Prospective randomized trial of endoscopic vs open radial artery harvest for CABG: clinical outcome, patient satisfaction and mid-term RA graft patency.

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Abstract

Background and Aim Endoscopic radial artery (RA) harvest (ERAH) is an alternative to open RA harvest (ORAH) technique. Our aim was to compare clinical outcome, patent satisfaction and 1-year angiographic patency rates after ERAH and ORAH. Patients and methods 50 patients undergoing multivessel CABG were prospectively randomized to two groups. In the ERAH group (25 patients) the RA was harvested endoscopically and in the ORAH group (25 patients) openly. Results There were not differences between the groups in preoperative characteristics. Length of skin incision was shorter in ERAH ($p<0.001$) but there were not differences in the length of RA, harvest time, blood flow and pulsatility index after ERAH and ORAH. Wound healing was uniformly smooth in ERAH and there were 2 haematomas and 1 infection in ORAH. Postoperatively, major neuralgias were present in 5 patients in ORAH and none in ERAH ($p=0.05$) and minor neuralgias in 11 and 3 patients ($p=0.02$) respectively. Twenty-four patients in ERAH and 4 in ORAH graded their experience as excellent ($p<00001$). One-year angiographic RA patency was 90% without intergroup difference. Target vessel stenosis $< 90\%$ adversely affected RA patency ($p<0.0001$). Conclusions In expert center, ERAH has no negative impact on time harvest, length and quality of RA conduit. Moreover, ERAH may provide better wound healing, and is associated with less neuralgias, excellent cosmetic result and better patient satisfaction. RA graft patency is unaffected by the harvesting technique and is excellent when placed to a target coronary artery vessel with stenosis $> 90\%$.

INTRODUCTION

Radial artery (RA) has been initially used in the early 1970s (1) but was abandoned because of high incidence of early graft failure and suboptimal clinical outcomes (2). Following better understanding of the anatomy and physiology of the RA, namely the thickness and the reactivity of its muscular wall rendering it prone to spasm and the beneficial effects of vasodilating agents and calcium channel blockers in preventing vasospasm (3-5) RA has since 1990s been established as a reliable arterial graft superior to saphenous vein and in some reports even comparable to internal mammary artery for CABG (6-11).

Initially RA has been harvested with an open technique (12), however encouraged by the good outcomes observed with endoscopic harvest of the long saphenous vein (SVG) (13), surgeons have also applied endoscopic techniques to harvest the RA (13,14,15,16).

The aim of our study was to compare the clinical outcome, the degree of patient satisfaction and one-year angiographic RA patency rates in two cohorts of patients that were prospectively randomized to undergo multivessel, first time, elective CABG using (amongst other conduits) RA that was harvested using endoscopic or open techniques.

PATIENTS and METHODS

The study was approved by the Ethics and Research Board Committee of our hospital (King Fahd Military Medical Complex, Dhahran, KSA) and informed consent was obtained by all patients involved.

Between 2016 and 2018, 50 patients undergoing isolated, first time, elective multivessel CABG with the use of one pedicled RA taken from the non-dominant hand were prospectively randomized, using the envelope randomization method, to two groups. In the first group (n=25 patients) the RA was harvested endoscopically. In the second group (n=25 patients) an open harvest technique was employed. Other types of conduits, such as LIMA, right internal mammary artery and SVG (harvested also endoscopically in all patients) were used as required.

These two groups were compared with regard to the following parameters:

Preoperative : demographics, comorbid conditions, cardiac function.

Intraoperative : length of skin incision, length of harvested RA, time harvest of RA, aortic clamping time, cardiopulmonary bypass time, RA graft flow and pulsatility index.

Postoperative : clinical outcome, wound healing (haematomas, wound discharge, infection), neuralgias (major or minor), vascular complications, limitation of hand activity (hand function), patient satisfaction, LV function (transthoracic ECHO) and 1-year RA patency by means of 64 slice CT angiography.

To assess patient satisfaction a brief questionnaire was filled in by the patients 12 months after their operation asking them to classify their overall feeling from the RA harvest procedure in their arm (taking into account symptoms of pain, neuralgias, numbness, tingling, or any other symptom, hand function, cosmetic result) into one of the five categories: poor, average, good, very good and excellent.

