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Original article

Reconstructing diffusely-diseased LAD using long-opening LAD-Endarterectomy followed by direct LIMA anastomosis versus indirect LIMA grafting to an on-lay saphenous vein patch: Comparative prospective study

Ihab Abdelfattah ^a, Abdallah Osama Mahfouz ^b, Mohammad Abdelrahman Hussein ^{a,*}^a Department of Cardiothoracic Surgery, Kasr El Aini Faculty of Medicine, Cairo University, Egypt^b Department of Cardiothoracic Surgery, Fayoum University, Egypt

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Abstract

Background: Surgical revascularization of CAD patients having diffusely-diseased LAD is a difficult surgical problem. Following long LAD-endarterectomy (LAD-LCE), some surgical centers prefer long direct LIMA-to-LAD grafting; others perform LIMA grafts to on-lay SVG patch. Favoring either technique depends on multiple factors and is still questionable. This study was performed to compare the experience and early results of using direct LIMA-to-LAD anastomosis with endarterectomy to indirect anastomosis by LIMA-to on-lay SVGs during standard CABG.

Methods: Thirty patients who had IHD with diffusely-diseased LAD coronary vessel were included in a prospective comparative study starting from March 2011 till March 2014, in Kasr al Aini's University Hospitals. All patients had diffusely-diseased LAD for which they were subjected to long opening LAD-CE. Patients were divided into two groups: Group I (15 patients) underwent direct long segment LIMA-to-LAD implantation with CE; while in group II (15 patients) underwent LIMA grafting on an on-lay SVG. Follow-up was done over the first year postoperatively: major cardiac adverse events, death, MI, hospital readmission, reoperation and/or revascularization were followed since discharge and over one year later.

Results: Two patients died in each group (total mortality 13%). In group I, one due to refractory LV failure; and one due to refractory ventricular arrhythmias. In group II, a patient died due to mediastinitis and a second patient died due to progressive liver failure. There were no MI, CHF, or CNS complications.

Conclusion: LIMA-to-LAD following long-opening LAD-LCE could be safely-performed using both techniques. Both procedures were technically successful to revascularize diffusely-diseased LAD.

Abbreviations: CABG, Coronary Artery Bypass Grafting; CAD, Coronary Artery Disease; CE, Coronary Endarterectomy; CHF, Congestive Heart Failure; CNS, Central nervous system; CPB, Cardiopulmonary Bypass; IABCP, Intraaortic balloon counterpulsation. Statistical significance if result <0.05; ICU, Intensive Care Unit; LAD, Left Anterior Descending; LAD-LCE, Left Anterior Descending Long Coronary Endarterectomy; LIMA, Left Internal Mammary Artery; MI, Myocardial infarction; PO, Postoperative; SV, Saphenous vein; SVG, Saphenous Vein Graft.

* Corresponding author. Tel.: +20 1110222665(mobile).

E-mail addresses: ihabfattah@gmail.com (I. Abdelfattah), Obad100@gmail.com (A.O. Mahfouz), dr_cts2010@yahoo.com (M. Abdelrahman Hussein).

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Keywords: Coronary artery disease; Coronary by-pass; Endarterectomy; LIMA patch; Onlay vein patch

1. Introduction

It is well-known that coronary artery bypass graft (CABG) surgery significantly increases life expectancy, so complete myocardial revascularization should be the main goal of the surgical intervention process [1–3]. As there is a growing trend towards the increased use of percutaneous interventions, the number of high-risk and elderly patients referred for CABG operation has increased [4].

Because the diffusely diseased nature of the LAD lesion(s) in the fragile elder patient subset is frequently encountered, complete myocardial revascularization may not be always satisfactorily achieved by conventional bypass techniques [5].

Coronary endarterectomy in the LAD vessel is a procedure that has been proposed as a possible solution for revascularization of a diffusely-diseased LAD [5,6]. However, many surgeons are still avoiding the use of this procedure because of the conflicting and controversial opinions [7–9]. Technically, LAD-CE is done by the traction technique [10]. LIMA-LAD anastomosis is then done. This procedure was accused to be responsible for postoperative mortality ranging between 3 and 11% [4–6]; and postoperative MI ranging between 5 and 14% [5–9]. Moreover, LAD-CE was claimed to result in uncertain mid and long-term PO clinical results [8–11].

