Původní sdělení | Original research article

Evaluation of an effect of profundoplasty on peripheral tissue perfusion in patients with peripheral arterial disease using transcutaneous oximetry

Dominik Maduda, Luboš Kubíček, Katěrina Bílá, Robert Staffa

2nd Department of Surgery, Center for Vascular Diseases, Faculty of Medicine, Masaryk University and St. Anne's University Hospital Brno, Brno, the Czech Republic

ARTICLE INFO

Article history:
Submitted: 8. 4. 2024
Accepted: 19. 8. 2024
Available online: 7. 10. 2024

Klíčová slova:
Ischemická choroba dolních končetin
Profundoplastika
Transkutánní oxymetrie

SOUHRN

Úvod: Arteria profunda femoris (APF) je důležitou tepnou, která v případě postižení arteria femoralis superficialis (AFS) zabezpečuje perfuzi tkání dolní končetiny přes tzv. kolaterální řečiště. Izolovaná angiochirurgická rekonstrukce, plastika APF (profundoplastika), je ve vědecké literatuře diskutovaným tématem, co se týče významu kolaterálního řečiště a jeho přínosu ke zlepšení klinického stavu pacienta. Cílem projektu je zhodnotit dopad izolované profundoplastiky na zlepšení prokrvení dolní končetiny, a tím přispět v rozhodovacím procesu indikace tohoto typu výkonu.
Metodika: Do této prospektivní monocentrické studie byli zahrnuti pacienti se symptomatickou ischemickou chorobou dolních končetin (ICHDK) ve stadiu klaudikačních potíží, klidových bolestí nebo s tkáňovým defektem hodnoceným dle Rutherfordovy klasifikace stupněm 1 až 5. Kritériem pro zařazení byla významná stenóza APF s konkomitantním uzávěrem AFS a insuficientním výtokem pro bypass. S odstupem jednoho a šesti měsíců od výkonu byly hodnoceny změny klaudikačního intervalu, Rutherfordova klasifikace a přítomnost chronické končetinu ohrožující ischemie (CLTI). Měření transkutánní tenze kyslíku ($TcpO_2$) bylo využito k objektivizaci úrovně perfuze a oxygenace tkání.
Výsledky: V průběhu dvou let byla profundoplastika provedena u 45 pacientů – u 23 pacientů klaudikantů a 22 pacientů s CLTI (9 s klidovou bolestí, 13 s ischemickým defektem). Ve skupině klaudikantů došlo k prodloužení klaudikačního intervalu ze 128 m před operací na 505 m po šesti měsících od revaskularizace. Ve skupině CLTI došlo k signifikantnímu zlepšení a vymizení klidových bolestí u všech pacientů, což bylo objektivizováno zlepšením $TcpO_2$ na bérci o 52 % na hodnotu 52 mm Hg a na dorzu chodidla o 143 % na hodnotu 35,8 mm Hg. Ovlivnění osudu těžších forem CLTI jenom izolovanou profundoplastikou je již obtížnější úkol a i tak došlo ke zhojení akrálního ischemického defektu u 61,5 % pacientů s přežitím bez potřeby amputace (amputation free survival) po šesti měsících 76 %, kdy tři pacienti v průběhu sledování podstoupili vysokou amputaci ve stehně. U pacientů s defektem byl pooperačně také pozorován nárůst hodnot $TcpO_2$, kdy na bérci a nártu došlo k 1,3- a 1,6násobnému zvýšení hodnot (na 43 mm Hg, resp. 27 mm Hg).
Závěr: Profundoplastika jako izolovaná procedura revaskularizace pacientů s ICHDK je nadále metodou volby u selektivní skupiny pacientů. Dle naší studie je nejefektivnější k léčbě klidových bolestí nebo k prodloužení klaudikačního intervalu, ale může přispět i k hojení menších akrálních defektů. V literatuře absentující konsenzus na tzv. $TcpO_2$ threshold pro hojení defektů byl naší studií pozorován při hodnotě 27 mm Hg, resp. 35,8 mm Hg pro vymizení klidových bolestí.

