Low Energy of Endovenous Laser Ablation of The Great Saphenous Vein Under Ultrasound Guided Femoral Block Anesthesia is Safe and Effective as a Day Case Procedure

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Purpose

To assess clinical outcomes, complication rates, and unit energy applied using 980 nm diode endovenous laser treatment at average 11 watts energy applied for symptomatic great saphenous vein (GSV) reflux disease. In addition assess the efficacy & safety of ultrasound guided femoral block anesthesia for day case surgery.
Methods and Materials

Sixty consecutive leg varicose veins in 45 patients (12 men, 33 women; mean age 38.23 years, were included in the study, and a chart review was conducted. Nine limbs (15%) had recurrence of disease after previous surgical or sclerotherapies. Three limbs (5%) had prior surgical ligation, 5 limbs (8.3%) had sclerotherapy with recurrence, and 1 limb (1.6%) had stab avulsion ambulatory phlebectomy prior to endovenous laser ablation. The endovenous laser treatment was performed in 37 left legs and 23 right legs. Thirty patients (66.6%) had unilateral treatment. Fifteen patients (33.3%) had bilateral treatment. Seventy-eight percent (47/60) of the limbs presented with visible varicose veins, and 90% (54/60) had spider veins in the legs. Medical history review (Table 1) showed that 10% (6/60) of the patients had a prior history of superficial phlebitis or resolved thrombus within the deep veins, 76% (46/60) had a family history significant for varicose veins, 57.5% (19/33) of the women had used oral contraceptive pills, and 48% (16/33) of the women had a positive pregnancy history with varicosities worsened during the pregnancy. Seventy-six percent of the patients (46/60) admitted to having jobs or habits that made them stand for long periods. Thirty-nine percent took pain medicines for their varicosities, and 74% elevated their legs to relieve symptoms. Furthermore, 45% (27/60) of the patients complained of skin color changes (dermatitis), 8% (5/60) of venous stasis ulceration, 75% of leg tiredness (45/60), 70% (42/60) of leg pain, and 55% (33/60) of leg edema (Table 2). The diagnosis of venous incompetence with reflux was made with clinical evaluation and color duplex Doppler studies in all patients. We performed color duplex studies in cross-sections and longitudinal sections with the patient standing. Maximum and mean diameters of GSV were measured. We tested flow on color duplex images by manual compression-release of the calf to provoke reflux. Reflux was defined as >0.5 sec of reverse flow. The common femoral vein, superficial femoral vein, and popliteal veins were also evaluated by duplex Doppler, and patients with thrombus in deep veins were excluded from endovenous laser ablation therapy. The CEAP classifications of the patients were recorded (Table 3).

Table 1: Patient demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Male</td>
<td>73.4%</td>
</tr>
<tr>
<td>Female</td>
<td>26.6%</td>
</tr>
<tr>
<td>Among women</td>
<td></td>
</tr>
<tr>
<td>HRT use</td>
<td>48%</td>
</tr>
<tr>
<td>Parous</td>
<td></td>
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</table>
History of:

Varicose veins in family 76%
Prior superficial phlebitis or resolved DVT 10%
Prolonged standing job 76%

Table 2: Presenting symptoms

<table>
<thead>
<tr>
<th>% of limbs</th>
<th>Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>90%</td>
<td>Spider veins</td>
</tr>
<tr>
<td>78%</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>70%</td>
<td>Leg pain</td>
</tr>
<tr>
<td>75%</td>
<td>Leg fatigue</td>
</tr>
<tr>
<td>55%</td>
<td>Leg edema</td>
</tr>
<tr>
<td>45%</td>
<td>Venous stasis: dermatitis</td>
</tr>
<tr>
<td>8%</td>
<td>Venous stasis: ulceration</td>
</tr>
</tbody>
</table>

