside the stent [4]. However, further research is needed to assess the efficacy and safety of this method [5].

The aneurysm sac pressure (ASP) measurement after stent-graft deployment is one of the promising research directions. Previous studies show that ASP can be successfully and less invasively measured during endovascular repair [6,7] and proved the relationship between increased ASP and AAA growth or presence of endoleak (1 year after EVAR) [8,9]. Using the experimental model of endotesion, Skillern et al. concluded that high ASP after EVAR might be bounded to the need for reintervention in future [10].

In this study, we aimed to assess differences in the ASP between patients undergoing BEVAR and those subjected to MFM implantation. For this purpose, pressure measurements were performed during the procedure by means of an ultra-thin pressure guide wire used in interventional cardiology.

2. Materials and Methods

2.1. Study Design

This was a prospective experimental study based on the analysis of invasive pressure measurements obtained during endovascular TAAA repair.

2.2. Patients

The study included 22 patients with TAAA. The group treated with BEVAR included 14 patients (12 men and 2 women; aged 73 ± 7), while 8 patients (6 men and 2 women; aged 76 ± 4) underwent MFM implantation. The characteristic of patients is presented in Table 1.

Table 1. The clinical and demographic characteristics of patients enrolled in the study.

Variable	BEVAR	MFM
Gender		
female	2	2
male	12	6
Age (M ± SD)	73 ± 7	76 ± 4
Risk factors		
cerebral stroke	1	1
heart failure	7	3
diabetes mellitus	1	2
chronic obstructive pulmonary disease	1	2
renal insufficiency	1	2
arterial hypertension	12	6
obesity (BMI > 30 kg/cm^2)	5	4
nicotinism	14	8
peripheral artery disease	6	4
cancer	-	2
Aneurysm diameter (mm)	60.5 ± 9.9	69.9 ± 17.1

2.3. Branched Endovascular Aneurysm Repair

BEVAR is performed using vascular access sites in the groin (in some cases additional axillary or brachial artery access is required). During the procedure, fluoroscopy and angiography are used to guide the accurate placement of the main stent-graft component with branches extending to the celiac trunk, superior mesenteric artery, and the right and left renal arteries. The main stent-graft component should be deployed with appropriate

branches extending above the visceral and renal artery ostia. Moreover, it should be correctly placed relative to the aortic axis to ensure that the stent-graft branches are as close as possible to the ostium of the celiac trunk, superior mesenteric artery, and left and right renal arteries. After the correct deployment of the main stent-graft component, it is extended by the branched component to the iliac arteries. The ipsilateral limb of the stent-graft is extended into the common iliac artery, which ensures a complete endograft seal on this side. The contralateral limb is left without extension, with flow directed to the lower part of the aneurysm. The aim of this stage is to achieve temporary aneurysm sac perfusion through patent lumbar arteries, thus reducing the risk of spinal cord ischemia [11]. Next, using the upper extremity access, stent-grafts are deployed to connect the branches of the main stent-graft component to target renal and visceral arteries. All stent-graft components are tightened together using dedicated pressure balloons.

The second stage of the procedure is performed after 2 to 4 weeks by adding the missing component to the common iliac artery on the contralateral side. This results in complete aneurysm exclusion.

2.4. Multilayer Flow Modulator Implantation

In MFM (Figure 1) procedures, the venous access device is implanted via the femoral vein in the groin. First, subtraction angiography of the aorta and its branches is performed with a pigtail catheter to identify aortic lesions and landing zones. Then, a stent compressed in the deployment system is advanced into the aorta via the femoral artery access. The proximal end of the stent is deployed in the landing zone in the healthy segment of the aorta above the aneurysm. The stent is then released using the pin-and-pull delivery system. The outer sheath of the stent is pulled off, causing the stent to expand in the aortic lumen. The stent should be delivered slowly to achieve the correct position of the expanding stent relative to the anatomy of the aorta and its branches. Because the stent compressed in the deployment system is much longer than after expansion, the distal landing zone in the healthy aortic segment below the aneurysm should be carefully delineated under computed tomography angiography guidance. The main stage of MFM implantation is completed once the distal end of the stent is released from the deployment system into the distal landing zone. At the end of the procedure, follow-up angiography is performed, the endovascular device is removed, and dressing at the access site is applied.