ABSTRACT

Introduction: Profunda femoris artery (PFA) is an important artery that provides perfusion of the lower limb tissues via collateral circulation in case of superficial femoral artery (SFA) occlusion. Isolated angiovascular reconstruction, APF reconstruction (profundoplasty), is a debated topic in the scientific literature regarding the importance of collateral circulation and its contribution to improving the patient's clinical condition. This project aims to evaluate the impact of isolated profundoplasty on the improvement of lower limb perfusion and thus to contribute to the decision-making process for the indication of this type of procedure.
Methods: This prospective single-center study enrolled patients with peripheral artery disease (PAD) in the stage of claudication, rest pain or presence of tissue foot ulcer assessed according to Rutherford classification grade 1 to 5. Inclusion criteria were significant AFP stenosis with concomitant AFS closure and no

Address: MUDr. Dominik Maduda, 2nd Department of Surgery, Center for Vascular Diseases, Faculty of Medicine, Masaryk University and St. Anne's University Hospital Brno, Pekařská 664/53, 656 91 Brno, the Czech Republic, e-mail: dominik.maduda@fnusa.cz
DOI: 10.33678/cor.2024.065

Please cite this article as: Maduda D, Kubíček L, Bílá K, Staffa R. Evaluation of an effect of profundoplasty on peripheral tissue perfusion in patients with peripheral arterial disease using transcutaneous oximetry. Cor Vasa 2024;66:474–480.

distal runoff to the feet. Changes in claudication interval, Rutherford classification, and presence of chronic limb-threatening ischemia (CLTI) were assessed at one and six months after surgery. Transcutaneous oxygen tension ($TcpO_2$) was measured to objectify the tissue perfusion and oxygenation level.

Results: During two years, profundoplasty was performed in 45 patients, 23 claudicants, and 22 CLTI patients (9 with rest pain, 13 with foot ulcer). The claudicant group's intermittent claudication interval was prolonged from average 128 metres (m) preoperatively to 505 m six months after revascularization. In the CLTI group, there was a significant improvement and disappearance of rest pain in all patients, which was objectified by an improvement in $TcpO_2$ on the calf by 52% to 52 mmHg and on the dorsum of the foot by 143% to 35.8 mmHg. Controlling the fate of more severe forms of CLTI by isolated profundoplasty alone is already a more difficult task, and even so, healing of the acral ischemic defect occurred in 61.5% of patients with amputation free survival at six months of 76%, with three patients undergoing high amputation in the thigh during follow-up. Postoperatively, an increase in $TcpO_2$ values was also observed in patients with the foot ulcer, with 1.3 and 1.6 times increases in the tibia and calcaneus (to 43 mmHg and 27 mmHg, respectively).

Conclusion: Profundoplasty as an isolated procedure for revascularization of patients with PAD remains the method of choice in a selective group of patients. Our study shows it is the most effective for treating rest pain. However, it may contribute to healing of smaller acral ulcers or prolong the claudication interval. The lack of consensus in the literature on the so-called TcpO2 threshold for defect healing was observed by our study at 27 mmHg and 35.8 mmHg for resolution of rest pain, respectively.

Keywords:
Peripheral artery disease of the legs
Profundoplasty
Transcutaneous oximetry

Introduction

Profunda femoris artery (PFA) is an important artery that provides perfusion to the tissues of the lower limb through the collateral circulation in case of closure of the superficial femoral artery (SFA).[1] With the development of endovascular interventions in the management of PAD, there has been a decline in open surgical procedures. However, in certain cases a simple vascular surgical intervention may be the only hope for limb salvage.[2,3] Profundoplasty is an example of such a procedure. Profundoplasty either alone or as a procedure complementing proximal vascular reconstruction, e.g., with aorto-femoral bypass, is common in vascular surgical practice.

As an isolated vascular surgical intervention, it becomes more important in SFA closure when femoropopliteal bypass is impossible due to poor infrapopliteal outflow.[4] It is a procedure that can be performed even under local anesthesia with low morbidity/mortality and a high technical success rate and is therefore suitable for higher risk patients.[5,6] Profundoplasty can be effective in patients with significantly restrictive claudications but less effective to save the limb, when, on the contrary, arterial reconstruction in the form of distal bypass is often necessary.[7] According to Diehm et al. isolated PFA revascularization is insufficient to promote wound healing. However, it may be a treatment option for patients with critical limb threatening ischemia (CLTI) with rest pain.[6]

Transcutaneous oxygen tension ($TcpO_2$) measurement was used to objectify lower extremity tissue perfusion and oxygenation. Transcutaneous oximetry is a noninvasive method used to determine peripheral tissue perfusion at the capillary level based on measurement of the partial pressure of oxygen diffusing through the skin.[8]

The project aims to evaluate the impact of profundoplasty as an isolated angiosurgical procedure in patients with symptomatic PAD associated with PFA stenosis and SFA closure when distal bypass is not possible due to poor performance of popliteal/tibial arteries.

