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MICROSURGERY FOR THE CREATION OF ARTERIOVENOUS FISTULAS IN PATIENTS WITH RADIAL ARTERIES DIAMETER SMALLER THAN 1.6 MM

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Summary
In End-stage Renal Disease patients, the distal forearm is the preferred site for hemodialysis access, however forearm vessels have small diameter and according to Guidelines a radial artery internal diameter smaller than 1.6-2 mm is strongly predictive of early failure of the arteriovenous fistula (AVF) because of stenosis and obstruction. It could happen for some patients to not be considered suitable for distal forearm AVF because of poor peripheral vessels, so in these cases the micrusurgical technique can be very helpful in handling such "inadequates" vessels for lower-arm fistula creation.
This study is an investigation of long-term patency of distal radio-cephalic AVFs created under microscopic guidance by using small radial arteries (less the 1.6 mm diameter) in adult patients with chronic renal failure and without severe comorbidities. In a sample of 31 patients, at 1 year postoperatively, the mean primary patency rate was 67.7% (21 functioning AVFs out of 31) and that is quite the same result of AVFs' made with arteries larger than 2 mm.

Key words: microsurgery, arteriovenous fistula (AVF), end-stage renal disease (ESRD), radial artery

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INTRODUCTION

In the last decades, the aging of the population and the increase in life expectancy are leading to long-term hemodialysis in elderly, diabetic and atherosclerotic patients with severe impairment of the peripheral circulation. In these patients, the creation and maintenance of a patent and well-functioning arteriovenous fistula (AVF) is a demanding and often arduous challenge and it explains the increasing use of permanent central venous catheter implants (pCVC) as the definitive vascular access for the hemodialysis.
Vascular access is historically defined as the "Achille's heel" of dialysis, the weakest point, that affects the patients survival and quality of life.
The permanent vascular accesses, currently used in extracorporeal hemodialysis practice, consist of:
- native arteriovenous fistulas (nAVF);
- prosthetic fistulas in synthetic material (pAVF);
- two-way cuffed central venous catheters (CVC).

In patients on chronic hemodialysis the native AVF (made with patient's own vessels) or prosthetic ones (made by the insertion of bridge prostheses between artery and vein) are preferable to CVCs, and native AVFs represent the preferred method for vascular access in patients with end-stage renal disease (ESRD) because, compared to AV graft and CVCs, they are associated with fewer complications (thrombotic, infectious, ischemic ones), improved access survival with a long-term patency (65-70% at three years) and lower mortality risk [1-3].

Native AVFs are generally made by an end-to-side anastomosis between the final part of a major vein and the lateral wall of an artery, and the most used is the distal radio-cephalic fistula, which involves anastomosis at the level of the lower third of the forearm (lower arm) between the radial artery and the cephalic vein. It currently represents the gold standard among all AVFs and permanent vascular accesses, according to the National Kidney Foundation (NKF) / Dialysis Outcomes Quality Initiative (DOQI) and European Society for Vascular Surgery (ESVS) [4,5].

It is suggested to use first the more distal vessels rather than the proximal ones in order to preserve the vessels in the upper side of the forearm for a possible late use, in case of failure of the first vascular access.

Complications related to vascular access represent the major specific cause of morbidity in ESRD patients. In fact, they are responsible for over 15% of hospitalizations and have a very high cost, estimated at more than 50 million dollars per year in the United States alone [6,7].

Substantial efforts have been expended to develop strategies for improving the long-term patency of the fistula and maintaining adequate blood flow without complications as well as for safeguarding the patient's vascular heritage in order to ensure the possibility of new vascular accesses in case of failure of the previous one.

The distal radio-cephalic AVF (lower arm) and the more proximal radio-median or radio-cephalic nAVF (middle arm) are certainly the best vascular access because they carry a lower risk of vascular access "Steal syndrome" compared with the upper-arm AVFs, however Guidelines indicate that a radial artery internal diameter smaller than 1.6-2 mm is strongly predictive of early failure because of stenosis and obstruction [4,8-13].

According to these Guidelines, It could happen for some patients to not be considered suitable for distal forearm AVF because of poor peripheral vessels, secondary to diabetes, calcification or peripheral arterial disease; in these cases the micrusurgical technique can be very helpful in handling such "inadequates" vessels for lower-arm fistula creation.

