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Short-term Follow-up of Duplex Guided Angioplasty for Femoropopliteal Arterial Occlusive Disease

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aim: The aim of this study is to evaluate initial and short-term result of duplex guided angioplasty (DGA) for treatment of femoropopliteal arterial lesions.
Methods: From October 2017 to September 2020, 50 limbs in 50 patients (30 males) underwent DGA in our institution. The study was conducted on patients suffered from chronic lower limb ischemia of grade IIb, III and IV (according to Fontaine Classifications) resulting from femoropopliteal lesions (occlusion or stenosis). Arterial access was done under duplex guidance followed by advancing a guidewire across the diseased femoropopliteal segment(s). The diseased segment(s) were then balloon-dilated. Intimal dissection or residual stenosis causing diameter reductions greater than 30% were stented with a self-expandable stent under duplex guidance. Completion duplex examinations and ankle brachial indices were obtained after the procedure.
Results: The mean age of patients was 64 ±8 years. Critical ischemia was the indication in 44%, and disabling claudication was the indication in 6% of cases. Technical success was achieved in 46 cases (92%). 31 cases (62%) went through transluminal crossing of the lesions using duplex guidance alone, 11 cases (22%) went transluminally using duplex combined with contrast-free fluoroscopic assistance and 4 cases (8%) was subjected to subintimal angioplasty using combined techniques. Stenting was done in 24 cases (48%), 16 cases (32%) were having floating intimal flap; while the other 8 cases (16%) had residual stenosis > 30%. A primary patency rate of 92% was obtained by the end of the 12 months follow-up period.

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Conclusion: Duplex can be used as a first strategy for the treatment of femoropopliteal arterial diseases. However, the pitfalls in DGA technique make it insufficient to replace the classic fluoroscopy.

Keywords: Duplex guided angioplasty; femoropopliteal.

1. INTRODUCTION

Duplex scanning has become an invaluable tool for the vascular surgeon. Several clinical and experimental investigations have confirmed the accuracy of duplex ultrasonography by comparing the degree of peripheral vascular disease noted on arteriography [1-3]. Since the early 1990s, vascular surgeons have been trying to employ Duplex to perform percutaneous transluminal angioplasty (PTA) without the use of contrast material and fluoroscopy [4].

Duplex guided angioplasty (DGA) eliminates the risk factor of radiation exposure for everybody involved in the procedure. Moreover, patients with impaired renal function and elevated serum creatinine levels or diabetics may benefit the most due to lack of exposure to contrast materials and increased risk of developing contrast-induced renal failure [5,6].

The aim of this study is to evaluate initial and short-term results of DGA in patients with femoropopliteal arterial lesions.

2. PATIENTS AND METHODS

This is a prospective study that was conducted from October 2017 to September 2020 on 50 limbs in 50 patients admitted to Vascular Surgery Department, Tanta University Hospitals. The study was approved by the Research Ethical Committee of Tanta Faculty of Medicine with a written informed consent obtained from all patents in the study. The study included patients suffered from grade IIb, III and IV chronic lower limb ischemia (according to Fontaine Classifications), resulting from stenotic or occlusive femoropopliteal lesion; patients with normal or impaired renal functions of serum creatinine level >1.5 mg/dl and patients with hypersensitivity to contrast media. Patients with infragenicular or aorto-iliac lesions were excluded from the study. Patients with coagulopathy, as well as, unsalvageable limbs were also excluded from the study.

Demographic and preoperative data including, clinical presentation (Fontaine classifications), associated comorbidities, ankle brachial index (ABI) measurement; were collected from each patient. Routine preoperative laboratory investigations were performed as well. Anatomical (site, length and nature of the lesion whether stenosis or occlusion) and hemodynamical (peak systolic velocity (PSV) and velocity ratio across the lesion) data of the limb arterial tree was obtained from preoperative duplex scanning (using Philips Affinity 50G ultrasound machine with L12-4 MHz linear probe), followed by marking the lesion on the skin surface. We used Trans-Atlantic Inter-Society Consensus (TASC) classification for morphological categorization of femoropopliteal lesions. Aspirin and clopidogrel were started 48 hours before the procedure and continued during the follow-up period.