Owing to concerns in LAD-CE, cardiac surgeons shifted to focus on new techniques that can avoid its use [12–14]. Recently, different means of LAD reconstruction using LIMA patch long-segmental anastomosis; and indirect LAD patching to a long saphenous vein patch were introduced in this special subgroup of patients to afford complete myocardial revascularization [14–16].

Early results comparing these approaches are still conflicting, and only a limited number of studies have reported the comparative clinical outcome, patency rates, and the incidence of cardiac-related events during postoperative follow-up [11]. Due to these heterogenous and composite nature of the (elder) patient population (having many inter-influencing co-morbidity factors), these studies were not able to provide solid conclusions [15–19].

2. Objective

This comparative prospective study reviews our experience and early results of reconstruction of the diffusely diseased LAD by conventional standard CABG. This study compares LIMA-to-LAD direct long anastomosis versus indirect LIMA grafting to an on-lay Saphenous vein patch following long-opening LAD-LCE.

3. Patients and methods

3.1. Participant patient population

This comparative prospective study was carried out after obtaining the approval of the local ethical committee and patients' written informed consent in Kasr El Aini's University Hospitals, during the time span between March 2011-and-March 2014. Thirty patients with CAD associated with diffusely-diseased LAD among other coronary atherosclerotic lesions were enrolled. All patients underwent elective standard CABG surgical coronary revascularization during which LIMA was grafted to LAD by either of the described techniques after long-opening LAD-CE. All operations were done using CPB under moderate hypothermia and 20-min intermittent blood-enriched antegrade cardioplegia.

3.2. Inclusion criteria

Diagnosis of advanced IHD with marked ischemia (>70% stenosis) of multiple coronary vessel together with diffusely-diseased LAD. Diagnosis was reached by clinical examination and investigations (e.g.: ECG, echocardiography, coronary angiography and Thallium study). All patients were submitted for long-opening LAD-CE.

3.3. Exclusion criteria

Associated cardiac lesion other than CAD (valvular disease, myocardial aneurysm); recent non-healed MI (before 3 weeks); persistent congestive heart failure (CHF); redo surgery; or poor ejection fraction (LVEF%) \leq 30%.

3.4. Patient grouping

Patients were divided into two groups after proper matching for demographic data and surgical risks for coronary cardiac surgery.

Group I (15 patients): Underwent long segment direct LIMA-to-LAD anastomosis.

Group II (15 patients): Underwent LIMA-LAD grafting via Saphenous vein patch.

Preoperative Demographic Data are shown in [Table 1](#).

3.5. Follow-up

Results were obtained and comparatively studied after the first month and first year postoperatively regarding mortality and morbidity using regular clinical examination visits combined by echocardiography and other investigations as needed.

3.6. Statistical analysis

Perioperative data values were collected in tables form in means \pm SD. The Kaplan–Meier method was used to analyze actuarial survival and freedom from ischemic symptoms. Statistical analysis was performed using SPSS software (release 12.0.1 for Windows; SPSS, Chicago, Illinois). Statistical significance was assumed if a p value of 0.05 or less was achieved.

4. Methods

4.1. Technique of standard CABG surgery (used in all patients)

A midline sternotomy followed by aortic root and common atrial cannulation. Distal anastomotic points were fashioned using 7–0 Prolene after cardiac arrest was reached by antegrade intermittent blood-enriched cardioplegia. Finally (after LAD

Table 1
Preoperative patient demographics.

