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Original Article

Hybrid Revascularization for Chronic Limb-Threatening Ischemia in Diabetic Patients

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Abstract

Chronic Limb-threatening Ischemia (CLTI) is a massive challenge in terms of revascularization for vascular surgeons. In this article, we studied the hybrid surgical method including open and endovascular surgery in diabetic patients with CLTI. In this prospective study, all the diabetic patients who refer to Golestan Hospital, Center of Vascular Surgery in the South of Iran, because of CLTI were added to this study. Patients were divided into three groups: open surgery, hybrid and angiography. Ischemia and lower limb ulcers were evaluated for all patients. Among 33 participants in the study, 13 were women (39.4%) and 20 were men (60.6%). Age range of participants was 47 to 90 years. The rate of gangrene`s outbreak in three different methods of surgery was: open surgery 7(70%), hybrid 6(67%), and angiography 7 (50%) (P=0.558). The rate of bleeding was: mild 13 (39.4%), moderate 15(45.45%), and severe 5(15.15%). Patients who underwent hybrid surgery, in compare to other two groups, in terms of infected lower limb had better healing process. Angiography in healing ulcer and ischemia grade has a short-term effect while hybrid surgery and open surgery has long-term effect. In the one-month-follow-up after operation the number of patients who needed minor amputation in those who underwent hybrid surgery was higher. For reaching better results in terms of amputation, more studies are required.

Keywords: Diabetes Mellitus, Ulcer, Revascularization, Hybrid surgery, Open surgery, Angiography

Introduction

Diabetes is one of the chronic illnesses which in the recent decades the number of diabetic patients has increased incredibly [1]. Diabetic patients suffering Chronic Limb-threatening Ischemia (CLTI) make a high-risk subset of diabetic foot ulceration (DFU) with prognosis [2]. After diagnosing diabetes mellitus, progress towards amputation, foot ulcer, and infection happens [1]. It has been predicted that this subset`s burden on the health care system and treatment staff to improve life expectancy, population aging, and diabetes contagion throughout the world, would incredibly increase [2].

Managing diabetic patients suffering diabetes mellitus and CLTI, considering side-along ailments and Anatomical pattern of distal atherosclerotic vascular disease is really challenging [3-6]. Existence of diabetic arteriopathy due to the body ischemic situation obstacles ulcer`s curing [1]. It has been estimated that up to 25% of the diabetic patients suffers foot ulcer and 15 to 30 times more than non-diabetic patients they are exposed to amputation [7-9]. Although many of diabetic patients suffer Femoropopliteal arteries, Tibial artery bypass can be an appropriate option for revascularization and saving the body part [10, 11]. Through restoration of coronary blood flow in lower-limbs, we can remove ischemia, the most important reason of diabetic foot ulcer [1]. CLTI is a massive challenge in terms of revascularization for vascular surgeons and the treatment`s aim, is a united method which leads to an excellent technical result without any side effects or any more involvements [12]. In hybrid reconstructions, patients in different levels by using endovascular and open revascularization method simultaneously, are often cured. In recent years, these methods have been used a lot, especially by vascular surgeons, because they are master in doing open surgery and endovascular. Hybrid methods are better methods for patients with many side-long ailments and recently have been preferred when needed. Less side effects and deaths, and also reduction in the

Figure 1. Elimination of popliteal artery stenosis with balloon angioplasty

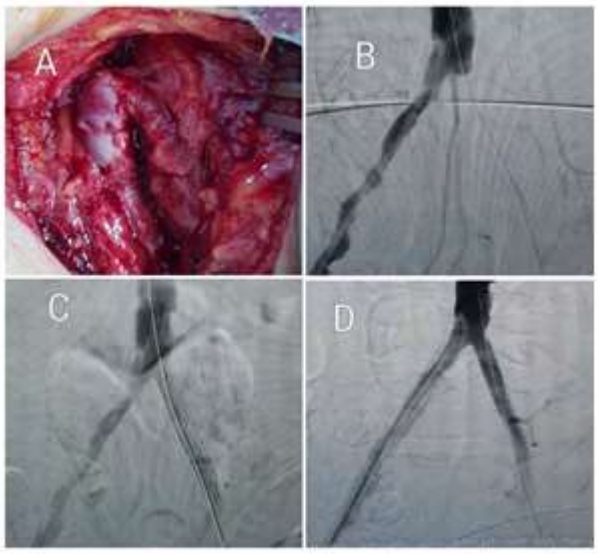

Figure 2. Hybrid surgery in a diabetic patient with bilateral lameness and nocturnal pain. (A) left femoral artery endartectomy, (B) then left common iliac artery stenting, (C) then right common iliac artery balloon angioplasty (D) finally re-angiography of the arteries, and (A) closure of the endarterectomy site with Safen vein patch.

convalescence and staying in hospital and especial caring are other advantages of this less-aggressive method. Therefore, in this article, we studied the hybrid surgical method including open and endovascular surgery in diabetic patients with CLTI.