At the same time, to evaluate the effect of collateral support on the improvement of the patient's clinical complaints both subjectively (claudication and rest pain) and objectively (change in $TcpO_2$ value and change in ischemic skin defect status).

Material and methods

Forty-five patients with PAD who underwent reconstructive surgery in the form of profundoplasty at the 2nd Department of Surgery, St. Anne's University Hospital in Brno participated in this prospective study between January 2022 and December 2023.

All patients with symptomatic PAD at the stage of claudication, rest pain or presence of tissue defect assessed according to Rutherford classification (RC) grade 1 to 5 were included in the study. Patients with RC grade 6 associated with a high rate of mortality and high morbidity were not included in the study because of the low probability of defect healing.[9]

Another inclusion criteria were a significant APP stenosis > 50% with concomitant technically unresolvable stenosis or closure of the AFS and insufficient popliteal/tibial artery outflow when femoropopliteal bypass or endovascular intervention in CLTI patients is with no benefit. We know that in the claudicants group, there is no indication of bypass, even with a possibility of distal runoff.

Patients with concomitant lesions of the pelvic arteries first underwent revascularization in this area (possibly as a hybrid procedure), ensuring the same starting position as patients with isolated involvement of the arteries in the groin.

Prior to the procedure, computed tomography angiography (CTA) was performed in all patients to describe and identify the degree of involvement of the inflow arteries, PFA, SFA, and quality of the tibial outflow. Peripheral angiography was performed to evaluate an outflow in tibial region in cases when it was necessary and when the femoral access was possible.

The study population was divided into two groups, a group of patients with claudications (Rutherford 1–3) and a group of patients with CLTI with subgroups of pa-

tients with rest pain (RC 4) and ischemic acral defect (RC 5). In the claudicant group, the change in claudication interval and the degree of difficulty according to RC were evaluated. The second group evaluated CLTI symptomatology (change in rest pain, presence/healing of defect) with change in Rutherford classification scores. Clinical success was considered to be either the elimination of rest pain or complete healing of the ischemic defect, thus improving the RC grade by at least one grade, or more than 2 grades in the case of patients with a defect. Amputation-free survival was defined as the follow-up period without amputation above the ankle. All data were statistically processed using Statistica 14 software (StatSoft Inc., USA). T-test was used for data with parametric distribution to calculate statistical significance (p-value <0.05 was considered statistically significant) for changes in claudication interval, changes in the presence of CLTI and RC.

As an auxiliary method to objectify the level of perfusion and oxygenation of lower limb tissues, the determination of transcutaneous oxygen tension was used.

Follow-up

Patients indicated for profundoplasty were evaluated for clinical findings, a detailed medical history was taken and $TcpO_2$ was measured at two sites in the infrapopliteal region before the procedure. Further follow-up was performed 1 and 6 months after the surgery, when the clinical findings and $TcpO_2$ measurements were assessed again (the position of both electrodes remained the same during the study to ensure data validity). Ultrasound or CTA was performed in only a few patients with clinical deterioration.

Transcutaneous oxygen tension

It is a non-invasive method in which adhesive electrodes are applied to the skin. According to the pressure gradient, oxygen diffusion occurs between tissue capillaries and the electrode membrane through the avascular layer of the epidermis. The electrodes heat the surrounding skin, creating local hyperemia and thus facilitating oxygen diffusion. The device then records the $TcpO_2$ (partial pressure of oxygen) value in mmHg.[10,11] According to several studies, it is evident that TcpO2 values correlate with increasing skin ischemia,[12] with physiological values independent of electrode position being approximately 60 mmHg[13] and values associated with inadequate tissue blood supply with non-healing wounds being represented by heterogeneous values of 20–40 mmHg.[12,14–16] The optimal $TcpO_2$ cut off point for wound healing has not yet been accurately determined due to the heterogeneity of study results.[16]

Our study used a Radiometer TCM400 device with two electrodes to measure $TcpO_2$ (**Fig. 1**). Currently, there is no precise recommendation for electrode placement.[17] Electrode placement was performed at two sites in the infrapopliteal area with one electrode on the dorsum of the foot and the other electrode on the anterolateral edge of the calf muscles about 10 cm below the knee (**Fig. 2**). The patient was in a supine position during the examination. After calibration of the device followed by placing the electrodes on the patient's skin, the electrodes were heated to 45 °C and after 10 min of measurement, the pO_2 value in mmHg was read.