Variable	Group I (no 15) (LIMA-LAD directly)	Group II (no 15) (LIMA-LAD on SVG patch)	p Value
Age (years)			
- Range	34–70	37–67	—
- Mean	46 \pm 3.5	42 \pm 4.6	0.22 ^a
Male ratio %	10 (66%)	12 (80%)	0.13 ^a
BSA [mean/m ²]	1.67 \pm 0.02	1.67 \pm 0.02	0.35 ^a
BMI (KG/m ²)	22.5 \pm 4.8	21.3 \pm 3.9	0.55 ^a
Diabetes Mellitus	5 (33%)	6 (40%)	0.55 ^a
Systemic Hypertension	7 (46%)	6 (40%)	0.21 ^a
Ex-Cigarette smoking	11 (73%)	9 (60%)	0.16 ^a
Previous MI	4 (26%)	3 (20%)	0.43 ^a
Unstable angina pain	6 (40%)	7 (46%)	0.33 ^a
Mild Ischemic MR	2 (13%)	3 (20%)	0.14 ^a
Mean NYHA class	3 \pm 0.7	2.9 \pm 0.5	0.44 ^a
6 min walking distance	50 \pm 20	46 \pm 12	0.23 ^a
Mean LV Ejection Fraction %	45 \pm 2.1	47 \pm 1.5	0.42 ^a
Left Coronary System	15 (100%)	15 (100%)	0.11 ^a
- Left main stem	3 (20%)	5 (33%)	0.14 ^a
- LAD	15 (100%)	15 (100%)	0.65 ^a
- Diagonal artery	2 (20%)	3 (20%)	0.25 ^a
- Left circumflex branch	8 (53%)	9 (60%)	0.33 ^a
Right coronary artery	6 (40%)	4 (26%)	0.24 ^a

LAD: Left Anterior Descending BSA: Body Surface Area BMI: Body Mass Inde MI: Myocardial Infarction MR: Mitral Regurge LV: Left Ventricle Values are expressed in mean \pm SD Statistical significance: Value < 0.05.

^a Result value was not found having statistical-significance.

revascularization) LIMA was opened together with infusion of a warm potassium-free blood via aortic root. Following resumption of myocardial contractility, proximal anastomoses were fashioned using 6-0 sutures Prolene on a beating heart after placement of a side-occlusion clamp. In main-stem lesions, prerequisites for an IABP were secured (local draping + sterilization \pm local femoral artery identification via insertion of an arterial line).

4.2. Technique of LAD long endarterectomy “LAD-LCE”(both groups)

CE is indicated when LAD has many segmental narrowings, so that anastomosing one segment would not adequately revascularize the territory of that vessel. Final decision to endarterectomize the LAD vessel was to be taken intraoperatively according to the judgment of the operating surgeon (Nishi et al, 2005) [25]. Endarterectomy was required when no adequate segment of a vessel, supplying viable muscle with reversible ischemia & good distal run-off was suitable for successful safe grafting (STS registry <http://www.sts.org>) [20].

Procedure: “The Long-open Technique”: The ventral surface of the LAD was dissected starting near the take-off of the diagonal branch extending caudad. LAD arteriotomy (average ≥ 2 cm) was initially-done in the area expected most-likely to have blood flow (blue color denotes possible patency). The incision was tailored according to the length of the yellow-thrombus. A dissection plane was made between the atheromatous plaque and the intima using fine spatula. A 2-0 silk filament was passed around the thrombus prior to applying gentle traction along its longitudinal axis moving it sideways until the farthest proximal and distal dissection possible before its removal by sharp division. Moving towards the apex, the lowermost tapering end of the thrombus (which should be clearly-seen) is extracted.

The proximal end of the endarterectomy should be distal to the most proximal lesion, to avoid competitive flow through the native coronary artery, to the level of the first diagonal branch at most (Meyers et al, 2012) [23]. Careful inspection must prove presence of a smooth tapering distal end. If found irregular, the distal end of the incision was enlarged to allow complete removal of the residual part. After complete extraction, additional dose of cardioplegia was given to flush out any debris that may have embolized distally. A visible flow of retrograde flow via diagonal and septal branches is indicative of successful endarterectomy. The endarterectomized LAD vessel was washed by heparinized saline to wash-out any possibly-remaining residual fragments. LIMA was then anastomosed to LAD after appropriate longitudinal splitting. Patients received PO anticoagulation. Low-molecular-weight heparin was initiated 6 h after ICU arrival. After 48 h PO, warfarin sodium & aspirin (2 tabs/75 mg) were given instead & continued maintaining an International Normalized Ratio between 2 and 2.5 for the 1st.PO month (Nishi et al, 2005) [25] (Fig. 1).