Materials and Methods

In this prospective study, all the diabetic patients who refer to Golestan Hospital, Center of Vascular Surgery in the South of Iran, because of CLTI were added to this study. Signed informed consent was obtained from all patients. There is no age limitation in this study (Ethical code: IR.AJUMS.HGOLESTAN.REC.1400.009).

Patients were classified into three groups: For the first group a compound of open and endovascular surgeries (the hybrid group) was done (Figure 1). For all the patients with hybrid surgery method an endarterectomy surgery of common femoral artery (CFA) was performed. For the second group an open surgery in the form of bypass with a large saphenous vein or with a polytetrafluoroethylene (PTFE) graft (bypass group) was done (Figure 2). For the third group an endovascular surgery which included stenting and setting balloon angioplasty was performed.

Medical history of all the patients beside their side-long ailments were asked. Some factors such as smoking, heart disease, blood pressure, dyslipidemia, kidney problems were concerned. For all the patients who had not done contraindication for computed tomography angiography (CTA), we did Chest arteries, stomach, hip, and lower limbs CTA. In cases which the amount of creatinine was more than 1.5, after consulting with nephrologist, creatinine modifications according to the especial protocols for CTA patients were done. This protocol consists hydrating patient with 0.9% saline and a bicarbonate vial in every liter of liquid he/she receives (maximum of 3 vials in every 24 hours) before and after CTA. Patients in terms of nephropathy resulting from contrast were checked again for creatinine in the next 72 hours. If their creatinine was over 1.5, it would be followed up in terms of nephropathy resulting from contrast for the next 14 days.

Owing to the Covid-19 pandemic, in this study patients were checked for this illness, too. Because Covid-19 causes massive vasculitis which increases the vastness and intensity of vascular involvement.

Every earlier documents of each patient including former surgeries, sonographies, CT scans, and other experiments were re-analyzed. For every patient ischemic examination and checking ulcers in limbs were done. According to Global Anatomic Staging System (GLASS) the level of vascular anatomic involvement for each patient was determined [13]. Ankle Brachial Index (ABI) was used for measuring vascular involvement [14]. Every patient`s ulcer was graded by means of WIFI and all the patients of the

Figure 3. A diabetic patient with ischemia and severe ulcers who had been referred to a hospital clinic.

Figure 4. A diabetic patient with gangrene in the Forefoot area who was referred to the hospital emergency department

study were studied through WIFI>2. The chronic ischemic stage of body was analyzed and determined based on Rutherford. Ischemia and severe ulceration of a diabetic patient referred to a hospital clinic are shown in Figure 3. TASC segmentation was used to measure losses. Pain intensity was analyzed according to Pain Scale Chart.

The levels of amputation were classified into Minor (Forefoot amputation>) and Major (Forefoot amputations<). Figure 4 shows the gangrene of the Forefoot area in a diabetic patient who was referred to a hospital emergency department. The amount of bleeding in the surgery was classified into three groups named Without Bleeding (200 cc>), Low Bleeding (200-1000 cc) and Heavy Bleeding (100cc<).

Descriptive statistical methods were used to describe the variables in order to analyze the data. Independent t-test and analysis of variance were used to analyze the data if the SS score was normal; otherwise, the Mann-Whithney and Kruskal-Wallis nonparametric tests were used. Chi-square test was used to evaluate the association between esophageal varices and SS and other variables. Data analysis was performed using SPSS Ver 22.

Results

Among 33 participants in the study, 13 were women (39.4%) and 20 were men (60.6%). Age range of participants was 47 to 90 years with the average of 64±9.486. According to the patients` conditions, 10 had open surgery (30.3%), 9 underwent hybrid surgery (27.3%), and 14 (42.4%) experienced angiography. The age average of these three groups in order were 63.10±13.16, 67.44±8.87, and 61±7.14 (table 1).