2.1 Technique

The procedures were performed by three vascular surgeons, who are members in the Egyptian Society of Vascular Surgery. There was no difference in results among all surgeons. The procedures were done under local anesthesia (10 cc xylocaine 2% at the puncture site) in an operating room containing the duplex machine, and fluoroscopic C Arm (Ziehm vision R, manufactured by Ziehm Imaging, Germany).

2.2 Access Site

Access was obtained under duplex guidance either through ipsilateral antegrade approach through common femoral artery (CFA) using AVANTI® 6 Fr. × 11 cm sheathe (Cordis, USA), or contralateral CFA using cross-over sheath (Flexor® 6 Fr. × 55 cm, Cock, USA) and with the help of fluoroscopy to cross the aortic bifurcation in cases with superficial femoral artery (SFA) osteal lesions. followed by intravenous administration of 5000IU of unfractionated heparin (Fig. 1).

2.3 Crossing the Lesion

Using a standard 0.035 inch x 260 cm ZIP hydrophilic guide wire (Boston Scientific, USA) to

cross the lesion intraluminally (Fig. 2). In cases of failure of intraluminal passage of the guide wire, subintimal dissection was initiated with the help of a directional catheter (4&5 Fr. selective Bern angiographic catheter, Boston Scientific, USA) supporting the guide wire followed by re-entry in the arterial lumen which was confirmed by color flow imaging.

2.4 Angioplasty

According to measurements obtained by duplex, angioplasty was done using 4&5 mm Mustang PTA balloon (Boston Scientific, USA) under duplex guidance (Fig. 3).

2.5 Completion Duplex Scan

Following removal of the balloon angioplasty catheters to identify possible areas of plaque dissection (Fig. 4), thrombosis and residual stenosis (Luminal defects of >30% diameter reduction with velocity ratio ≥2 across the stenosis).

2.6 Stenting

For segments with plaque dissection and residual stenosis, and according to duplex measurements; stenting was done using self-expanding stents (6 Fr. Innova self-expandable stent, Boston Scientific, USA) under duplex guidance (Fig. 5).

2.7 Postprocedural Workup

Minor amputation for gangrenous parts and complete duplex scanning was performed prior to hospital discharge.