The aim of this study is to investigate the long-term patency of distal radio-cephalic nAVFs created under microscopic guidance by using radial arteries less than 1.6 mm in diameter in adult patients with chronic renal failure and without severe comorbidities.

MATERIALS AND METHODS

Patients and study design

In the period between January 2020 and December 2021, at the Nephrology Unit of "Villa dei Fiori" Clinic of Mugnano di Napoli (Italy), 31 patients underwent arteriovenous fistula surgery by using microsurgical technique on radial arteries with a diameter less then 1.6 mm, making a distal radio-cephalic AVF (18/31) or a "middle arm" radio-median or radio-cephalic AVF (13/31).

All the 31 patients (21 female, 10 male; age range 19-65 years; mean age 56.2 ± 12.4), at the time of surgery, suffered from an end-stage chronic renal failure and among them 19 patients were still in conservative treatment and 12 had recently undergone hemodialysis with a temporary CVC in femoral vein.

Among them, 9 patients suffered from polycystic disease, 2 obstructive kidney stones and pyelonephritic nephropathy, 7 previous glomerulonephritis, 19 blood hypertension, 16 type II diabetes mellitus, 1 cardiac arrhythmia, 1 autoimmune diseases (SLE), 3 myeloma (Tab. I).

Any anticoagulant or antiplatelet therapy has been switched to low molecular weight heparin thromboprophylaxis, according to the guidelines, under close nephrological control [4,5].

Preoperative evaluation

All the patients have been studied with a "Preoperative Vascular Mapping for AVF making", or else by collecting anamnesis, physical examination, echo-color doppler (a phlebographic study was performed in two cases for suspicion of central venous stenosis because of a previous catheterization in critical area or the presence of a pacemaker), wrist radial artery reactive hyperemia

Table I. ESRD etiology among patients of the sample.

Patients	31
AGE (average ± SD)	56.2 ± 12.4
M/F	10/21
Nephro-angio-sclerosis	9%
Glomerulonephritis	22%
AD polycystic kidney	29%
Obstructive nephropathy	6%
Diabetic nephropathy	19%
Other causes	15%

test and Allen test for ischemia (if reperfusion does not occur within 8 seconds after the compression applied on the ulnar artery is removed, the radial artery should not be chosen for an AVF).

A preoperative Doppler-ultrasound "Vascular Mapping" study has been done in all the cases, considering the following parameters: 1) radial arterial diameter, choosing vessels smaller than 1.6 mm; 2) the thickness of the wall, that must be calculated evaluating the Intima-Media Thickness or IMT, which in healthy patients on the radial artery ranges from 0.19 to 0.35 mm and in ESRD ones from 0.3 to 0.7 mm; 3) the doppler flow rate of the vessel (Qa); 4) the resistance index (RI); 5) the vessel elasticity, evaluated with the reactive hyperemia test; 6) the presence of vascular calcifications and stenosing plaques [14].

A careful preoperative evaluation should also consider any possible double arterial vascular district (due to high or axillary radio-ulnar bifurcations), the patency of the venous stream, the diameter of the vein to be fistulated (that should be > 2 mm) and the percentage of vein dilation (which should be at least 30% after applying a tourniquet or better a sphygmomanometer cuff to the arm with a pressure of 50 mmHg for at least 2 minutes) [15].

The criterion for distal radio-cephalic AVF making was the absence of vessels stenosis along the site chosen for anastomosis; the presence of smooth parietal calcifications (IMT < 0.4 mm), as small as not causing stenosis, was not considered among the exclusion criteria.

The mean diameter of the radial artery was 1.48 mm +/- 0.16 mm, while that of the cephalic vein was 2.32 mm +/- 0.21 mm.

Surgical procedure

The microsurgical technique requires the use of a highly efficient binocular vision image enlarger, in other terms an operating microscope. For this purpose, the MGV 3-phase ophthalmic microscope (with magnification at 5x, 10x, 20x) was used, combined with a Zeiss ophthalmic loupe (with magnification at 4.3x and working distance at 400 mm) during the dissection [16].

All the operations have been performed by the same surgical team, consisting of a nephrologist trained in vascular access surgery for hemodialysis and a hand surgeon skilled in microsurgery.