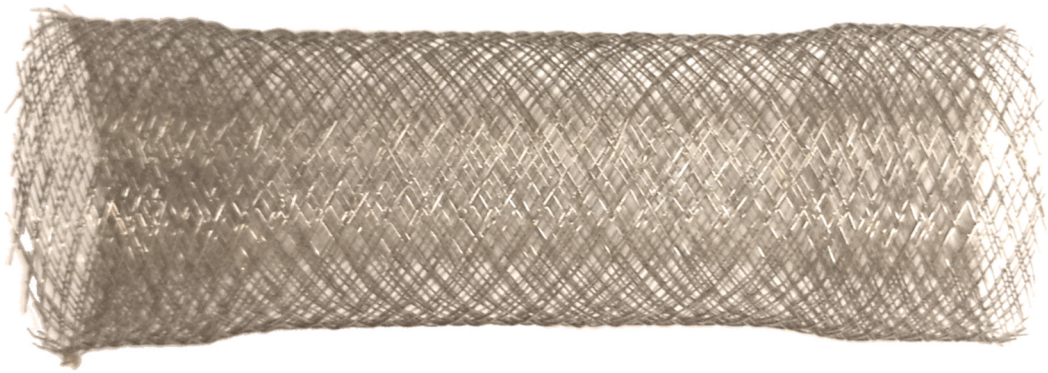

Figure 1. Multilayer Flow Modulator (Cardiatis SA, Isnes, Belgium).

2.5. Measurement Technique

In patients undergoing BEVAR, pressure measurements were done during the second stage of the procedure, before and after the iliac branch stent-graft placement using the contralateral femoral approach. In patients undergoing MFM implantation, the measurements were done before and after stent deployment.

Using local anesthesia with lidocaine, a vascular access port was implanted via the left radial artery. The port was then used to introduce a 0.014-inch pressure guide wire (Comet, Boston Scientific, Marlborough, MA, USA) with a catheter. Under fluoroscopic guidance,

the guide wire was advanced to place the pressure sensor inside the aneurysm, while the distal end of the catheter was positioned in the aorta above the aneurysm.

At each step of the procedure, a simultaneous measurement of ASP and aortic pressure (AP) above the aneurysm was performed, and the results were recorded in an electronic form. Diastolic blood pressure, systolic blood pressure, and pulse pressure were also recorded both for ASP and AP. Moreover, the systolic pressure index (SPI), diastolic pressure index (DPI), and pulse pressure index (PPI) were calculated as a quotient of the ASP and AP values. After the procedure, the guide wire and the catheter were removed under fluoroscopic guidance. The vascular access device was also removed, and the compression dressing was applied at the puncture site.

2.6. Statistical Analysis

For statistical analysis, the Statistica 13.3 software was used (StatSoft, Cracow, Poland). Variables were tested for normal distribution using the Shapiro-Wilk test. The t test was used for the comparison of variables between groups. The level of significance was set at a p value of less than 0.001.

3. Results

Pressure measurements were performed in all 22 patients. The presence of a guide wire in the aneurysm sac did not affect the procedure.

There were no significant differences in baseline SPI, DPI, and PPI (i.e., measured before aneurysm repair) between groups. The comparison of SPI, DPI, and PPI measurements after the procedure revealed that SPI and PPI were lower in the BEVAR group than in the MFM group (both $p < 0.001$).

Changes in SPI, DPI, and PPI before and after the procedure were also assessed within each group. The results for the BEVAR group are shown in Figure 2, and for the MFM group, in Figure 3. A drop in SPI and PPI was noted in patients undergoing BEVAR ($p < 0.001$), while no changes were revealed in patients undergoing MFM implantation.

Early outcomes (30 days after the procedure) are presented in Table 2. Aneurysm diameter in BEVAR group slightly decreased (60.5 ± 9.9 before treatment, 56.2 ± 11.7 after 30 days), while in the MFM group remains similar (69.9 ± 17.1 before treatment, 70.9 ± 17.4 after 30 days). Successful aneurysm occlusion occurred in nine of BEVAR cases. The other five cases had endoleak. The severe complication rate was much higher in the MFM group. There was one case of death due to acute intestinal ischeamia.