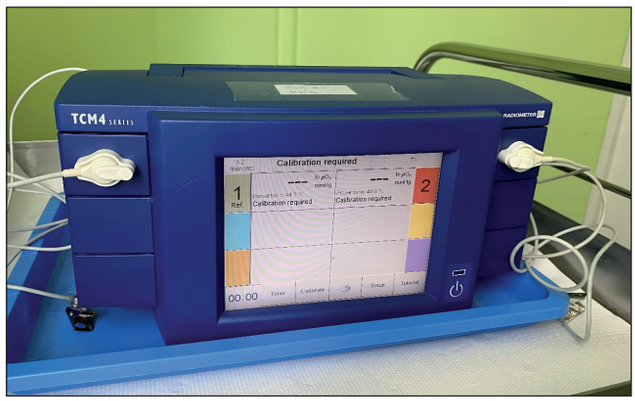

Fig. 1 – Radiometer TCM400 monitor is a portable unit providing measurements of transcutaneous oxygen tension ($TcpO_2$).

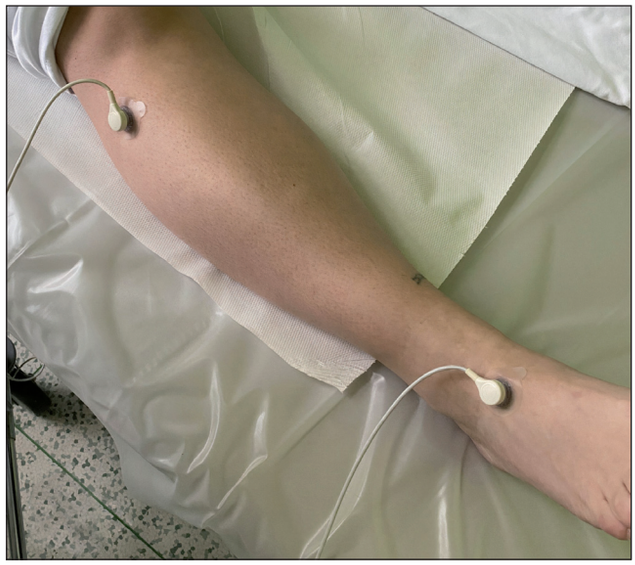

Fig. 2 – Position of electrodes during the measurement – one electrode on the dorsum of the foot and the other electrode on the anterolateral edge of the calf muscles.

Procedure

Under general or epidural anesthesia, a longitudinal groin incision was performed, followed by preparation of the CFA, SFA, and PFA. Longitudinal arteriotomy starts from the CFA to the healthy parts of the PFA. Subsequently, endarterectomy was performed and closure of the artery with a patch of artificial or autologous material in the form of vena saphena magna (VSM) or desobliterated SFA artery. The concomitant iliac stenosis (if present) was

addressed at the same time by an endovascular hybrid procedure.

Postoperative therapy included aggressive lipid lowering therapy with management of diabetes mellitus (if present) and dual antiplatelet therapy (acetylsalicylic acid [ASA] 100 mg and clopidogrel 75 mg daily) for three months, followed by ASA alone for life.

Demographics

Forty-five patients with PAD were included in the study, 23 claudicants (RC 1–3) and 22 CLTI patients, including 9 patients with rest pain (RC 4) and 13 patients with peripheral skin defect (RC 5). In the CLTI group, there was a more significant representation of patients with DM, 45% versus 30% representation in claudicants (p = 0,3). Ischemic heart disease, with its most severe form in the form of myocardial infarction, also dominated the CLTI group. There was a higher representation of patients with a history of smoking in the milder form of PAD group.

Twenty-three patients were managed as a hybrid procedure (pelvic artery PTA + profundoplasty). The most common patch form was artificial prosthetic material – polyester-urethane Vascular-Patch (B. Braun Medical Ltd, UK) in 20 patients. Seven patients were treated with bovine XenoSure patch (LeMaitre Vascular, Inc., USA), and 18 autologous grafts with VSM or AFS patch were used mostly in patients with CLTI. The choice of patch material was always up to the surgeon's preference and clinical situation (**Table 1**).