The operations were performed under local anesthesia with 7.5% Ropivacaine. A 5-6 cm longitudinal skin incision was designed at the distal or middle third of forearm, depending on the anastomosis to be chosen, along the direction of the vessel, with care to preserve the lateral antebrachial cutaneous nerves.

The isolation of the cephalic or the median vein and the detachment from the deep planes was then practiced, by using vascular loops, for a sufficient length (mean 3-4 cm) to help the transposition to the site of the anastomosis, and the collateral branches were tied. Then the antibrachialis fascia was opened and the isolation and detachment of the radial artery, by using vascular loops, was performed.

With the aid of the operating microscope or surgical loupe, the vein was cut and washed with heparinized physiological solution, in order to evaluate the patency of the vase and to exclude any lacerations of the wall; the tip of the vessel was shaped into a flute beak, by using Potts scissors.

The artery was then clamped with vascular clamps and the arteriotomy was performed by using first an eye scalpel and completing the longitudinal incision of the vessel, for a length of 8-10 mm for the distal radio-cephalic AVF and of 5-7 mm for the middle-arm ones, with Potts microsurgical scissors, then frequently washing the vessel with heparinized physiological solution.

The end-to-side anastomosis was then made, helped by vascular approximator and under microscopic guidance, through two continuous sutures in 8-0 or 9-0 monofilament polypropylene, starting from the proximal angle and suturing first the posterior wall and then the front. A continuous suture has been preferred by surgeons because it is the one most used in this type of vascular surgery, according to the european guidelines, as well as the most confident technique for the surgeons, based on their expertise [4,5].

When anastomosis completed, the artery was declamped and both any bleeding and patency of the AVF were verified, in order to test the functionality of the anastomosis by perceiving a classic thrill produced by the blood flow (Fig. 1).

The success of the procedure was evidenced by the auscultation of the continuous murmur with systolic reinforcement in the first part of the vein.

The duration of the entire surgical procedure was approximately 90 minutes.

Fluids and pain killers have been administered hours after the surgery, under strict control of the nephrologist.

Antithrombotic prophylaxis with low molecular weight heparin has been continued for one month after surgery, or in some selected cases switched back to patient's own anticoagulant therapy.

Follow-up protocol

During the first 48 hours after surgery, all the patients underwent close ultrasound monitoring of the patency of the newborn fistula and, once verified the absence of clinical complications for the patients or vascular ones along the upper extremity, on the third day of hospitalization they have been discharged.

All patients have been reevaluated at 2 weeks and monthly after surgery, both clinically (by perceiving of the