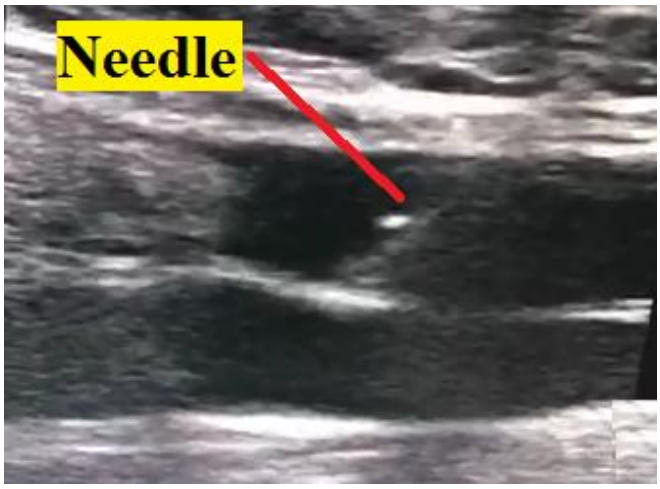

Fig. 1. Arterial access under duplex guidance

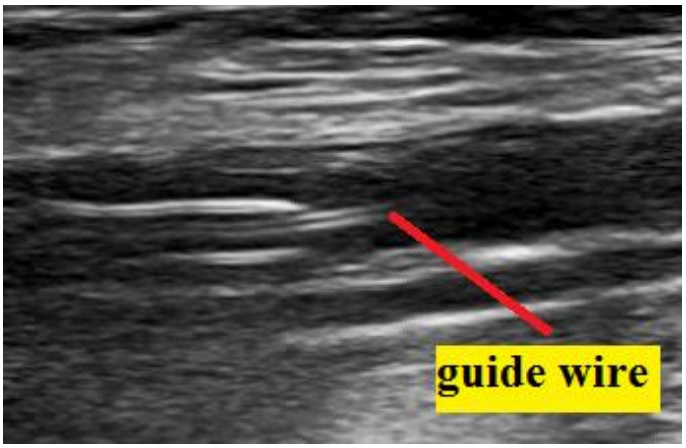

Fig. 2. Advancing the guide wire across SFA

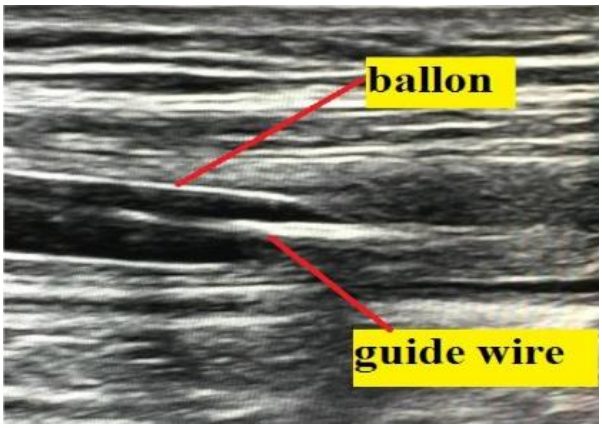

Fig. 3. Balloon inflated across the diseased arterial segment

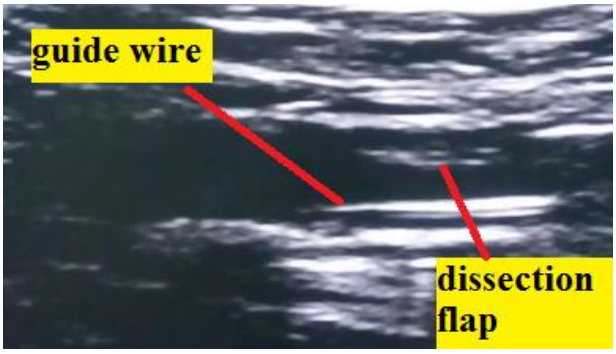

Fig. 4. Dissection flap after balloon dilatation

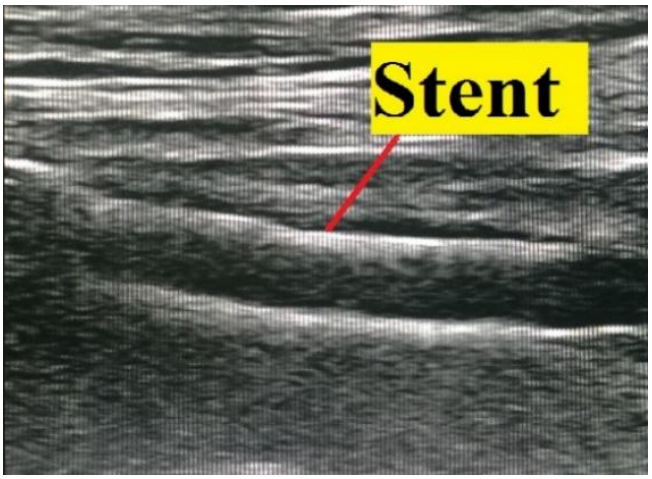

Fig. 5 Stent deployed across the arterial lesion

2.8 Follow-up Visits

Visits were scheduled in the outpatient clinic within a month after the procedure and every 3 months thereafter for a period of one year. Patients underwent clinical assessment for distal pulse, improvement of claudication distance and limb salvage or amputation. They went ABI measurements, as well as, duplex scanning to detect significant restenosis or re-occlusion (significant restenosis is defined by diameter

reduction >70%, and re-occlusion is defined by absence of color flow).

Our primary end point was the patency of the lumen after angioplasty for less than 30% lumen reduction. The secondary end point was the clinical success for improved ABI, improved claudication distance or healed amputated stump.

2.9 Statistical Analysis

The collected data were organized, tabulated and statistically analyzed using Statistical Package for The Social Sciences (SPSS) version 25 manufactured by SPSS, international Business Machines (IBM) company, United States of America. For categorical data, the number and percentage were calculated for each observation. For numerical data, the range, mean and standard deviation were calculated. The correlation between variables was calculated by Pearson's correlation coefficient (r). The level of significance was considered at probability value of $P < 0.05$ using the Wilcoxon signed rank test.