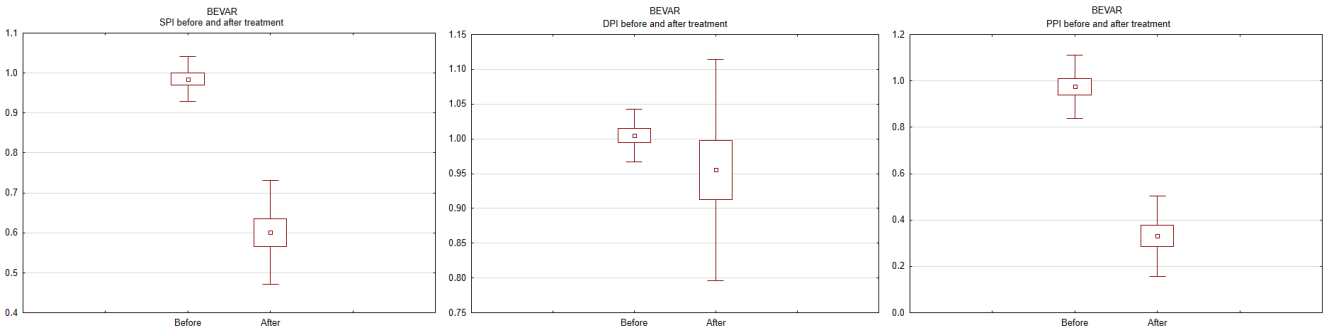

Figure 2. Systolic pressure index (SPI), diastolic pressure index (DPI), and pulse pressure index (PPI) at baseline and after branched endovascular aneurysm repair.

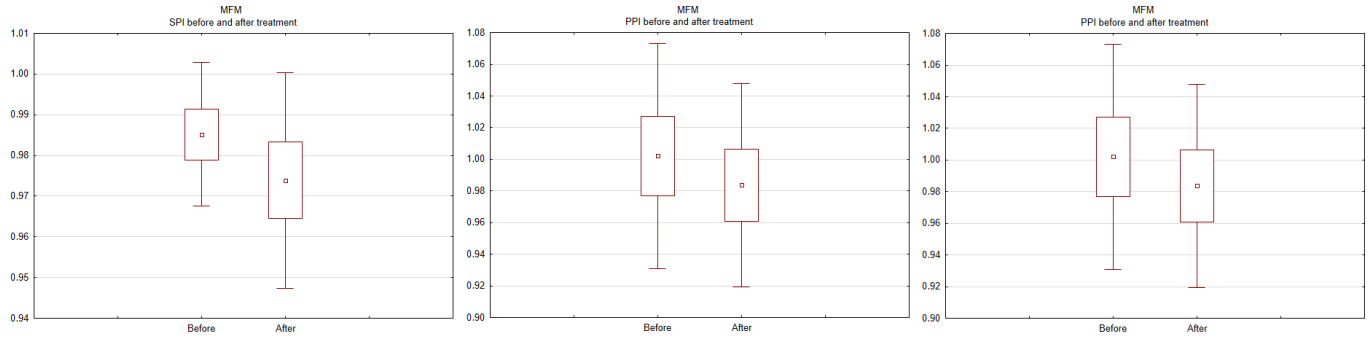

Figure 3. Systolic pressure index (SPI), diastolic pressure index (DPI), and pulse pressure index (PPI) at baseline and after implantation of the multilayer flow modulator. The mean SPI, DPI, and PPI values after the procedure were as follows: 0.60 ± 0.13, 0.95 ± 0.16, and 0.33 ± 0.17, respectively, for the BEVAR group, and 1.00 ± 0.03, 0.98 ± 0.12, and 1.04 ± 0.04, respectively, for the MFM group.

Table 2. Early outcomes (30 days after procedure).

Variable	BEVAR	MFM
Aneurysm diameter (mm)	56.2 ± 11.7	70.9 ± 17.4
Successful aneurysm occlusion	9 (64.3%)	1 (12.5%)
Visceral arteries patency	55/56 (98.2%)	30/32 (93.8%)
Severe complications		
death	-	1 (12.5%) (intestine ischemia)
myocardial infarction	-	1 (12.5%)
acute kidney injury	1 (7.1%)	2 (25.0%)
acute limb ischemia	2 (14.3%)	1 (12.5%)
graft migration	-	2 (25.0%)
Reinterventions	4 (28.6%)	3 (37.5%)

4. Discussion

Numerous authors described the use of MFM implantation for the treatment of aortic aneurysms. These were mostly preliminary studies in a limited number of patients, concluding that further research is needed to investigate the method [5,12–14]. A case report was published that described the emergency use of MFM for the treatment of aortic dissection, outside the indications for use [15]. The most extensive experience with the MFM technique was reported by Sultan et al. [12,16,17]. Several published papers describe findings from in-vitro [16], animal [17], and early clinical studies [12].

Lowe et al. [18] assessed mortality and side-branch vessel patency in 14 patients undergoing implantation of MFM stents for TAAAs and perirenal aneurysms involving the visceral vessels. The authors reported an all-cause mortality rate of 21%, while side-branch vessel patency was observed in 98% of cases. However, a significant increase in aneurysm diameter despite implantation and several cases of MFM dislocation requiring reintervention were also noted.