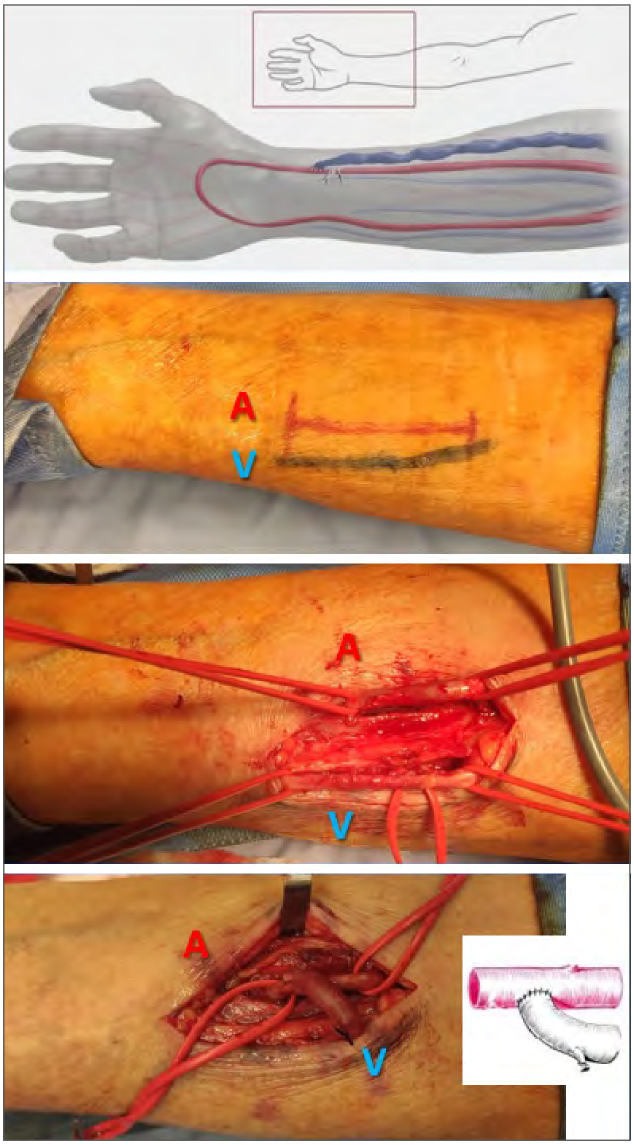

Figure 1. Microsurgical anastomosis between the radial artery (A) and the cephalic vein (V) at the forearm.

thrill on palpation and systolic murmur and venous pulsation on auscultation) and with Doppler ultrasonography (by evaluating of arterial and venous diameter increasing, the blood flow of the AVF with vascular examination at the level of the above-elbow brachial artery, and excluding any stenosis, aneurysms or thrombosis). Unless there were any problems, the next check was established at 1 year. The maturation of vascular access was defined as vascular access correctly used for hemodialysis [17].

An AVF is defined "mature" when the venous diameter allows venipuncture with large caliber needles and the flow rate reaches 600 ml/min, the vein diameter ≥ 6 mm and the under skin depth of the vessel less than 6 mm (this is the "Rule of 6", as to say: flow greater than

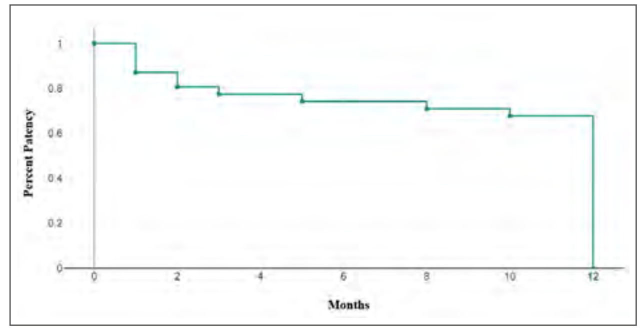

Figure 2. Primary patency by Kaplan-Maier survival curve.

600 mL/min, diameter at least 6 mm, depth no greater than 6 mm).

Statistical analysis

Data analysis was parformed using the DATAtab Online Statistics Calculator, in order to determine the proportion of "early failure" within 3 months of treatment and "late failure" throughout the one year follow-up. The Kaplan-Meier method was used to calculate the primary patency survival curve (Fig. 2).

RESULTS

All the procedures ended, at the time of surgery, with full patency of the anastomosis at the vascular declamping and all the patients have been discharged from the hospital with a full patent fistula, according to the strictly postoperative ultrasound monitoring.

For classification purposes, AVF failures have to be distinguished in "early failure", as to say within three months after surgery, subclassifying as "very early failure" the ones that occur during the first month after the anastomosis achieved, and "late failure", that is to say after three months.

The incidence of "very early failure" was 12.90% (4/31patients). The causes of the failure were:

- thrombosis within the first two weeks after surgery in 2 patients (10th day);
- lack of maturation (patent but unfunctional AVF) associated with Juxta-anastomotic stenosis in 2 other patients, causing a diminish of the flow till the occlusion.

In all these four patients, the following treatment was the creation of a more proximal AVF.

Another 3 patients, two months after setting up the vascular access, had a good patency of the nAVF but the flow rate was insufficient for dialysis needs, thus defining a condition of "early failure", whose total amount rose to 7 patients (22.5% of the sample).

Table II. Average of the diameters (Ø), the strength index (RI) and the flow rate (Qa) at 3 months after surgery.