Clinical examination of the patients showed that 60.6% of the patients suffered gangrene. The rate of gangrene`s outbreak in three different methods of surgery was: open surgery 7(70%), hybrid 6(67%), and angiography 7 (50%) (P=0.558). The rate of bleeding was: mild 13 (39.4%), moderate 15(45.45%), and severe 5(15.15%). Analyzing the intensity of outbreak of lower limb ulcer in the patients showed that mild, moderate, and severe intensity in them before operation in order were 13 (39.4%), 8 (24.24%), and 6 (18.18%), respectively.

Other clinical factors of the patients such as amputation abundance which was analyzed before surgery was 9 (27.7%) and was minor. 14 (42.4%) patients also had rest pain. The rate of ischemia before operation was 2 and 3 which each one in order had 21 (36.64%) and 12 (36.36%) abundance. Before operation, the patients` quality of life was classified into three groups of mild, moderate, and severe which in order had 3 (9.1%), 14 (42.42%), and 16 (48.48%) abundance. Also analyzing ABI indicated that the abundance of grade 0, 1, 2, and 3 before surgery in all the patients in order was 2 (6.07%), 5(15.15%), 12(36.36%), and 14 (42.42%). Modifications which

Table 1. Frequency of Gangrene, Bleeding, Foot Ulcer and Wound Healing in patients

Variables			Groups			P-Value
			Open Surgery (n=10)	Hybrid Surgery (n=9)	Angiography (n=14)	
Age, mean± SD			13.16 ± 63.1	8.87 ± 67.44	7.14 ± 61.00	
Gangrene, n (%)			7 (70%)	6 (67%)	7 (50%)	0.558
Bleeding, n(%)	Mild		1 (10%)	1 (11%)	11 (78%)	0.001
	Moderate		4 (40%)	8 (89%)	3 (22%)	
	Severe		5 (50%)	0	0	
Foot Ulcer, n(%)	Before Surgery	No	2 (20%)	1 (11.1%)	3 (21.4%)	0.355
		Mild	4 (40%)	2 (22.2%)	7 (50%)	
		Moderate	2 (20%)	4 (44.5%)	2 (14.3%)	
		Severe	2 (20%)	2 (22.2%)	2 (14.3%)	
	1 month after Surgery	No	2 (20%)	2 (22.2%)	3 (21.4%)	0.001
		Mild	3 (30%)	3 (33.4%)	4 (28.6%)	
		Moderate	4 (40%)	2 (22.2%)	5 (35.7%)	
		Severe	1 (10%)	2 (22.2%)	2 (14.3%)	
Wound Healing, n(%)	1 month after Surgery	Whole Healing	1 (10%)	0	2 (14.2%)	0.02
		Heal Edges	1 (10%)	3 (33.4%)	4 (28.6%)	
		No change	5 (50%)	1 (11.1%)	4 (28.6%)	
		Worse	3 (30%)	5 (55.5%)	4 (28.6%)	
	3 month after Surgery	Whole Healing	2 (20%)	1 (11.1%)	2 (14.3%)	0.507
		Heal Edges	2 (20%)	4 (44.4%)	4 (28.6%)	
		No change	3 (30%)	1 (11.1%)	6 (42.8%)	
		Worse	2 (20%)	3 (33.4%)	2 (14.3%)	
	6 month after Surgery	Whole Healing	2 (20%)	2 (22.2%)	1 (14.2%)	0.109
		Heal Edges	4 (40%)	5 (55.5%)	4 (28.6%)	
		No change	1 (10%)	2 (22.2%)	7 (50%)	
		Worse	1 (10%)	0	2 (14.2%)	

were done after operation are shown under three groups in table 2.

Discussion

Patients suffering CLTI usually need revascularization in different parts of their body [15]. Because of multilevel disease, especially in CLTI patients, often in iliac as well as the femoral arteries and in a large amount is required in infrapopliteal [16-19]. In the recent years, applying vascular hybrid methods has increased [16]. Our goal is analyzing the consequence of hybrid interferences including open and endovascular surgeries in patients suffering CLTI.

This study indicates that the amount of bleeding in open surgery is significantly more than two other surgery methods. In hybrid surgery, the amount of bleeding is mild and in angiography it is so minor. This difference had been predicted and is in a direct relation to the method of surgery and cutting.