4.3. Long LIMA-to-LAD direct anastomosis (group I)

Procedure: Following LAD-CE, the dissected intact-pedicle LIMA was then longitudinally-opened and then continuously-anastomosed to the endarterectomized LAD using 7–0 prolene suture. (Myer et al,2012) [23] (Fig. 2).

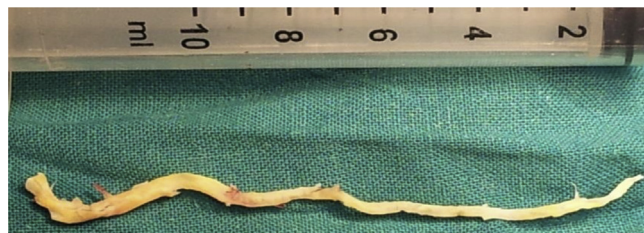


Fig. 1. Long LAD-CE specimen. This intact atheroma was removed by the long-opening CE compared to a 10-ml syringe. It shows 6 septal perforating branches & a tapering distal end.

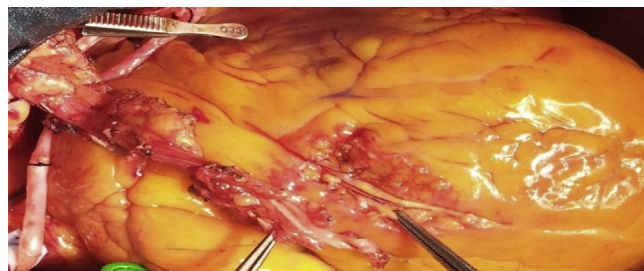


Fig. 2. Long LIMA-to-LAD direct anastomosis after LAD-CE starting just distal to diagonal branch till near LV apex.

4.4. LIMA-to-LAD via SVG patch (group II)

Indications & Prerequisites: Presence of extensive atheromatous plaques downstream starting from 1st. major proximal lesion usually extending for a segment as long as ≥ 2 cm [14,20].

Procedure: A long superficial arteriotomy (≥ 2 cm) was made along the course of the diseased LAD. The tip of the arteriotomy incision was then extended to reach the disease-free proximal and distal territories of the LAD vessel. The LIMA was then opened longitudinally, adjusting its appropriate length to the length of the LAD arteriotomy. A segment of the saphenous vein was longitudinally-split and then anastomosed to the LAD open edge. LIMA was then anastomosed to an opening in the SVG using continuous, 7–0 polypropylene suture. (*STS registry* <http://www.sts.org>) [20]. (see Fig. 3)

5. Results

5.1. Operative data

No statistical significance was found between the operative times of the 2 groups (total surgical time, CPB time, and cross-clamp time). Similarly, there was no statistically significant difference concerning the number of anastomotic points fashioned; need for DC shocks, inotropics or IABCP for safe weaning off-CPB (Table 2).

5.2. In-hospital postoperative course

There was no difference of statistical significance between the two groups as to ICU events (regaining full consciousness, inotropic support, assistance by mechanical ventilation, stay time, as well as mean ICU and hospital stay times (Table 3).

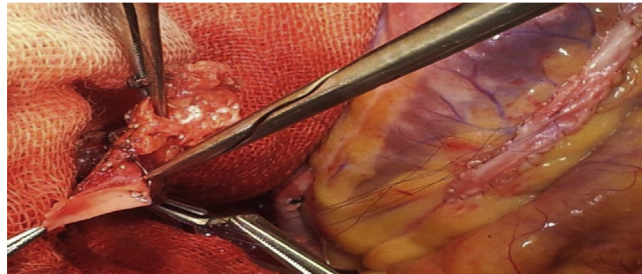


Fig. 3. Suturing LIMA pedicled graft to a hole in a long SVG patch sewn to LAD after LAD-CE.