24 Patients (3 mth postop)	Lower arm AVFs	Middle armAVFs
Radial artery	Ø 3.89 ± 0.55 mm	Ø 3.91 ± 0.63 mm
Fistulized vein	Ø 6.50 ± 1.34 mm	Ø 5.90 ± 1.27 mm
Resistance index (RI)	0.38 ± 0.07	0.31 ± 0.03
Flow rate (Qa)	925 ± 130 ml/min	873 ± 180

They were therefore reoperated with proximalization of the anastomosis, obtaining a "successful maturation" due to the increased caliber and flow rate of the vessels obtained thanks to the preparation of the first fistula.
In the remaining 24 patients undergoing hemodialysis, the average of the diameters (Ø), the strength index (RI) and the flow rate (Qa) at 3 months have been reported in Table II.
During the first year of dialysis, after 5 and 8 months of regular treatment, 2 patients reported AVF stenosis, as to say a "late failure" caused by repeated venipuncture and required revascularization and 1 patient died of cardiac arrest (despite the fact that his fistula was well-functioning at the time), but it must be included in the "late failure". The remaining 21 patients had a normal dialysis course with well-developed AVFs and no significant vascular complications.
At 1 year postoperatively, the mean primary patency rate was 67.7% (21 functioning AVFs out of 31) and that is quite the same result of AVFs' made with arteries larger than 2 mm (Fig. 3) [18,19].

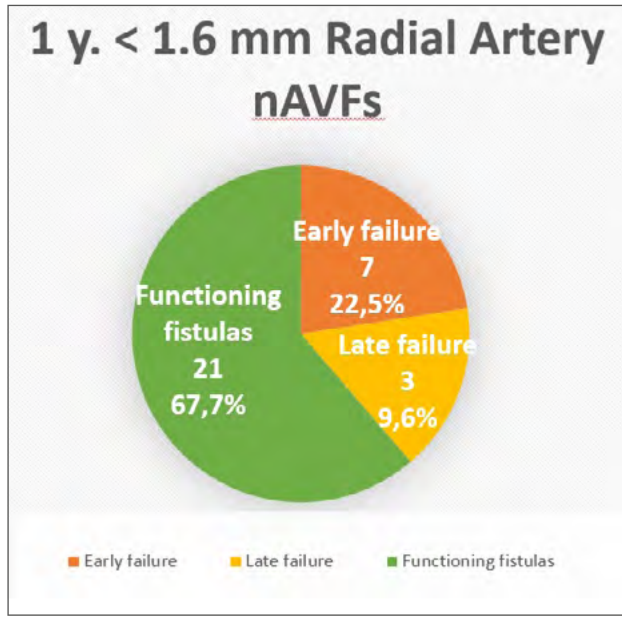

Figure 3. 1 year FU: successes and failures in the sample.

DISCUSSION

Hemodialysis purification, in 3-4 hours of treatment, occurs at a flow of ~ 300 ml/min (range 200-400 ml/min), therefore the fistula has to ensure this flow meanwhile the artery continuing to perfuse the limb.
The "Ideal AVF" has to fulfill three conditions: 1) to be easy to use for hemodialysis; 2) to maintain the target blood flow at all times; 3) to remain patent for long-term use.
In practice, many ESRD patients develop obstruction or stenosis of the fistula and require the creation of multiple AVFs in order to continue hemodialysis; such complications occur due to injury to the vascular endothelium caused by repetitive vascular puncturing [20].
As soon as the AVF anastomosis is completed, the presence of thrill on palpation and auscultation is the indicator of good functionality, as well as the presence of pulsation of the vessels, because of a possible influx resistance, could be predictive of thrombosis.
Because of the lack of tunica media in the vein, below the anastomosis there is an uncontrolled blood flow into the vein but, time later, some compensatory mechanisms will take place so that both the venous tunic thickens, increasing its resistance, and the artery increases its caliber, determining a progressively controlled flow into the below anastomosis vessels.
For the low resistance at the anastomosis level, a distal radio-cephalic AVF receives 75% of the blood flow from the radial artery and 25% from the ulnar, by the inversion of blood flow through the palmar arch. The retrograde quota can even reach 100% in case of thrombosis of the artery proximal to the anastomosis and maintain in any case the patency of the AVF [21].
The flow rate of the radial artery before the anastomosis is generally 20-30 ml/min and one day after surgery increases to 200-300 ml/min till 600-1200 ml/min after about one month, when the AVF is defined "fully matured" [22].
A well-functioning AVF should have a blood flow of 800-1500 mL/min; a flow < 300 ml min is insufficient and predictive of thrombosis. The AVF flow is defined low if < 600 ml/min, normal when between 600-1500 ml/