3. RESULTS

During the study period 50 limbs of 50 patients (30 males) with mean age 64 ±8 years (ranged between 55 and 83 years) underwent DGA for femoropopliteal lesions; of which, 6 patients (12%) were suffering disabling claudication, 10 patients (20%) were having rest pain and 34 patients (68%) suffered grade IV chronic ischemia according to Fontaine classifications. Concomitant risk factors are illustrated in table (1).

Duplex study showed completely occluded arterial segment in 26 cases (52%), while stenotic lesions were found in 24 cases (48%) (Fig. 6).

The duration of the procedure ranged between 45 to 90 minutes with mean length 55 minutes ±11. Immediate technical success, defined as the ability to cross and dilate the lesions with/out stenting with less than 30% stenosis, was achieved in 46 cases (92%). PTA failed in 4 cases (8%), who showed TASC D lesions and underwent open surgical repair. The procedural results are demonstrated in table (2).

3.1 Limb Salvage

Minor amputation of preprocedural gangrenous toes was performed in 33 cases (66%) after successful revascularization, while 1 case showed spread of infection beyond the ankle joint and went below knee amputation.

Table 1. Patient characteristics

Patient characteristics	N=50
Sex	
Male	30 (60%)
Female	20 (40%)
Age (years)	
Mean ±SD	64 ±8
Comorbidities	
Diabetes	44 (88%)
Smoking	28 (56%)
Hypertension	34 (68%)
Ischemic heart disease	23 (46%)
Carotid artery disease	21 (42%)
Hyperlipidemia	27 (54%)
Cerebrovascular disease	32 (64%)
Renal impairment	30 (60%)
Fountain Classifications	
IIb	6 (12%)
III	10 (20%)
IV	34 (68%)
TASC classifications	
TASC class A	9 (18%)
TASC class B	16 (32%)
TASC class C	20 (40%)
TASC class D	5 (10%)

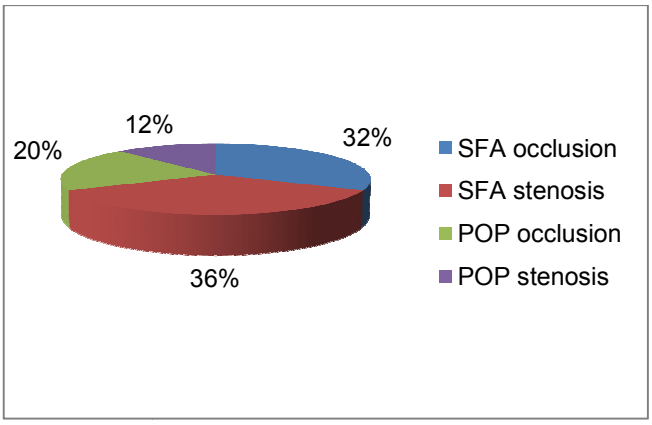

Fig. 6. Distribution of femoropopliteal lesions

Table 2. Procedural results

Procedural data	N= 50
Arterial access:	
• Ipsilateral antegrade approach	48 (96%)
• Ipsilateral retrograde approach after failed re-entry	1 (2%)
• Contralateral CFA approach	2 (4%)
Technical success:	46 (92%)
• Transluminal duplex guidance only	31 (62%)
• Transluminal duplex guidance combined with contrast-free fluoroscopy	11 (22%)
• Subintimal duplex guidance combined with contrast-free fluoroscopy	4 (8%)
Stenting:	24 (48%)
• For intimal dissection	16 (32%)
• For residual stenosis > 30%	8 (16%)
Postprocedural complications:	
• death	0
• Postprocedural hematoma	4 (8%)
Procedural time for:	Mean ±SD
• TASC class A	50 minutes ±10
• TASC class B	55 minutes ±15
• TASC class C	65 minutes ±20
• TASC class D	60 minutes ±30