In the multicenter STRATO trial including 20 patients, Vaislic et al. [19] reported high efficacy and safety of MFM implantation, with a branch vessel patency rate of 96% at 12 months. In a follow-up report from the STRATO trial [20], the authors reported a branch vessel patency rate of 100% at 24 months and 97% at 36 months in 11 patients who continued the follow-up. No cases of stent dislocation were noted at 3 years. Moreover, there were no cases of renal or liver function deterioration. However, at 36 months, the aneurysm diameter was stable in only nine of the 20 patients (45%). Moreover, there were seven cases of death (35%) at 36 months, none of which were confirmed to be related to the aneurysm [20].

In a systematic review of 15 studies assessing the use of MFM in a total of 171 patients with complex TAAA pathology (three observational cohort studies, three multicenter cohort studies, and nine case reports), Hynes et al. [21] reported an all-cause survival rate of 53.7% at 12 months. These results are in line with our current findings. The authors concluded that further research is needed before the method becomes widely used in clinical practice [21].

Most studies on MFM treatment for TAAAs were conducted on small patient groups. The outcomes for vessel patency, mortality rates, progression of aneurysm diameter, and stent dislocation are satisfactory or at least promising.

Most authors emphasized the need for further research; however, usually, no follow-up studies were conducted [4]. In contrast, studies on the use of BEVAR and fenestrated endovascular aortic repair for TAAAs usually include many patients and report good outcomes, with an acceptable risk of complications and mortality.

In this study, we performed invasive ASP measurements to assess the perioperative efficacy of MFM implantation. To date, there have been only a few reports of ASP measurement in patients with TAAAs. One of the studies reporting ASP measurements was by Baum et al. [6] in 27 patients. Among 17 patients with endoleaks, ASP was the same as systemic pressure in 15 patients and one-half systemic pressure in two patients. Sonesson et al. [7] measured ASP in 10 patients after endovascular abdominal aortic aneurysm repair, who showed an aneurysm shrinkage of more than 6 mm at 1-year follow-up or later. They showed a marked reduction in ASP after the procedure, and almost no systolic/diastolic fluctuation, resulting in a nonpulsatile curve (PPI = 0%) [7]. Our previous research showed that ASP measurement is a safe and reliable way to determine the efficacy of treatment. Moreover, the results were correlated with an enlargement of the treated aneurysm [22].

5. Conclusions

Our results confirm that MFM implantation is not associated with a reduction in ASP. In each of the eight patients treated with MFM implantation, no significant fluctuations in ASP were noted. On the other hand, patients undergoing BEVAR showed a significant reduction in ASP, indicating successful aneurysm repair.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy restrictions.

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Wrocław, 22.11.2022

Maciej Antkiewicz
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

OŚWIADCZENIE WSPÓŁAUTORA

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Maciej Antkiewicz

lek. Maciej Antkiewicz
specjalista chirurgii naczyniowej
PWZ 29475

Wrocław, 23.11.2022

dr Wiktor Kuliczkowski
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Wiktor Kuliczkowski

KIEROWNIK PRACOWNI HEMODYNAMIKI
Klinika Kardiologii
Uniwersyteckiego Szpitala Klinicznego
im. Jana Mikulicza-Radeckiego we Wrocławiu
dr hab. n. med. Wiktor Kuliczkowski

Wrocław, 23.11.2022

dr Marcin Protasiewicz
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

OŚWIADCZENIE WSPÓŁAUTORA

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Marcin Protasiewicz

Wrocław, 22.11.2022

dr inż. Magdalena Kobielarz
Katedra Mechaniki,
Inżynierii Materiałowej
i Biomedycznej
Politechnika Wrocławska

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Magdalena Kobielarz

Wrocław, 23.11.2022

dr Piotr Barć
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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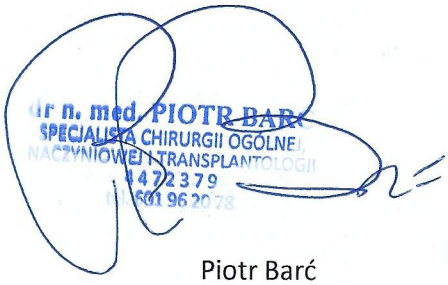

Piotr Barć

Wrocław, 1.10.2021

dr Maciej Malinowski
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Maciej Malinowski

Wrocław, 23.11.2022

Katarzyna Frączkowska-Sioma
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
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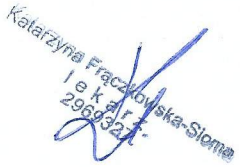
Katarzyna Frączkowska-Sioma