Table 2
Surgical data.

Variable	Group I (no 15)	Group II (no 15)	p Value
Total surgical Time (min)			
- Mean	250 \pm 15	272 \pm 6	0.43 ^a
- Range	220–305	215–310	–
Cardiopulmonary bypass time (min)			
- Mean	155 \pm 7	167 \pm 5	0.62 ^a
- Range	91–195	99–177	–
Cross-clamp Ischemic Time (min)			
- Mean	127 \pm 2	131 \pm 5	0.44 ^a
- Range	110–141	117–150	–
Mean No. Distal points	2.4 \pm 0.4	2.5 \pm 0.3	0.24 ^a
Weaning Off-Bypass Data:			
- Spontaneous on Hot shot	8 (54%)	8 (54%)	0.44 ^a
- Spontaneous + DC Shock	3 (20%)	2 (13%)	0.34 ^a
- DC Shock + inotropics	3 (20%)	4 (26%)	0.65 ^a
- Hot shot + DC + Inotropics + IABCP	1 (6%)	1 (6.6%)	0.14 ^a

^a Data is not statistically-significant.

Table 3
Postoperative data.

Variable	Group I (no 15)	Group II (no 15)	p Value
Regain of full consciousness ^a	15 (100%)	15 (100%)	0.26 ^b
Inotropic Support (mean hours)	24 ± 1.2	26 ± 3.1	0.55 ^b
IABCP	4 (26%)	4 (26%)	
Mechanical ventilation (mean hrs)	11 ± 2	14 ± 3	0.22 ^b
Mean ICU Stay (hours)	122 ± 8	130 ± 5	0.62 ^b
Mean Hospital Stay (days)	6 ± 1.5	7 ± 1.8	0.33 ^b

^a Within 1st. 24 h PO IABCP: Intraaortic Balloon Counterpulsation.

^b Result is not statistically-significant.

5.3. Morbidity and mortality

Mortality: Two patients died in each group (total mortality 13%). In group I, the first patient died due to progressive refractory left ventricular failure despite massive inotropic support and IABCP assistance; while the second patient died due to refractory ventricular arrhythmias (LV tachycardia then VF) not controllable by anti-arrhythmic medical therapy. In group II, the first patient (diabetic) died from mediastinitis; while the second patient (HCV+) died due to progressive liver-cell failure.

Morbidity: In both groups, there were no serious morbidity complications eg: MI, CHF, and CNS. Total morbidity was 20% (6 patients). Group I morbidity was 20% (3 patients) as recurrent attacks of supraventricular extrasystoles arrhythmias (controlled by Amiodarone IV then orally) in 2 patients (13%); and mechanically-assisted PO ventilation for 36 h in a single patient (6%). Group II morbidity occurred in 3 patients (20%) as: intercostal tube re-insertion for left sided moderate to-severe haemorrhagic pleural effusion in 2 patients (13%); and superficial wound infection needing frequent dressing and wound debridement in a single patient (6%) (Table 4).

PO follow-up 1 month after hospital discharge (Table 5).

PO follow-up 1 year after operation (Table 6):

Patients in the two groups expressed obvious PO clinical improvement as detected by absence of anginal pains, better effort tolerance (by NYHA class, longer 6 MWD) and better cardiac contractility (LVEF%) by echocardiographic follow-up.

No readmissions or reinterventions for cardiac events encountered over the follow-up period.

6. Discussion

Nowadays, many Cardiac surgeons are confronted with the dilemma of the escalating number of patients having diffuse LAD lesions distal to a first major proximal lesion [7–11]. The presence of multiple atheromatous plaques usually complicates the surgical procedure and adversely affects the long-term patency of LIMA graft [3–8].

Table 4
Postoperative morbidity and mortality.