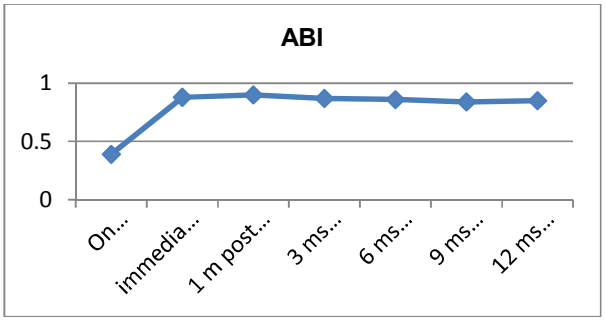

Fig. 7. Mean ABI during follow-up visits

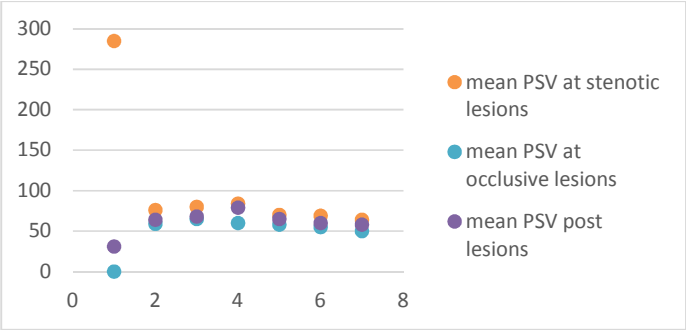

Fig. 8. Mean PSV during follow-up visits

3.2 Hemodynamic Changes

ABI changed preprocedural from a mean of 0.39 ±0.13 (ranged 0.25 - 0.7) to postprocedural of 0.88 ± 0.1 (ranged 0.78 - 1). *P* value of 0.003 demonstrated a significant increase of ABI after the procedure. There were no statistically significant changes between early postprocedural ABI and ABI measured along follow-up visits (Fig. 7). Also, *P* value of 0.001 demonstrated a significant change of PSV whether at or beyond lesions before and after the procedure. There were no statistically significant changes between early postprocedural PSV and PSV measured along follow-up visits. (Fig. 8).

Follow-up visits showed primary patency rate of 92% at the end of the one-year follow-up. Four cases (8%) showed SFA restenosis (they were unstented lesions), 3 of them had healed wound of previously amputated gangrenous toe with no other critical ischemic manifestation; while the other case complained disabling claudication and went successful revascularization with stenting under duplex guidance.

4. DISCUSSION

This study supports our belief that DGA is the best alternative to classic fluoroscopy for the treatment of femoropopliteal arterial occlusive diseases. As well known for duplex scanning being an important diagnostic and a surveillance tool, it has also been proven to be an integral part of endovascular intervention through clear visualization of guide wires, sheaths, balloons and stents [7,8]. The benefit of DGA comes mainly through avoiding radiation and the use of contrast material. The avoidance of ionizing radiation is one of the most major advantages of duplex-guided PTA, which is considered a minor problem for the patient but a distress and potential hazard for the medical personnel [9]. As endovascular procedures become an increasingly significant portion of the vascular surgeon's practice, radiation exposure may impose a real health hazard that needs to be recognized and minimized. As pointed out by Lipsitz et al.[10] the deleterious effects of radiation exposure are cumulative and permanent, and the onset of signs and symptoms can be delayed. The risk for contrast-induced nephropathy has been well documented to double with every 20 ml of iodinated contrast administered [11,12]. Co2 angiography is found to be a safe and effective alternative method for patients with renal impairment avoiding the dye. However, it still involves radiation; relatively contraindicated in patients with chronic obstructive pulmonary disease (COPD) and it requires a special delivery system which is not always available [13]. The Duplex offers multiple unique features: (1) guiding puncture of the target vessel to gain the arterial access, which may be difficult with blind attempts particularly in obese patients or small vessels; (2) visualization of guide wires and catheters in relation to the lesions throughout the procedure; (3) precise measurement of the vessel diameter, helping proper sizing of the balloons and stents; (3) confirmation of the adequacy of the procedure with B-mode and spectral analysis; (4) detection, as well as, management of postprocedural complications (example: access site pseudoaneurysm can be managed by ultrasound guided thrombin injection) [14]. Such importance of duplex ultrasound for vascular surgeons and technologist, he must have good experience in duplex mapping of aorto-iliac and infrainguinal arterial segments and be able to recognize different endovascular tools and devices on imaging screen. Despite all these advantages, Krasznai et al.[15] reported failed duplex imaging during DGA for iliac lesions due to bowel gases, so all patients were starved overnight and