Through analyzing the intensity of lower limb ulcer in the patients both before operation and one month after that, we found out that those who underwent hybrid surgery, cured better than those who were operated by the other two surgery methods. They shifted from "moderate" and "severe" to "mild" and "no". Whereas, lower limb ulcer in other patients who underwent other methods of surgery shifted from "mild" to "moderate". Also, following up patients` ulcer curing one month after the operation realized that, angiography had the best result in it and significantly its patients of "whole healing" and "heal edges" were more than other two methods. After three-month-follow-up and six-month-follow-up it was understood that those who underwent hybrid surgery and open surgery cured better and in the

Table 2. Clinical variables before and after surgery

Variables	Groups		Before Surgery	1 month after surgery	3 month after surgery	6 month after surgery
Amputation, n(%)	**Open Surgery (n=10)**	No	8 (80%)	7 (70%)	5 (50%)	4 (40%)
		Minor	2 (20%)	2 (20%)	2 (20%)	2 (20%)
		Major	0	1 (10%)	3 (30%)	4 (40%)
	Hybrid Surgery (n=9)	No	6 (66.4%)	3 (33.3%)	3 (33.3%)	3 (33.3%)
		Minor	3 (33.3%)	5 (55.5%)	4 (44.4%)	4 (44.4%)
		Major	0	1 (11.1%)	2 (22.2%)	2 (22.2%)
	Angiography (n=14)	No	9 (64.2%)	9 (64.2%)	9 (64.2%)	8 (57.1%)
		Minor	4 (28.5%)	4 (28.5%)	4 (28.5%)	4 (28.5%)
		Major	0	1 (7.3%)	1 (7.3%)	2 (14.2%)
	P-Value		0.414	0.03	0.09	0.269
Rest Pain, n(%)	**Open Surgery (n=10)**		4 (40%)	7 (70%)	4 (40%)	3 (30%)
	Hybrid Surgery (n=9)		5 (55.5%)	5 (55.5%)	5 (55.5%)	5 (55.5%)
	Angiography (n=14)		5 (53.7%)	8 (57.2%)	7 (50%)	7 (50%)
	P-Value		0.104	0.530	0.530	0.878
Ischemi, n(%)	**Open Surgery (n=10)**	Grade 0	0	1 (10%)	1 (10%)	1 (10%)
		Grade 1	0	1 (10%)	2 (20%)	3 (30%)
		Grade 2	4 (40%)	5 (50%)	4 (40%)	4 (40%)
		Grade 3	6 (60%)	3 (30%)	3 (30%)	2 (20%)
	Hybrid Surgery (n=9)	Grade 0	0	0	0	0
		Grade 1	0	2 (22.3%)	2 (22.3%)	2 (22.2%)
		Grade 2	4 (44.6%)	2 (22.3%)	4 (44.4%)	5 (55.6%)
		Grade 3	5 (55.4%)	5 (55.4%)	3 (33.3%)	2 (22.2%)
	Angiography (n=14)	Grade 0	0	0	0	0
		Grade 1	0	6 (42.9%)	6 (42.9%)	6 (42.9%)
		Grade 2	13 (92.9%)	7 (50%)	8 (57.1%)	8 (57.1%)
		Grade 3	1 (7.1%)	1 (7.1%)	0	0
	P-Value		0.60	0.047	0.042	0.008
Quality of Life, n(%)	**Open Surgery (n=10)**	No pain	0	2 (20%)	3 (30%)	2 (20%)
		Mild pain	1 (10%)	2 (20%)	2 (20%)	4 (40%)
		Moderate pain	3 (3%)	4 (40%)	4 (40%)	3 (30%)
		Severe pain	6 (60%)	2 (20%)	1 (10%)	1 (10%)
	Hybrid Surgery (n=9)	No pain	0	0	1 (11.1%)	2 (22.2%)
		Mild pain	0	4 (44.4%)	4 (44.5%)	4 (44.5%)
		Moderate pain	5 (55.5%)	4 (44.4%)	2 (33.3%)	2 (22.2%)
		Severe pain	4 (44.5%)	1 (11.1%)	1 (11.1%)	1 (11.1%)
	Angiography (n=14)	No pain	0	2 (14.3%)	1 (7.1%)	3 (21.5%)
		Mild pain	2 (14.3%)	4 (28.6%)	5 (35.7%)	6 (57.1%)
		Moderate pain	6 (42.8%)	6 (42.8%)	7 (50%)	3 (21.4%)
		Severe pain	6 (42.8%)	6 (42.8%)	1 (7.1%)	2 (14.3%)
	P-Value		0.176	0.154	0.314	0.202
ABI	**Open Surgery (n=10)**	Grade 0	1 (10%)	2 (20%)	1 (10%)	2 (20%)
		Grade 1	1 (10%)	1 (10%)	1 (10%)	3 (30%)
		Grade 2	3 (30%)	4 (40%)	4 (40%)	2 (20%)
		Grade 3	5 (50%)	3 (30%)	4 (40%)	3 (30%)
	Hybrid Surgery (n=9)	Grade 0	1 (11.1%)	2 (22.2%)	3 (33.4%)	3 (33.4%)
		Grade 1	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)
		Grade 2	4 (44.4%)	3 (33.4%)	2 (22.2%)	2 (22.2%)
		Grade 3	3 (33.4%)	2 (22.2%)	2 (22.2%)	2 (22.2%)
	Angiography (n=14)	Grade 0	0	1 (7.2%)	2 (14.2%)	3 (21.5%)
		Grade 1	3 (21.5%)	3 (21.5%)	3 (21.5%)	3 (21.5%)
		Grade 2	5 (35.7%)	6 (42.8%)	6 (42.8%)	6 (42.8%)
		Grade 3	6 (42.8%)	4 (28.5%)	3 (21.5%)	2 (14.2%)
	P-Value		0.416	0.202	0.090	0.092