Table 3: CEAP classification

<table>
<thead>
<tr>
<th>CEAP</th>
<th>Characteristics</th>
<th>% of patients &amp; (no.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical classification</td>
<td>Lacks visual or palpable signs of venous disease</td>
<td>0 90%(54/60)</td>
</tr>
<tr>
<td>Class 0</td>
<td>Telengictasia, reticular veins, malleolar flare</td>
<td>78% (47/60)</td>
</tr>
<tr>
<td>Class 1</td>
<td>Varicose veins</td>
<td>55% (33/60)</td>
</tr>
<tr>
<td>Class 2</td>
<td>Edema without skin changes</td>
<td>34% (20/60)</td>
</tr>
<tr>
<td>Class 3</td>
<td>Venous disease and skin changes</td>
<td>8% (5/60)</td>
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<td>Class 4</td>
<td></td>
<td>0</td>
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<tr>
<td>Class 5</td>
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<tr>
<td>Class 6</td>
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<tr>
<td>Etiologic classification</td>
<td>Congenital Cause</td>
<td>Primary</td>
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<tr>
<td>Present since birth</td>
<td>Undetermined</td>
<td>Associated, known</td>
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<td></td>
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<tr>
<td>Anatomic classification</td>
<td>Superficial</td>
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</tr>
<tr>
<td></td>
<td>veins</td>
<td></td>
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<tr>
<td></td>
<td>100%</td>
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<tr>
<td></td>
<td>Deep</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>veins</td>
<td></td>
</tr>
<tr>
<td></td>
<td>65% (22/34)</td>
<td></td>
</tr>
<tr>
<td>Pathophysiologic class</td>
<td>Venous reflux</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Venous outflow</td>
<td></td>
</tr>
<tr>
<td></td>
<td>obstruction</td>
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</tbody>
</table>

**Clinical Outcomes and Data Analysis**

Postoperative evaluations assessing clinical outcomes and duplex ultrasound of the GSV were performed within 1 month, 6 months, 1 year, and then yearly after the endovenous laser treatment. Duplex ultrasound was used as it has shown to be highly sensitive (0.92-0.95) in identifying the competence of saphenofemoral and saphenopopliteal junctions.

The endpoint of the study was the measurement of clinical outcomes and complications. Clinical success was defined as occlusion of the GSV by duplex ultrasound and disappearance of clinical symptoms. Clinical failure was defined as patency or recanalization of the treated GSV or any significant residual symptoms. Complications were listed as minor and major. Minor complications were defined as temporary and self-limiting symptoms without any clinical sequelae, and major complications were defined as those involving further intervention or permanent sequelae. The patients were followed up to 18.5 months (mean 12.19 months). To assess unit energy delivered during the treatment, GSV diameter and length, total energy delivered, laser pull back speed,
and total laser ablation time were recorded. Energy in joules (J) per length of GSV in centimeters was calculated. All laser procedures were done under ultrasound guided femoral block associated with tumescent anesthesia (infiltration of local anesthetic along course of GSV, perivenous.)

• **Techniques**

After informed consent was obtained, the patient's medial lower thigh was prepared and draped in the usual sterile fashion. Regional anesthesia by femoral block technique, Ultrasound and Peripheral Nerve Stimulator guided, all patients were premeditated by 1-2 mg midazolam IV before starting the procedure. All patients were in the supine position with extended both legs. In obese patients, pillow was placed underneath the hips to facilitate the palpation of the femoral artery. The femoral artery and nerve were visualized using a high resolution ultrasound device (Sonosite, S-nerve, C11 probe, 11-mm broadband curved array transducer with a frequency of 4-7 MHz). These structures were marked on the skin. A 22-gauge B-bevel shaped insulated stimulating needle was advanced under stimulation (Stimuplex, B Braun, and Bethlehem, PA). The endpoint used for injection was an ipsilateral quadriceps contraction at 0.2 mas. At this point, 10-15mL of lidocaine 1% were injected slowly after negative aspiration. Needle advancement and the injection of local anesthetic were visualized with ultrasound. A sensory level to cold temperature in the femoral nerve distribution was established within 10-15 min.