Wrocław, 23.11.2022

Katarzyna Kulikowska
Oddział Chirurgii Naczyniowej
Wojewódzki Szpital Specjalistyczny we Wrocławiu

OŚWIADCZENIE WSPÓŁAUTORA

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Lek. Katarzyna Kulikowska
2964725
specjalista chirurgii naczyniowej

Katarzyna Kulikowska
Kulikowska
Katarzyna

Wrocław, 22.11.2022

Marcin Merenda
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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lek. Marcin Merenda
specjalista chirurgii
ogólnej i naczyniowej
4194630

Marcin Merenda

Wrocław, 1.10.2021

Krzysztof Jacyna
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
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Krzysztof Jacyna

Wrocław, 22.11.2022

dr Tomasz Dawiskiba
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Tomasz Dawiskiba

dr n. med. TOMASZ DAWISKIBA
SPECJALISTA CHIRURGII OGÓLNEJ
NACZYNIOWEJ I TRANSPLANTOLOGII
9560175

Wrocław, 28.11.2022

Prof. dr hab. Dariusz Janczak
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Dariusz Janczak

Wrocław, 22.11.2022

Maciej Antkiewicz
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Maciej Antkiewicz

lek. Maciej Antkiewicz
specjalista chirurgii naczyniowej
3129475

Wrocław, 23.11.2022

dr Marcin Protasiewicz
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Marcin Protasiewicz

Wrocław, 23.11.2022

dr Wiktor Kuliczkowski
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Wiktor Kuliczkowski

KIEROWNIK PRACOWNI HEMODYNAMIKI
Klinika Kardiologii
Uniwersyteckiego Szpitala Klinicznego
im. Jana Mikulicza-Radeckiego we Wrocławiu
dr hab. n. med. Wiktor Kuliczkowski

Lublin, 23.11.2022

Prof. dr hab. Tomasz Zubilewicz
Katedra i Kliniki Chirurgii Naczyń i Angiologii
Uniwersytet Medyczny w Lublinie

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Tomasz Zubilewicz

Lublin, 23.11.2022

dr hab. Piotr Terlecki
Katedra i Kliniki Chirurgii Naczyń i Angiologii
Uniwersytet Medyczny w Lublinie

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dr hab. n. med. Piotr Terlecki
spec. chirurgii ogólnej
spec. chirurgii naczyniowej
spec. angiolog
Nr 1474074

Piotr Terlecki

Wrocław, 22.11.2022

dr inż. Magdalena Kobielarz
Katedra Mechaniki,
Inżynierii Materiałowej
i Biomedycznej
Politechnika Wrocławska

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Magdalena Kobielarz

Magdalena Kobielarz

Wrocław, 28.11.2022

Prof. dr hab. Dariusz Janczak
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Dariusz Janczak

Wrocław, 22.11.2022

Maciej Antkiewicz
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
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Maciej Antkiewicz

lek. Maciej Antkiewicz
specjalista chirurgii naczyniowej
3129475

Wrocław, 23.11.2022

dr Wiktor Kuliczkowski
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
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Wiktor Kuliczkowski

KIEROWNIK PRACOWNI HEMODYNAMIKI
Klinika Kardiologii
Uniwersyteckiego Szpitala Klinicznego
im. Jana Mikulicza-Radeckiego we Wrocławiu
dr hab. n. med. Wiktor Kuliczkowski

Wrocław, 23.11.2022

dr Marcin Protasiewicz
Katedra i Klinika Kardiologii
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Marcin Protasiewicz

Lublin, 23.11.2022

Prof. dr hab. Tomasz Zubilewicz
Katedra i Kliniki Chirurgii Naczyń i Angiologii
Uniwersytet Medyczny w Lublinie

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Tomasz Zubilewicz

Lublin, 23.11.2022

dr hab. Piotr Terlecki
Katedra i Kliniki Chirurgii Naczyń i Angiologii
Uniwersytet Medyczny w Lublinie

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dr hab. n. med. Piotr Te
spec. chirurgii ogólnej
spec. chirurgii naczyniowe
spec. angiolog
Nr 1474074

Piotr Terlecki

Wrocław, 22.11.2022

dr inż. Magdalena Kobielarz
Katedra Mechaniki,
Inżynierii Materiałowej
i Biomedycznej
Politechnika Wrocławska

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Magdalena Kobielarz

Magdalena Kobielarz

Wrocław, 28.11.2022

Prof. dr hab. Dariusz Janczak
Katedra i Klinika Chirurgii Naczyniowej,
Ogólnej i Transplantacyjnej
Uniwersytet Medyczny
im. Piastów Śląskich we Wrocławiu

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Dariusz Janczak