Assessment of collateral blood flow and exclusion criteria

Adequacy of collateral ulnar circulation in the non-dominant hand was preoperatively assessed with a modified Allen's test and a Doppler study (17-19). Those found to have incomplete palmar arch or inadequate collateral blood flow were not enrolled. Additional assessment of collateral flow was also done intraoperatively using a digital oxygen saturation probe. Excluded were from the study patients with chronic renal failure already on dialysis or likely to require dialysis in the future. Patients in whom the RA of the non-dominant has been used for coronary angiography or other transradial catheterization procedure were not included in order to avoid the risk of endothelial damage and RA occlusion (20-21).

Endoscopic RA harvest technique

The RA in all patients of ERAH group was harvested by an expert surgical assistant who has since 2012 performed a total of 462 cases before participating in this trial. The same operator has initiated the program of endoscopic SVG harvesting in our institution in 2010. Currently all SVG and RA conduits are harvested endoscopically.

Arm preparation . The donor arm was shaved and prepared from the shoulder to the fingers. A Stockinet was placed over the humerus of the donor arm and a tourniquet applied over the Stockinet and connected to the insufflation device. Endoscopic harvesting was performed using the VASO-VIEW® HemoPro Endoscopic Vessel Harvesting System (Getinge AB, Maquet Cardiovascular, Santa Clara, CA.).

A longitudinal 2-3cm incision was made in proximity to the wrist crease over the radial artery. A pressure cuff was applied above the hand and inflated to 150-200mmHg and both time of inflation and pressure were monitored and documented. The RA with the venae comitantes were dissected as one pedicle directly through the lateral fascia. Then, the endoscope with its conical tip was advanced over the radial artery to allow for the insertion of the port. The port was inflated with air to create a seal and carbon dioxide insufflated at a flow rate of 3L/min and pressure 10-12mmHg to create a tunnel. The anterior aspect of the RA was dissected first with the aid of the conical tip followed by the lateral and posterior aspects. The conical tip was then removed, and the endoscope positioned into the Endoscopic Vessel Harvesting System. Fasciotomy was done using direct low intensity energy force. Dissection of the tissues was performed by grasping them between the jaws of the cannula and gentle traction and rotation of the tool so as to apply controlled tension. The branches of the RA were caught between the Jaws by pulling the Toggle into the middle position, all branches were divided, and the radial artery pedicle was freed from the surrounding tissues. The proximal part of the RA after it was brought out of the skin through a 0.5cm long horizontal skin incision it was divided and ligated. The radial artery was cannulated at the proximal end and 30mg of papaverine was flushed in it. The radial artery was examined closely for arterial spasm, bleeding and arterial hematomas. Arterial branches were ligated before grafting with metal clips. The incision was closed using 4-0 Vicryl/Monocryl suture.

Open RA harvest technique

A standard open radial artery harvesting technique was performed as previously described (12). A skin incision was made over the course of the RA in the forearm of the nondominant hand starting from the felt pulsation of the artery till its origin from the brachial artery. The RA was harvested as a pedicle with the venae comitantes using low intensity monopolar electrocautery. No-touch technique was used, and care was taken to avoid vessel trauma during surgical manipulation. The side branches were secured with vascular clips and after haemostasis the wound was closed using 3/0 and 4/0 Vicryl and monofilament sutures. Fascia was not closed in order to prevent the occurrence of compartment syndrome.

In both techniques , the dissection was done before heparinization and RA divided after heparin was given. A soft drain was inserted in the wound and after skin closure the hand and arm were wrapped tightly with a bandage. An abdominal pad was placed under the wrap and the tourniquet deflated and removed. After completion of CABG and heparin reversal, the tight wrap was taken down and rewrapped loosely over the entire arm. The proximal anastomosis of RA was constructed in an end-to-side fashion to the aorta using 7/0 Prolene. Graft flow and pulsatility index were measured and recorded in all patients using transit time doppler flowmeter (Medistim, Medtronic, USA). Calcium channel blockers and oral nitrates were administered immediately postoperatively and continued for at least 6 months after surgery.

Follow-up

In addition to routine monthly follow-up, the study patients were seen 1 year after their discharge from the hospital. Apart from history taking and clinical examination, they had 12 lead ECG, transthoracic ECHO and 64 slice CT coronary angiography.

RESULTS

Statistical Analysis

Continuous variables are expressed as means values with standard deviation and the proportions as percentages. The differences between the groups for the categorical variables were compared with chi square or Fisher's exact test and continuous variables with unpaired Student's t test or nonparametric test (Kruskal Wallis). A p value of less than or equal to 0.05 was considered statistically significant. Statistical analysis was performed using SPSS, version 11, Chicago, IL.