Table 1 – Demographics and clinical characteristics

Characteristics	Claudicants (RC 1–3)	CLTI (RC 4–5)	*P*-value
Number of patients (n)	23	22 (9–13)	
Age (mean, SD)	69 ± 7.9	73 ± 6.9	0.07
BMI (mean)	28.6	28.4	0.87
Male gender (%)	82	69	0.27
DM (%)	30	45	0.3
Hyperlipidemia (%)	86.9	91	0.7
IHD (%)	26	50	0.1
MI (%)	17	32	0.3
Hypertension (%)	96	100	0.33
Renal insufficiency (%)	4	14	0.28
Smoking (%)	83	59	0.08
Hybrid procedure (%)	57	45	0.46
Patch type (%)			
Protetic	65	23	
Bovine	9	23	
Autolog	26	54	

BMI – body mass index; DM – diabetes mellitus; IHD – ischemic heart disease; MI – myocardial infarction; SD – standard deviation; smoking – former or active smoker.
Hybrid procedure (PTA of iliac artery + profundoplasty).

Results

APF revascularization was performed in all patients with 100% technical success with 0% mortality throughout the study. Forty-five surgical procedures in the form of profundoplasty were performed for 23 patients with claudications and 22 patients with CLTI. Concomitant pelvic artery stenosis was managed by a hybrid procedure in 23 patients (13 patients in RC 1–3 and 10 patients in RC 4–5) (**Table 2**).

Surgical wound healing was complicated in 8 patients due to surgical wound infection (Szilagiy grade – I [3 times], grade II [5 times]). Infection of deep structures with fascia disruption did not occur. All wounds were healed ad integrum by local and negative pressure therapy (Vivano Tec), 5 patients even by administration of i.v. antibiotics.

Claudicants group (RC 1–3)

The initial mean length of the claudication interval was 128 m, which corresponded to a mean RC classification of 2.15. At one month after the procedure, the mean claudication interval increased to 410 m and at six months to 505 m (absolute increase of 377 m on average, 3.94 times the initial value, p = 0.00005). Patients evaluated postoperatively as asymptomatic were excluded from the claudication interval assessment.

Rutherford's class improved by 0.65 points (from an initial value of 2.15) to 1.5 points at one month to a final value of 1 point at six months (p = 0.0000045).

The initial $TcpO_2$ value averaged 39.6 mmHg at the calf and 20.3 mmHg at the dorsum of the foot. After six months, the calf value improved to 51 mmHg – a 28% improvement (p = 0.0006), but the significant increase in values occurred mainly at the periphery of the limb, with values at the dorsum of the foot showing an overall improvement of 79% with a mean value of 36.5 mmHg (p = 0.00038). This increase in values clearly indicates improved tissue perfusion in correlation with subjective prolongation of the claudication interval with a positive change in RC.

During follow-up, a MALE (major adverse limb event) occurred in two patients, both with early closure of the iliac artery; one patient resolved with PTA, the other with implantation of an iliac-femoral bypass. Complicated healing in surgical site in the groin occurred in three patients with Silagyi grade of infection – one time grade I, two times grade II. In one patient, subjective discomfort worsened during follow-up with shortening of the claudication interval (patient who underwent reoperation with implantation of ilic-femoral bypass). Three patients got lost to follow-up.

CLTI group (RC 4–5)

Subgroup RC 4

Out of nine patients with rest pain two got lost to follow-up. Significant clinical improvement was observed in all remaining seven patients with rest pain (RC 4), with all patients experiencing resolution of rest pain and an improvement in RC by a mean of 3 points (p = 0.0002).

Table 2 – Procedure outcomes

	Claudicants (RC 1–3): n = 23				Rest pain group (RC 4): n = 9				Tissue loss group (RC 5): n = 13			
Follow-up – months	0	1	6	*P*-value	0	1	6	*P*-value	0	1	6	*P*-value
Intemittent claudation (m)	128	410	505	< 0,0001	–	–	–	–	–	–	–	–
RC	2.15	1.5	1	< 0.0001	4	1.28	1	0.0002	5	3.3	2.1	0.0008
$TcpO_2$ (mmHg)												
Calf	39.6	45.9	51	0.0006	34	51.7	52	0.0005	32.5	40.4	43	0.016
Dorsum of the foot	20.3	28.35	36.5	0.0003	14.7	36.2	35.8	0.001	17.4	23.5	27.7	0.007
MALE (n)	2				0				1			
Groin infection (n)	Szilagyi I			1	Szilagyi I		1		Szilagyi I		1	
	Szilagyi II			2	Szilagyi II		1		Szilagyi II		2	
Amputation free survival (%)	1 month			6 months	1 month		6 months		1 month		6 months	
	100			100	100		100		92		76	
Lost to follow-up (n)	3				2				0			

Data are presented as mean.
m – metres; MALE – major adverse limb event – referred to major amputation above the ankle level or reintervention in one month after the procedure; RC – Rutherford classification; $TcpO_2$ – transcutaneous oxygen pressure.