min, high between 1500-2500 ml/min and very high flow rate for values > 2500 ml/min [11-13].
According to literature, the patency of nAVFs made with radial arteries bigger than 1.6 mm in diameter is about 60-70% after one year and 50-60% at two years, and thrombosis is the prevalent cause of AVF loss [23].
The 80% of all complications are stenosis and all stenotic lesions (venous, arterial or anastomotic ones) cause a flow rate (Qa) reduction till the thrombosis; therefore, the direct measurement of Qa is the most suitable method for early detection of a stenosis (K/DOQI Guideline 11) [24].
Some Authors say that the "early failure" of an anastomosis is associated with the use of small caliber arteries (< 1.6 mm); Malovrh reported a 55% of "very early failures" and a 65% of "early insufficiency" in association with radial arterial diameter < 1.5 mm, while Wong recorded a 100% of "early insufficiency" in case of arterial diameters < 1.6 mm [25-27].
In our study, perhaps thanks to the microsurgical support, the total amount of "early failure" was 22,5%, far lower than the percentages reported in the previous articles, relating to the use of the traditional vascular surgical technique.
However, the ideal cut-off for the arterial diameter in order to obtain an optimal maturation and adequacy of an AVF is unknown, probably other factors, such as the presence of atherosclerosis, may play a decisive role.
There are very few articles relating to the use of the microsurgical technique in nAVF creation, and among them Pirozzi et al. incentivizes microsurgery apply, reporting a primary patency rate of 68 ± 10% at 1 year in ESRD adults with an internal diameter < 1.6 mm in the radial artery [28]. This study has so far not been considered sufficient to justify the application of microsurgical techniques for this purpose, yet surelly it seems a promising data, and, moreover, it can be superimposed on the results achieved by our study of 67.7% functioning fistulas at 1 year.
On the other hand, excellent results have been obtained in pediatric population for lower arterial diameters (1-1.5 mm) using microsugery associated with preventive hemostasis, by showing a much lower "early failure" rate of 5-10% [29,30].
The latter vessels could very well dilatate and remodel their structure to the same extent as of those vessels of a larger diameter.
Microscopy with fine focus and 20x magnification enables the surgeon to both assess the condition of the intima by checking for intimal tears, atherosclerotic plaques and friable lesions in calcified areas, and to perform a more meticulous and safer anastomosis thanks to a precise handling of vessels, suture positioning and sharp intima-to-intima vessel-wall apposition.
The findings of this study, as to say a mean primary patency rate of 67.7% (21 functioning AVFs out of 31) by choosing vessels smaller than 1.6 mm diameter, suggest that the functional patency rate is high when Microsurgical technique is applied, however a comparative cost-benefit analysis should be conduced for the "microsurgical *vs* conventional approach" to state that Microsurgery is a suitable strategy for AVF placement in patients requiring hemodialysis. Likewise, a wider study combined with a broader learning curve in microsurgical anastomosis could further improve the success rate of the procedure.

CONCLUSIONS

Microsurgery has completely changed the approach to peripheral district vascular procedure and, according to the results of this study, the guidelines concerning the vessel parameters to be respected in order to create a patent AVF have to take in consideration a criteria modification when microsurgical technique is applied in arteriovenous anastomosis. Thanks to the microsurgical approach, very distal small vessels have been chosen to make a nAVF, both preserving the upper arm vessels for an eventually secondary procedure and reducing the complications rate associated to the anastomotic technique.
Safeguarding the vascular heritage, especially in "young adult" patients, is one of the main aims to be achieved, considering that in case of any thrombotic or infectious accidents the preservation of upper arm vessels could allow to set up a new vascular access on still intact vessels. Respecting the vascular setting meanwhile creating a fully functioning fistula in order to perform a good dialysis therapy should be the primary goal for the surgeon, for the sake of bringing the patient to the desired kidney transplant in the best conditions of maximum physical and clinical well-being.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

MP: A, DT, S, W
DP: D, DT

Abbreviations

A: conceived and designed the analysis
D: collected the data

DT: contributed data or analysis tool
S: performed the analysis
W: wrote the paper
O: other contribution (specify contribution in more detail)

Ethical consideration

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.
Written informed consent was obtained from each participant/patient for study participation and data publication.

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