After regional anesthesia, clexan 40 mg s.c given as our protocol, prophylaxis for DVT for all patients. The most distal GSV at a knee level was accessed using the Seldinger technique with a 5 Fr micro puncture set, under hand-held ultrasound guidance (Logic Book; GE Medical Systems, Milwaukee, WI, USA). A 5 Fr, 45 cm sheath (Vascular Solution, Maple Grove, MN, USA) was advanced over a 0.035-inch Bentson guide wire (Cook, Bloomington, IN, USA) through the GSV. Tumescent anesthesia was performed over the entire length of the GSV under hand-held ultrasound guidance (Logic Book; GE Medical Systems, Milwaukee, WI, USA). Attention was given to injecting tumescent anesthesia in the perivenous area, around the wall of the GSV, via a 25G needle under real-time sonographic guidance to produce the so-called saphenous eye appearance on ultrasound examination. This was performed to compress the GSV for circumferential displacement of laser energy and to dissect and separate the GSV from perivenous tissue to prevent skin burn or nerve damage [5]. The "heat-sink" effects of the anesthetic also help to reduce perivenous tissue damage from laser heat energy [5]. Tumescent anesthetic was made by mixing 250 ml of 0.9 normal saline and 30 ml of 1% Xylocaine with. Subsequently, a 600 lm bare-tip SMA 905 Fiber Optic Delivery Catheter or laser fiber (Vascular Solution, Maple Grove, MN, USA) was advanced through the sheath, and the laser fiber positioned about 1-2 cm below the saphenofemoral junction, as confirmed by ultrasound. Careful was taken to leave 2 cm of the tip of the laser fiber uncovered by the sheath, by retracting the sheath over the fiber. Subsequently, the entire length of GSV was ablated with a 980 nm diode laser (Angiodynamics, Queensbury,
NY, USA). For all patients, the power was set at 12 W at beginning till mid thigh than changed to 10 W till the site of entry of GSV, and the laser was run in continuous mode. The laser fiber pull-back speed was kept at about 0.25 cm/sec. Achieving the nearly constant pull-back speed was helped by measurement marks on the 45 cm sheath (Vascular Solution, Maple Grove, MN, USA). Manual compression over the treated site was applied during the laser pull-back to help increase the vessel wall contact with the laser heat. After the treatment, hemostasis at the venous access site was achieved by manual compression. Constant pressure was applied to the treated leg by immediately wrapping the leg with class II (30-40 mmHg) graduated compression stockings. Patients were kept in the day case department for 4 hours in accordance with the hospital protocol as regard regional anesthesia. After discharge, patients were encouraged to ambulate immediately and kept the treated leg above waist level when sitting or lying. No prescription-strength pain medication was given. The patient kept the class II graduated compression stocking on, except when sleeping and showering, until the follow up visit (mean 7 days). Postoperative clexan 40 mg s.c for 5 days was given as routine DVT prophylaxis.
Results

Using 980 nm diode continuous endovenous laser ablation, 100% initial technical success was noted. The technical success is measured by feasibility of the endovenous laser ablation technique. The mean diameter of the GSV in our patients was 0.9 cm. The mean length of saphenous vein treated was 40 cm. The mean energy applied during the treatment was 1600 J for mean treatment duration of 160 sec. The average laser fiber pull-back speed was 0.25 cm/sec. Mean energy applied per length was 40 J/cm. At 1 month follow-up, 100% occlusion rate was noted on treated veins by duplex Doppler examination.

No major complication was observed. No deep venous thrombosis or pulmonary embolism was noted. No skin burn or permanent nerve injury was noted. The following minor complications were observed. One patient (1.6%) developed hematoma at the percutaneous venotomy site, which was resolved with conservative treatment. This was related to inadequate manual compression and delayed application of the compression stocking. Nine (15%) patients developed thrombophlebitis on superficial tributary varices of the treated GSV, which resolved within two weeks. Thirty five patients (58.3%) developed ecchymoses or skin bruises along the treated GSV, possibly from direct laser ablation or needle punctures for tumescent anesthesia. These were self-limiting during the period of 1 week. Forty five percent of patients (27/60) developed mild hypersensitivity, tenderness, or "pulling" sensation along the treatment area, which was self-limiting over a 3 week period. An over-the counter nonsteroidal anti-inflammatory was used when indicated, but no narcotic prescription analgesic was needed by the patients. Fifteen patients (25%) developed temporary paresthesia in the treated leg. The symptom was noted as mild numbness in a spot in the calf area, which was self-limiting over 2-4 weeks without intervention. The paresthetic symptom resolved. One patient developed an allergy to the compression thigh stockings, and developed hives and skin irritation to the tapes holding the stocking at the upper thigh. No permanent focal neurologic symptoms or any debilitating symptom was noted from the femoral block (table 4). Six patients developed in the same day, decrease in motor power with standing and failure of support during standing that returned to normal after 6-8 hours. These patients required one day admission in hospital. Failure of effect of femoral block was noticed in seven (11.6%) procedures and they required an adjuvant sedation to tolerate the procedure. At follow-up times up to 16.5 months (mean 12.19 months) for all patients, 0% recanalization was noted. Ninety percent of patients improved clinically. Clinical failure in 10% resulted despite the absence of GSV reflux. These patients calf cramp/pain may be attributed to previous small vessel thrombosis in the calf, small perforator vein incompetency, or no venous causes. Eleven endovenous treatments (12%) were followed by adjunctive sclerotherapies on remaining spider veins and small residual varicose veins off the treated GSV for improved cosmetic results. Combined U/S guided foam injection of reflux tributaries during laser ablation was done for 21 cases (35%).
Table 4: Complications related to laser technique and femoral block