Table 3 – Characteristics of $TcpO_2$ in patients with limb loss

	Time to amputation	$TcpO_2$ of calf (mmHg)	$TcpO_2$ of dorsum of the foot (mmHg)	Reasons for amputation
Patient	One month	20	6	Rest pain, progression of gangrene
Patient	Three month	40	20	Septic shock
Patient	Six months	39	5	Rest pain, progression of gangrene

Time to amputation after the procedure, $TcpO_2$ – transcuatenous oximetry mean data before amputation.

$TcpO_2$ values indicated an immediate increase in values postoperatively at both the tibia and dorsum of the foot. After six months, we observed a 52% increase in $TcpO_2$ at the tibia to a value of 52 mmHg (p = 0.0005) and a 143% increase at the dorsi of the foot to a value of 35.8 mmHg (p = 0.001).

Subgroup RC 5

In the group of 13 patients with an acral defect, eight patients experienced healing of the defect during follow-up, assessed as a positive effect of the procedure in 61.5% of patients. There was a significant clinical improvement from the initial RC 5 score to 2.1 points in RC (p = 0.0008). One patient with a healed defect with the absence of claudication jumped straight to the asymptomatic RC 0 category, which may be influenced by the presence of neuropathy in the diabetic patient. In two cases, CLTI with the defect persisted until the end of follow-up. This group was also the only one to observe an incidence of above-knee amputation (AKA), which was observed in three patients (**Table 3**).

When $TcpO_2$ was measured six months after surgery, a 1.3-fold increase in calf values from the initial mean of 32.5 mmHg to 43 mmHg was measured (p = 0.016). A slightly higher value increase was observed at the dorsum of the foot by 1.6 times from 17.4 mmHg to 27.7 mmHg (p = 0. 007).

Follow-up of CLTI patients resulted in 85% amputation-free survival at six months after surgery. Amputation-free survival in patients with tissue loss was 92% and 76% at one month and six months, respectively. Patients with rest pain did not undergo the amputation procedure. Two patients with persistent acral defect refused the amputation procedure. An overall positive effect of the procedure in CLTI patients at six months (resolution of rest pain or healing of the defect) was observed in 75% of cases. Two patients in the CLTI group got lost to follow-up.

Discussion

In the cases of patients with intermittent claudication problems, the procedure significantly prolonged the claudication interval from an initial mean value of 128 m to a value of 505 m six months after surgery and improved Rutherford classification from an initial value of 2.15 to a final value of 1. Although the changes in the RC were

statistically significant, it is necessary to clarify that the RC has a wide range of individual grades (200 m); thus, even a slight improvement in one case may have the same effect on the shift in the RC as a more significant improvement in another case, thus we consider the assessment of the change in the claudication interval value as a more objective parameter for perfusion assessment.

$TcpO_2$ measurements in this group showed an overall improvement in mmHg values compared to the starting position of 28% at the calf (51 mmHg) and 79% at the dorsum of the foot (36.5 mmHg). This increase in values clearly indicates improved tissue perfusion in correlation with subjective prolongation of the claudication interval leading to a positive change in RC. These results suggest that profundoplasty may be an effective treatment modality for patients with milder forms of lower limb ischemic disease who are unable to undergo other forms of infrainguinal vascular reconstruction.

The disappearance of rest pain or healing of the defect was considered a treatment success in the CLTI patient group. A comparison of claudication intervals in this category is not meaningful because patients are usually limited in walking due to the presence of a skin defect or rest pain. In this study, we observed post revascularization clinical improvements in both subgroups of CLTI patients (RC 4, RC 5).

In patients with rest pain, resolution of CLTI symptoms was observed in 100% of cases, with an improvement in RC to a mean value of 1 with statistical significance ($p = 0.0002$), a large change may be influenced by diabetic neuropathy which is explained further. In correlation with the subjective improvement, there was an increase in $TcpO_2$ measurements, with a mean increase in calf values of 52% to 52 mmHg, but more significant was the 143% increase in dorsal foot values to 35.8 mmHg ($p = 0.001$).

The subgroup of patients with skin defects also showed a positive effect of the procedure, with 61.5% of patients (8/13 patients with healed defects). The mean value in the RC classification also improved significantly to 2.1 points in the RC ($p = 0.0008$). Mean $TcpO_2$ values showed a 1.3--fold increase in tibia to 43 mmHg ($p = 0.016$) and dorsum of the foot by 1.6-fold to 27.7 mmHg ($p = 0.007$). The increase is not as significant as in the rest pain group, probably related to the more advanced atherosclerotic findings of the tibial arteries in the higher CLTI class.