months the number of "worse" disappeared. While, in the group of patients operated by angiography, on the contrary to the one-month-follow-up, in the three-month-follow-up and six-month-follow-up it turned out that there is no healing in most of them. Okazaki et al. in their results indicate ulcer healing process up to 64% during the first year with moderate curing [20]. In another study, ulcer healing process in patients undergoing hybrid surgery is mentioned as moderate [21]. In general, in this study angiography showed a better healing just in the short-term. Whereas, hybrid surgery and open surgery turned out to have long-term healing. Analyzing results and side effects of hybrid method in 2020 in Finland in harmony with this study showed that this compound method can be an important tool and an effective method in vascular surgeries of patients suffering chronic femoral ischemia in terms of reducing pain. In this study, hybrid method is effective in healing ulcer, too [16]. While, in this study no significant difference in the quality of life in the studied group was not shown and healing pain of various methods of surgery had the same process. Also, ABI and rest pain in short-term and long-term had no significant difference, but in general in patients undergoing open surgery they had better results.

Analyzing ischemia grade in this study showed that the intensity of ischemia in various follow-ups after operation in different groups had significant differences. One month after angiography, ischemia grade healed more quickly. But, three months and six months after operation we faced better healing in patients who underwent hybrid surgery and open surgery. Therefore, ischemia grade in angiography shows better and faster healing in short-term, but after that the healing process stops while in hybrid surgery and open surgery healing process lasts longer. The amount of amputation in all three groups is almost the same and just in the one-month-follow-up the number of patients who underwent hybrid surgery required minor amputation was more. In this case we must notice that those who underwent angiography had better clinical status in compare to others and hereof for saving patients` health we couldn`t do randomization and the number of patients requiring amputation in the hybrid surgery in the analysis which we did before operation was more than others. Also, the number of patients without infected lower limb or with mild infected lower limb before operation, was lower than others. On the other hand, in the Elbadawy et al. study, it was reported that patients who underwent hybrid surgery had some side effects such as amputation and this method can be a safe treatment for patients suffering chronic femoral ischemia [22]. Another study aiming a comparison between open surgery and hybrid surgery reports that in the hybrid method we face less side-effects and the range of amputation in compare to open surgery is less, too [23]. In the study which Ward et al. did, it was indicated that the amount of amputation in the patients undergoing endovascular procedure in terms of revascularization, is higher than open and hybrid technique. And also in the patients undergoing hybrid procedure, there is no report for requiring any amputation. But due to their small circle of cases they could not mention this relation as a fact [24]. Therefore, for reaching a better result in terms of amputation, more studies are needed to be able to operate patients with better clinical status through hybrid method and analyze the results.

In general, this study shows that those patients who underwent hybrid surgery, in compare to other two groups, in terms of infected lower limb had better healing process. Angiography in healing ulcer and ischemia grade has a short-term effect while hybrid surgery and open surgery has long-term effect. In terms of life`s quality, reducing pain, rest pain, and ABI there is no significant difference in the studied groups. The amount of amputation in the three surgical groups is almost the same and just in the one-month-follow-up after operation the number of patients who needed minor amputation in those who underwent hybrid surgery was higher which this is because of the worse clinical status of those patients which underwent this method of surgery. Therefore, for reaching better results in terms of amputation, more studies are required.

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Conflict of Interest

The Authors declares that there is no conflict of interest

Ethical declaration

This study was performed in line with the principles of the Declaration of Helsinki

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