Variable	Group I (no 15)	Group II (no 15)	p Value
Mortality: total 4 (13%)	2 (13%)	2 (13%)	none
Morbidity: total 6 (20%)	3 (20%)	3 (20%)	0.34 ^c
- MI, CHF, serious CNS morbidity	none	None	—
- Supravent extrasystoles arrhythmia	2 (13%)	—	—
- Mechanical Ventilation for 36 h	1(6%)	—	—
- Intercostal tube re-insertion ^a	—	2 (13%)	—
- Superficial wound infection ^b	—	1 (6%)	—

MI: Myocardial Infarction CHF: Congestive heart failure CNS: Central nervous system Supravent: Supraventricular.

^a Right side moderate to-severe haemorrhagic pleural effusion.

^b Needing frequent dressing with wound debridement.

^c Value is statistically-non-significant.

Table 5
At one month postoperative Clinical Outcome.

Variable	Group I (no 13)	Group II (no 13)	p Value
Recurrence of anginal pain	none	none	–
Mean LVEF (%)	50 ± 1.6	51 ± 3.4	0.28 ^a
Mean NYHA class	1.7 ± 0.4	1.8 ± 0.5	0.37 ^a
6 min walking distance	140 ± 17	139 ± 13	0.19 ^a

^a Value is statistically-non-significant.

In 1957, Bailey et al., [22] introduced Coronary endarterectomy (CE) as a treatment modality for severely-atherosclerotic CAD (especially RCA) earlier before LIMA long patching, and even before CABG surgery became the standard therapy for CAD [22]. Various techniques were proposed as a solution including “jumping anastomoses” which creates more than one route to bypass arterial blood to the diseased LAD territory [4–7]. Differently, LIMA-LAD grafting was done on top of a saphenous vein patch [8–11]. Despite all, the need for more modifications of conventional techniques still exists in order to confirm obtaining satisfactory long-term outcomes [11].

Surgeons opposing CE wide-use expressed fears founded on the extreme value of achieving LAD patency considering it one of the main goals for a successful CABG surgery [17–20]. They were afraid of inducing myo-fibro-intimal proliferation. This, later on, could negatively affect early and long-term clinical and angiographic results [11,28] as the endarterectomized arterial wall acts as a scaffold for a new thrombus formation [9]. The LAD has diagonal and septal branches that occur in 2 different planes. Unidirectional traction on the plaque can cause shearing off branches [24].

CE supporters stated that under proper perioperative anticoagulant cover, normal endothelial covering can act, within reasonable time, to heal and limit possible thrombosis [9,12]. The “Open CE Technique” is specially-effective when plaque extraction is incomplete or when there's fear to fracture a delicate plaque [12]. Using a long arteriotomy (instead of undue & dangerous longitudinal traction during “Traction Technique”), provides enough safe exposure to extract the atherosclerotic core. They finally declared that LAD-CE is safer than was previously thought [8–10].

Open LAD endarterectomy with saphenous vein patch reconstruction combined with LIMA grafting was first reported by Fundaro & associates [27] in 1987, with subsequent technical modifications [16,19]. In 2005, Nishi et al. [25], showed good midterm angiographic results of that technique.

According to Myers PO et al. [23] and Lüscher et al., [26]; the combination of “open CE” to long LIMA-LAD on-lay patching had satisfactory early and late clinical outcomes and luminal patency of endarterectomized vessels. They attributed their better results to: 1st, a long arteriotomy exposes the whole arterial lumen with its side branches containing atherosclerotic occlusive material hence optimizing its complete removal, 2nd., LIMA on-lay patch grafting forms a new coronary lumen so that LIMA wall makes up about 75% of the circumference of the reconstructed vessel, hence globally enlarging the narrowed lumen. 3rd. reason is that LIMA provides better vasomotor function, particularly the capacity to adjust the flow rate in proportion to the distal runoff, a widely known essential function of living endothelium that produces and releases prostacyclin and other endothelium-dependent relaxation factors.