As expected, the incidence of major amputation was highest in the subgroup of patients with a skin defect. The mean $TcpO_2$ values at the calf and dorsum at the time just before amputation were 33 mmHg and 10.33 mmHg, respectively, which are lower values compared to patients with a healed defect (43 mmHg with $p = 0,07$, 27,7 mmHg with $p = 0,03$). Any of the patients with rest pain did not undergo the amputation procedure after revascularization. Follow-up of CLTI patients resulted in a 76% amputation-free survival rate at six months after profundoplasty in patients with tissue loss.

The diagnosis of CLTI is associated with a poor prognosis for limb salvage and patient survival. In cases where effective revascularization of the compromised limb has failed or is not possible, the incidence of AKA increases by more than 40% in the first year and the risk of death by approximately 20%,[18,19] with deaths associated with complications of AKA ranging from 62–78% in the first year.[20] The primary mechanism for reversing these consequences is revascularization. According to studies, isolated profundoplasty is an inadequate tool to prevent major amputation because of the almost always certain need for distal bypass surgery in CLTI patients.[5] In cases where distal bypass surgery or other reconstruction is not possible, profundoplasty may be considered as a ultimum refugium. The results of this study suggest that profundoplasty is an effective treatment for patients with lower limb ischemic disease who have occlusion of the SFA and stenosis of the PFA with no distal runoff to the feet. In claudicants with SFA closure, it has positive effects on prolonging the claudication interval. In patients with CLTI, it may contribute to the relief of rest pain, where the most significant effect has been observed; in some cases, it may also contribute to the healing of peripheral skin defects. In cases of significant loss of skin integrity with ischemia in patients in RC class 6, isolated profundoplasty may not be sufficient to heal the defect as described in studies (Savolainen and Diehm). Therefore, our study did not evaluate patients with the most advanced stage of CLTI.

Way Lam Yip's review highlights the ongoing controversy about the validity and reliability of transcutaneous oximetry.[21] However, according to other studies, $TcpO_2$ measurement may have a predictive value in the healing of ischemic and diabetic ulcerations,[22] predicting the risk of amputation or healing of the amputation stump in patients with PAD. Consensus on the exact $TcpO_2$ value that guarantees wound healing has not yet been established.[16]

Limitations

However, it is essential to note that this study has several limitations. One of these limitations is the limited number of patients and the other one is short-term follow-up, when two patients with persistent CLTI may also have developed proximal limb amputation in a short time frame. Another exemplary factor reducing the validity of assessing changes in Rutherford classification may be the 45% prevalence of diabetes in CLTI patients, which is associated with diabetic neuropathy, a risk factor for skin defect development, but may also bias patients' subjective complaints, such as claudication interval. A patient with a cutaneous defect, rated as RC 5, may jump straight to the asymptomatic patient class RC 0 (inability to perceive claudication due to neuropathy) after healing of the defect.

More extensive studies with longer follow-up could provide further information on the long-term results of profundoplasty and on potential complications. Further studies should also examine factors that may influence the efficacy of profundoplasty, such as lifestyle factors, comorbid conditions, and lesion characteristics of the arteries. Overall, this study's results support the use of profundoplasty as an effective surgical procedure for treating lower extremity ischemic disease in a selected group of patients. However, further research is needed to confirm these findings further and assess the long-term outcomes and complications of this procedure.

Conclusion

The results of this study suggest that profundoplasty remains an effective treatment modality in a selected group of PAD patients with PFA stenosis and concomitant SFA closure while being without distal outflow for eventual bypass grafting (or not indicated for a distal grafting in the case of claudicants). Claudicants with SFA closure showed positive effects of the procedure on claudication interval prolongation. In CLTI patient cases, acral defect healing was achieved in 61.5% of patients, but the greatest effect was observed in the treatment of rest pain. Even if there is still a lack of consensus in the literature on the so-called "$TcpO_2$ threshold", according to data observed in our study we would suggest the threshold for defect healing at 27mmHg and 35.8 mmHg for resolution of rest pain, respectively.

Conflict of interest

The authors declare that there are no conflicts of interest.

Funding

This work was carried out at St. Anne's University Hospital Brno, supported with local hospital grant in 2022–2023 with evidence number IIT/2022/03.