<table>
<thead>
<tr>
<th>Complications</th>
<th>Percentage of patients (no.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT &amp; PE</td>
<td>0</td>
</tr>
<tr>
<td>Skin burn</td>
<td>0</td>
</tr>
<tr>
<td>Nerve damage</td>
<td>0</td>
</tr>
<tr>
<td>Groin hematoma post nerve block</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>0</td>
</tr>
<tr>
<td>Thrombophlebitis</td>
<td>15% (9/60)</td>
</tr>
<tr>
<td>Skin ecchymoses</td>
<td>58.3% (35/60)</td>
</tr>
<tr>
<td>Pulling sensation &amp; hypersensitivity</td>
<td>45% (27/60)</td>
</tr>
<tr>
<td>Temporary paresthesia</td>
<td>25% (15/60)</td>
</tr>
<tr>
<td>Induration</td>
<td>16.6% (10/60)</td>
</tr>
<tr>
<td>Extension of hospitalization to one day</td>
<td>10% (6/60)</td>
</tr>
<tr>
<td>Minor hematoma post venotomy site</td>
<td>1.6% (1/60)</td>
</tr>
<tr>
<td>Skin allergy</td>
<td>1.6% (1/60)</td>
</tr>
</tbody>
</table>
Fig. 0

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Fig. 0

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Fig. 0

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Conclusion

Endovenous low energy laser ablation treatment of GSV using a 980 nm diode laser at average 11 watts with average 40 J/cm in continuous mode with safe and effective, resulting in 0% recanalization and low minor complication rates. Ultrasound guided femoral block appears as a good and safe anesthetic option for day case surgery with low risk of complications.
References

Personal Information

Ahmed Mohamed El-Marakby

Work address: Dr. Erfan hospital general hospital, Jeddah, KSA.

Home address: Villa, 22 El-Narges district, 5th settlement, New Cairo, Egypt.

Date of birth: 11-8-1973
Nationality: Egyptian

Tel. 00966556302944
E mail: ahmedmarakbi@hotmail.com

EDUCATION AND QUALIFICATIONS

- MD degree of general Surgery. Faculty of Medicine, Cairo University, December 2005.
- M.Sc. degree in General Surgery. Faculty of Medicine, Cairo University, March 2001, Signed up: Excellent.
- M.B. B.Ch. Faculty of Medicine, Cairo University, April 1998, Signed up: Excellent with honor.

WORK EXPERIENCE

- Current job:
  - Vascular consultant at Dr. Erfan and Bagedo hospital, Jeddah, KSA, since May 2005.
  - Lecturer of general and vascular Surgery at Cairo University Hospitals since December 2005.
  - Consultant of vascular surgery in New Kasr El-Eini teaching (French) and Manial specialized university hospitals, Cairo since 2005.

- Member of:
  - Egyptian society of vascular surgery since 2003.
  - Saudi vascular society since 2006.
Courses and seminars:

- Participated in 2 AAA procedures with quantum workshop hold in Leuven, Belgium at February 2003.
- Completed wound management seminar hold by Johnson and Johnson Company in Jeddah, KSA at February 2007.
- Attending a course in management of DVT by Saudi council of health at May 2007.
- Attending basic and advanced endovascular training course hold by the universities of Auckland and Waikato, New Zeland at November 2007.
- Complete course for Endovenous laser ablation for varicose vein at Leis page, Germany, 2008.
- Completed the basic life support provider course (CPR) according to guidelines of Saudi and American heart association. Certificate is valid till October 2011.
- Attending the advanced trauma life support course for doctors according to guidelines of American college of surgeons committee on trauma at King Fahd armed forces hospital, Jeddah, KSA. The certificate valid till 4 June 2012.

Papers and publications:


• Conferences and symposiums:

v Lecturer at 8th international symposium on vascular surgery update in collage of medicine, King Saudi University, Riyadh, KSA at January 2010.

v Attending with poster presentation at ESR (European society of radiology) conference, Vienna, Austria. At March 2009.


v Lecturer and of organizer committee of annual symposium of Jeddah Cardiovascular imaging and interventions at 2007, 2008 and 2009.

v Attended the annual congress of the Egyptian society of vascular surgery since 2000-2009.

v Lecturer at 7th international symposium on vascular surgery update in collage of medicine, King Saudi University, Riyadh, KSA at January 2008.

v Attending and active participation at the 26th annual meeting of Egyptian society of surgeons, February 2008.

v Attending first scientific meeting of the SSVS held in Jeddah, KSA. At March 2007.

v Attending 5th annual scientific conference of Saudi thoracic society at March 2007.

v Lecturer at 7th vascular surgery and 5th interventional radiology conference of Saudi germener hospital group, Jeddah, KSA. At November 2007.

v Attending updates in management of diabetic foot infection meeting hold in Dubai, United Arab Emirate at September 2006.