Ogus et al. [11] and Fitzgibbon et al. [33] did not use SVGs patches to enlarge the LIMA and then implant LAD. They considered it more time consuming, and even accused it of adversely-influencing the flow patterns by inducing subsequent turbulence due to the change in compliance of the three different components: the native artery, SVG, and LIMA. This repeated discrepancy, in turn, causes a decrease in the flow velocity ending by SVG atherosclerosis,

Table 6
At one year postoperative Clinical Outcome.

Variable	Group I (no 13)	Group II (no 13)	p Value
Recurrence of anginal pain	none	none	–
Mean LVEF (%)	55 ± 1.4	57 ± 0.12	0.22 ^a
Mean NYHA class	1 ± 0.3	1 ± 0.4	0.46 ^a
6 min walking distance	200 ± 26	210 ± 9	0.21 ^a

^a Value is statistically-non-significant.

failure, with recurrence of angina. However, supporters of SVG patching stated that SVG patches have the added value of enlarging the diameter of a severely-stenosed LAD. The ample length and the easy-harvesting were reported to add to its size-merits [13–19]. Fear against its postoperative thrombosis/occlusion, is not well-founded as Warfarin \pm Salicylates anticoagulation regimen (classically-needed following LAD-CE) is usually-effective to prevent its occurrence [13,16,17]. In our study, the absence of serious postoperative thromboembolic complications confirmed that opinion.

It was reported by many surgeons [3–8,10,23,25] that a serious limitation of LAD-CE is a factor that is related to the surgeon, who must adequately dissect and then remove the entire plaque as much as possible until its clearly-tapering distal end is seen. Absence of distal tapering means that the arteriotomy should be extended for more distance. We followed the same concept in our study. The success of our LAD-CE was confirmed by the acceptable blood back flow through the distal and the septal branches upon giving a dose of cardioplegia. This good flow could raise the saphenous SVG patch cover of the LAD in group II patients. Furthermore, anastomotic patency was proved post-operatively by the total disappearance of anginal pain, the higher LVEF%, the NYHA clinical step-up, and the longer 6 min-walking distance. The same conclusions were also reported by other surgeons [17,19,29,30].

In our study, there were no differences as to operative data (operative time, CPB time, ischemic time), CPB-weaning data (need for inotropics, DC shocks, IABCP), or postoperative data (ICU and hospital stay times). The measured values were of no statistical significance. Added to that, the follow-up data concerning the clinical condition showed an obvious improvement (mean NYHA class, LVEF%, and the 6 min walking distance). These findings were also reported in other series [8–11].

Our mortality and morbidity complications were mostly attributed to PO dysrhythmias. It was reported by many surgeons [2–6,11,15,23,33] that suture lines lying close to the LV apex are arrhythmogenic in nature. Due to proper bordering of our distal suture line secured from the apical zone, most of the arrhythmias could be medically dealt with and controlled. The average mortality rate in our study is matching with other rates reported for LAD-CE in the literature (average early and a mid-term survival rates between 71% and 92%) [4–11] and hence is acceptable. General reasons for the lesser-morbidity-mortality are multifactorial: Advances in patient selection/management, expert angiocath performance/interpretation, meticulous surgical technique with equidistant stitch placement avoiding intimal cracking by hesitation or multi-needle passaging, effective CPB and cerebro-myocardial protection (inotropics/IABCP), optimized ICU facilities and care, in addition to adequate PO anticoagulation and platelet-inhibition protocol.

Postoperative MI did not occur in any of our patients, contrary to other series like [8,10,15,23] who reported rates of MI ranging between 2.5 and 6%. Recent CE studies are reporting lower rates similar to our study [23–30].

6.1. Study limitations

Our study is limited by the fewer patient number and the relatively short postoperative follow-up (1 month and 1 year).

7. Conclusion

LIMA-to-LAD following long-opening LAD-CE could be safely-performed using either direct LIMA-LAD grafting or via SVG on-lay patching. Both procedures were technically-successful to revascularize diffusely-diseased LAD vessel with sound safety and acceptable complications during standard CABG surgery.

Conflict of interest

No conflict of interest.

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