Ethical statement

The local ethics committee at St. Anne's Hospital in Brno granted consent for the study and all participating patients signed informed consent.

References

1. Morris GC Jr, Edwards E, Cooley DA, et al. Surgical importance of profunda femoris artery. Analysis of 102 cases with combined aortoiliac and femoropopliteal occlusive disease treated by revascularization of deep femoral artery. Arch Surg 1961;82:32–37.
2. Guez D, Hansberry DR, Gonsalves CF, et al. Recent Trends in Endovascular and Surgical Treatment of Peripheral Arterial Disease in the Medicare Population. AJR Am J Roentgenol 2020;214:962–966.
3. Desoky HF, Zied SA, Karmota AG. Limb saving by profundoplasty in patients with no distal runoff. Egypt J Surg 2020;39:313–316.
4. Totolici B, Alexa M, Ciurdariu D. Profundoplasty – a solution for distal revascularization. Jurnal Med Aradean 2010;XIII:67–70.
5. Taurino M, Persiani F, Ficarelli R, et al. The Role of the Profundoplasty in the Modern Management of Patient with Peripheral Vascular Disease. Ann Vasc Surg 2017;45:16–21.
6. Diehm N, Savolainen H, Mahler F, et al. Does deep femoral artery revascularization as an isolated procedure play a role in chronic critical limb ischemia? J Endovasc Ther 2004;11:119–124.
7. Towne JB, Rollins DL. Profundaplasty: its role in limb salvage. Surg Clin North Am 1986;66:403–414.
8. Fife CE, Smart DR, Sheffield PJ, et al. Transcutaneous oximetry in clinical practice: consensus statements from an expert panel based on evidence. Undersea Hyperb Med 2009;36:43–53.
9. Lee RE, Patel A, Soon SXY, et al. One year clinical outcomes of Rutherford 6 chronic limb threatening ischemia patients undergoing lower limb endovascular revascularisation from Singapore. CVIR Endovasc 2022;5:32.
10. Vesterager P. Transcutaneous pO_2 electrode. Scand J Clin Lab Invest Suppl 1977;146:27–30.
11. Huch R, Huch A, Lübbers DW. Transcutaneous measurement of blood Po2 (tcPo2) – Method and application in perinatal medicine. J Perinat Med 1973;1:183–191.
12. Dowd GS, Linge K, Bentley G. Measurement of transcutaneous oxygen pressure in normal and ischaemic skin. J Bone Joint Surg Br 1983;65:79–83.
13. Zierler R, Sumner D. Physiologic assessment of peripheral arterial occlusive disease. In: Rutherford R (ed.). Vascular surgery, 3rd edition. Philadelphia: WB Saunders, 1999:140–163.
14. Burgess EM, Matsen FA 3rd, Wyss CR, et al. Segmental transcutaneous measurements of PO_2 in patients requiring below-the-knee amputation for peripheral vascular insufficiency. J Bone Joint Surg Am 1982;64:378–382.
15. Ratliff DA, Clyne CA, Chant AD, et al. Prediction of amputation wound healing: the role of transcutaneous pO_2 assessment. Br J Surg 1984;71:219–222.
16. Catella J, Long A, Mazzolai L. What Is Currently the Role of $TcPO_2$ in the Choice of the Amputation Level of Lower Limbs? A Comprehensive Review. J Clin Med 2021;10:1413.
17. López-Moral M, García-Madrid M, Molines-Barroso RJ, et al. Analyses of transcutaneous oxygen pressure values stratified for foot angiosomes to predict diabetic foot ulcer healing. J Tissue Viability 2023;32:480–486.
18. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007;45(Suppl S):S5–S67.
19. Barani J, Mattiasson I, Lindblad B, et al. Suboptimal treatment of risk factor for atherosclerosis in critical limb ischemia. Int Angiol 2005;24:59–63.
20. Ploeg AJ, Lardenoye JW, Vrancken Peeters MP, et al. Contemporary series of morbidity and mortality after lower limb amputation. Eur J Vasc Endovasc Surg 2005;29:633–637.
21. Yip WL. Evaluation of the clinimetrics of transcutaneous oxygen measurement and its application in wound care. Int Wound J 2015;12:625–629.
22. Leenstra B, de Kleijn R, Kuppens G, et al. Photo-Optical Transcutaneous Oxygen Tension Measurement Is of Added Value to Predict Diabetic Foot Ulcer Healing: An Observational Study. J Clin Med 2020;9:E3291.