were subjected to spinal anesthesia to relaxes the abdominal muscles for optimal visualization of the iliac arteries. Also, Ascher et al.[16] reported higher incidence of distal thrombosis and difficult visualization in heavily calcified tibial vessels while performing infragenicular DGA. Many studies have been reviewing the safety and efficacy of DGA in treatment of femoropopliteal diseases especially for patients with renal impairment as reported by Ascher et al.[8] and Mazzaccaro et al.[13] As well, our study concluded 30 patients (60%) with creatinine levels of ≥ 1.5 mg/dL.

More than half of our patients (52%) had occlusive, rather than stenotic lesions. Unlike Ahmadi et al.,[9] who showed most of their cases (70%) were having stenotic lesions; while no arterial occlusions were treated in Ascher et al.[8] by DGA. The majority of our patients (68%) were suffering grade IV chronic ischemia according to Fontaine classifications. In contrast to Ahmadi et al.,[9] Ascher et al.,[8] and Marks et al.[7] whose patient were mainly of grade IIb (62-79%).

Overall technical success was achieved in 46 cases (92%), of which, 31 cases (62%) went through transluminal duplex guidance alone. As a drawback of DGA technique is difficult visualization in severe calcifications and obesity, we combined duplex guidance with contrast-free fluoroscopy in 15 cases (30%) that went successful angioplasty (11 cases transluminal and 4 cases subintimal). We used the help of fluoroscopy without any contrast to assist either snaring the wire in 1 case (2%) subjected to retrograde approach, crossing the aortic bifurcation in 2 cases (4%) subjected to contralateral approach and ensuring the position of the wire tip distal in the tibials in 14 cases (28%). Also, Ahmadi et al.[9] reported immediate technical success in 88 patients (84.6%) using duplex guidance alone. They had difficult duplex visibility, as well, due to severe calcifications and contrast-based fluoroscopy was used for successful angioplasty in 9 patients (8.6%). Ascher et al.[17] reported overall technical success of 93% using DGA, of which, 45 cases (17.8%) were combined with contrast-based fluoroscopy.

PTA failed in 4 cases (8%) as they belonged to TASC class D. They went successful femoropopliteal bypass. Also, Ascher et al.[17] reported failed DGA in 17 cases (7%), eight of them belonged to TASC class c and the remaining 9 belonged to TASC class D. Only 2 cases of the 17 continued successfully with fluoroscopic guidance, while 5 cases underwent femoropopliteal bypass, 1 required below knee amputation because of a lack of revascularization options, and the remaining 9 patients are being observed. There was no periprocedural mortality. However, 4 cases (8%) showed postprocedural groin hematoma without significant hemoglobin (Hgb) drop down. None of them needed blood transfusion. They went successful hemostasis of puncture site through duplex guided compression.

In this study, the primary patency rate was 92% at the end of 12 months follow-up. In 1996 Katzenschlager et al.[18] reported initial 6 months follow-up of DGA for femoropopliteal arterial diseases with primary patency rate of 80.9%. This was followed by Ahmadi et al. study [9] in 2002 having 12 months follow-up of femoropopliteal DGA with primary patency rate of 60.2%. A six month follow-up study published by Marks et al.[7] in 2006 for femoropopliteal DGA demonstrated a primary patency rate of 69%. Serials of published studies by Ascher et al.[8,16,17,19-21] from 2005 to 2008 with 12 months follow-up period reported primary patency rate of 90%,59%, 52% and 46% for TASC A,B,C and D classifications respectively.

5. CONCLUSION

Our experiment with DGA with/out stenting showed that this technique is feasible and effective. It may be used as the first strategy in the management of femoropopliteal arterial diseases especially stenotic lesions. Patients with renal insufficiency or those with severe allergy to contrast material are the most benefit from the approach.

6. LIMITATION OF THE STUDY

The study had limitation of the small sample size of the study population, which was due to limited presentation of isolated femoropopliteal lesions.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

The study was approved by the Research Ethical Committee of Tanta Faculty of Medicine with a written informed consent obtained from all patents in the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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