Preoperative data

The two groups had similar demographics, left ventricular function and prevalence of comorbid conditions such as hypertension, diabetes mellitus, chronic obstructive airways disease, hyperlipidaemia and peripheral vascular disease (**Table 1**).

Intraoperative data

Harvesting of RA was uneventful in all cases in both groups and no conversion was necessary from the ERAH to ORAH. There was a statistically significant difference in the length of incision for RA harvest (2.4±0.4cm in ERAH vs 24.8±4.4cm in ORAH groups, $p<0.001$), as expected by the design of the study. However, the length of RA grafts (16.8±3.2cm vs 17.2±2.9cm, $p=0.23$) and RA harvest time (31±11min vs 28±12min, $p=0.32$) were similar in the ERAH and ORAH groups respectively, as were the duration of cardiopulmonary bypass (108±32min vs 102±28min, $p=0.56$) and aortic clamping (63±21min vs 59±18min, p=0.43). Likewise, there were not intergroup differences in the graft blood flow (ml/min) (51.7±24.1 vs 50.9 ±25.2, p=0.75) and PI index (2.1±0.8 vs 1.8±0.9, p=0.28). One RA graft in ORAH group required limited repair with 7/0 Prolene (**Table 2**).

Types of grafts and distribution of anastomoses to target vessel

There were no significant differences in the types of grafts used and the distribution of each type of graft to coronary artery target vessel. All 50 patients received 1 RA graft, 1 in-situ LIMA to LAD and 1 SVG. In addition, 5 patients in ERAH and 6 in ORAH group received right internal mammary artery (RIMA) conduit. Two patients in each group had their LIMA also sequentially anastomosed to the diagonal branch. Saphenous vein grafts were often used to bypass more than one target vessel in both groups resulting in the construction of 39 and 36 distal anastomoses in ERAH and in ORAH groups respectively (**Table 3**).

Regarding the distribution of RA graft to target vessels, most RA grafts in ERAH and ORAH groups were placed to obtuse marginal (OM) (n=21), followed by right coronary artery (RCA) (n=12), ramus intermedius (n=9), posterior descending artery (PDA) (n=5) and the diagonal branch (n=3), without significant intergroup differences (**Table 3**).

Early outcome

There were no deaths. All patients were discharged home after a mean hospital stay of 7±1.5 days vs 7±21 days (p=n.s.).

Wound healing

Wound healing was smooth in all patients after endoscopic harvest. In ORAH group 2 patients developed hematoma and were managed conservatively and one had infectious persistent discharge (*staphylococcus epidermidis*) and was treated with wound dressing and antibiotics.

Neurovascular complications, hand function and patient satisfaction

Acute ischaemic injury or vascular compromise of the hand were not seen.

At the time of discharge from the hospital, major neuralgias that restricted hand function were present in 5 patients in ORAH and none in ERAH group (p=0.05). At the same time point, minor neuralgias (numbness or tingling) were recorded in 11 and 3 patients in ORAH and ERAH groups (p=0.02). However, symptoms of neuralgia (minor or major) were no longer present in any patient of the ORAH or ERAH groups. No patient experienced vascular compromise, and all had normal hand function at 1-year follow-up. (**Table 4**).

The overall patient satisfaction from the outcome of RA harvest at 12 months in ERAH and ORAH groups was graded as follows: poor in 0 vs 0, average in 0 vs 6 (P=0.02), good in 0 vs 7 (P=0.007), very good in 4 vs 8 (P=0.3) and excellent in 21 vs 4 (P<0.00001) patients respectively (**Table 5)** . All patients in ERAH group were very pleased with the cosmetic result early and late after surgery.

Survival, LV function and angiographic RA patency

There were no deaths during the follow up period. All patients were doing well and no major cardiovascular events were recorded. Left ventricular ejection fraction (EF) assessed with transthoracic ECHO at 12-monthly follow-up was uniformly improved compared to preoperative status in both groups (55.5±9.8 vs 57.3±12.4, p=0.24).

Twelve months after surgery RA grafts were patent in 45 patients (90%) with 2 patients in ERAH and 3 patients in ORAH groups exhibiting significant (>50%) stenosis (p=n.s. between groups). The target coronary artery vessel in ERAH were the OM1 and the RCA and a stent inserted in both. In ORAH group the target vessel was the OM1 in one (managed with stent insertion in native OM) and the RCA in two patients, who were treated with stent insertion in the RA-to-RCA graft in one and conservatively in the other patient.