v Lecturer and attending at emergency and critical care scientific meeting at Dr. Erfan and Bagedo hospital, September 2006-2009.
v Attending and lecturer at cardiology scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending and lecturer at internal medicine scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending and lecturer at hospital grand round of Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending at neuroscience scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending the 3rd congress of North African and Middle East chapter of international union of angiology in Aswan, Egypt at March 2005.

v Attending the international vascular and endovascular congress at Alexandria, Egypt, October 2003.

v Attending and active participation in 21st summer meeting of the Egyptian society of surgery hold in Alexandria, Egypt at September 2003.

v Attending update on carotid artery disease meeting hold in Ghent, Belgium at March 2003.

v Attending and participate in live case presentation in sixth congress of the middle east and north African chapter of international society of cardiovascular surgery at October 2002.

- **Work experience:**

v Intern at Cairo University Hospitals for one year from 1-3-1996 to 28-2-1997 including 2 monthly rotations at the following sections: General Surgery, General Medicine, Gynecology & Obstetrics, Pediatrics, Emergency & Trauma (one month) & intervention radiology.

v Resident (SHO) in the department of general and vascular Surgery at Cairo University Hospitals from 16-3-1997 to 16-3-2000.

v Assistant Lecturer of general and vascular surgery at Cairo University Hospitals from April 2001 to October 2005.

v Lecturer of general and vascular Surgery at Cairo University Hospitals from October 2005 till now.

v Working as vascular attachment and trainee for three months at Leuven, Belgium under care of Professor Andree Nevelsteen from 1-3-2003 to 1-6-2003.
Vascular consultant at Dr. Erfan and Bagedo hospital from September 2005 till now

Job description and privilege:-

ý Responsible for all vascular and endovascular interventions including arterial, venous, dialysis and chemotherapy access and diabetic foot care

ý Responsible for running outpatient vascular clinic for 6 days/week with morning and afternoon shifts.

Procedures that carried from 2006-2009:-

ý Arterial bypasses including anatomical and extra-anatomical, most of bypasses were femoro-distal (infra-inguinal) with average 45 cases/year.

ý Carotid endarterectomy with average 5 cases/year.

ý AAA (open intervention) with average 4 cases/year.

ý Vascular injuries repair with average 20 cases/tar.

ý Arteriovenous access with average 60 cases/year.

ý Diabetic foot debridement and amputations with average 80 cases/year.

ý Varicose vein surgery and ELVES with average 50 cases/year.

ý Injection sclerotherapy at OPC with average 8 sessions/week.

ý Endovascular interventions including angioplasty and stenting, AV fistula and venous angioplasty, IVC filters Permicanth and Portacath insertions with average 55 cases/year.

Vascular work from 2006-2009:-

<table>
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<tr>
<th>Data</th>
<th>Out clinic</th>
<th>Operative procedures</th>
<th>Endovascular procedures</th>
<th>Peripheral interventions</th>
<th>Portacath insertion</th>
<th>Permicanth insertion</th>
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<td>170</td>
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<td>2007</td>
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<td>242</td>
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<tr>
<td>2008</td>
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<td>228</td>
<td>43</td>
<td>39</td>
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<td>2009</td>
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<td>378</td>
<td>44</td>
<td>48</td>
<td>14</td>
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<tr>
<td>total</td>
<td>14255</td>
<td>1018</td>
<td>112</td>
<td>93</td>
<td>34</td>
<td>1257</td>
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</tbody>
</table>
ACTIVITIES AND INTERESTS: playing basketball with good computer skill.

ADDITIONAL INFORMATION: married and having two daughters.

REFERENCES

v Professor Mohamed Sharkwy, professor of general and vascular surgery, Cairo University. Email: - sharkawy@link.net.

v Dr Kareem Alaska, consultant of Brighton University hospital, London, UK. Tel:- 004786502508. Email:- elsakka@doctors.org.uk

v Mustafa Halawa, consultant of vascular surgery, West Hertfordshire hospitals NHS Ttust, Vicarage road, Watford WD 18 0HB. Email: - Mustafa.halawa@whht.nhs.uk. Tel:- 01727897022.

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v Haney Zayed, locum vascular consultant, Guy’s and St. Thomas’ NHS Trust, Westminster Bridge road, London, UK SE1 7EH. Email: - hany.zayed@gstt.nhs.uk. Tel:- 00447899790607.

v Dr. Huda ELkatteb, cardiology consultant and head of cardiovascular department, Dr. Erfan and Bagedo hospital.

v Dr. Mohamed Erfan, COM of Dr. Erfan and Bagedo hospital, Jeddah, KSA.