RA graft patency in relation to preoperative target vessel stenosis of 90%

The stenosis of the target coronary artery vessel to which RA was grafted was $< 90\%$ in all five patients that developed RA graft stenosis at 12 months. Namely, the native vessel stenoses on preoperative coronary angiography was 70-80% in all 5 cases. Conversely, no significant RA graft stenosis was seen on in the remaining 45 patients in whom the RA was placed to a native target vessel with $> 90\%$ narrowing ($p<0.0001$).

DISCUSSION

This prospective randomized clinical trial shows that in experienced centre endoscopically harvested RA is safe and provides excellent early and mid-term clinical and angiographic outcomes bearing some advantages over the open harvest technique.

The aim of less invasive techniques is to minimize the trauma inflicted upon the patient without compromising the quality of work and the clinical outcome. Open RA harvest is a straightforward procedure that can be readily taught to an average surgeon (12). On the other hand, endoscopic RAH technique requires different set of skills, time consuming training and perseverance and is linked with a significant learning curve (22, 23).

In our unit, the program of endoscopic vein harvest (EVH) was started first in 2010 and after accumulation of large experience in EVH we proceeded to ERAH. A senior surgeon and a surgical assistant were involved in both programs from their outset acquiring in-depth knowledge and expertise, which they now pass to younger colleagues. As already mentioned, all ERAH procedures in the study were carried out by the same surgical assistant.

In this study, wrist skin incision was 2.4cm in ERAH compared to 24.8 in ORAH, yet the harvest time and the length of the RA graft were similar. Published data on time harvest for ERAH vs ORAH differs widely. In accordance with our findings (harvest time 31 vs 28min for ERAH and ORAH, p=ns), Patel et al reported in their case series similar harvest time for both groups (26 vs 22min) (15). On the other hand, Fouly in a retrospectively analyzed cohort of consecutive patients (16) and Kiaii et al in their prospectively randomized study (24) described significantly shorter harvest time for ERAH (40 vs 49min, $p<0.001$) and ORAH (36.5 vs 57.5min, $p<0.001$) respectively. Nonetheless, it should be noted that the ORAH times reported by Fouly (16) and Kiaii (24) (49min and 57min respectively) were much longer than those reported for ORAH by us and by Patel et al (15). In contrast, Rahouma et al in their meta-analysis found a longer harvest time after ERAH with a steep learning curve in inexperienced hands (22). Wound healing after ERAH was smooth and uncomplicated in all patients in this study echoing previously published work, which uniformly describes superior wound healing after ERAH, the obvious explanation for this being the shorter skin incision and the smaller dissection planes that are required compared to ORAH (15,16,22,24,25).

We recorded significantly less neuralgias after endoscopic harvest of RA in the early postoperative period, which could be attributed to smaller incision resulting in less cutaneous nerves being damaged, and the efforts made by the experienced surgical assistant to apply a RA "non-touch" harvest technique. Our findings are in agreement with those previously reported in prospectively randomized (24), propensity score matched (25) and case series (15) studies that reported fewer neurological complications after ERAH. On the contrary, in his retrospective study Fouly (16) recorded more cases of superficial radial nerve injury and hand numbness after ERAH vs ORAH (20% vs 5.2%, P=0.05) and ascribed this to his limited experience in endoscopically harvesting the RA.

Our data show that, performed in experienced center by expert operator, ERAH leads to better patient satisfaction than ORAH, which can be credited to smooth wound healing, lack of neurovascular complications and the excellent cosmetic result afforded by the endoscopic harvest technique (24).

The overall RA patency rate of 90% at 1-year angiographic follow up (without intergroup differences) in this study is comparable to previous reports addressing this topic (26-28). Although we examined a possible effect of several preoperative, intraoperative and postoperative parameters on RA graft patency, native coronary artery stenosis of $< 90\%$ emerged as the only significant factor adversely affecting RA graft patency ($p<0.00001$). This finding is in line with the results of the large angiographic study by Tatoulis et al who demonstrated that aorto-coronary RA graft patency is significantly improved when anastomosed to a coronary artery with a luminal narrowing of at least 80% (28).

CONCLUSIONS

The results of this prospectively randomized trial strongly suggest that in experienced hands the challenges posed by the endoscopic minimally invasive technique can be overcome without negative impact on the time harvest, the length and the quality of the RA conduit. Moreover, endoscopic radial harvesting may provide better wound healing, and is associated with less neuralgias, excellent cosmetic result and better patient satisfaction than the open harvesting technique.

The patency of aorto-coronary radial artery graft is unaffected by the harvesting technique used and is gratifying when placed to a target coronary artery vessel with stenosis greater than 90%.

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