ORIGINAL ARTICLE

LAPAROSCOPIC COMMON BILE DUCT EXPLORATION: PATIENT SELECTION FOR NON- EXPERIENCED SURGEONS

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Abstract

Background and study aims: Gall stones (Cholelithiasis) are a common health problem worldwide. Common bile duct (CBD) stones are the second most frequent complication of cholelithiasis and occur in 10% to 15% of patients. Most laparoscopic surgeons prefer the "single-stage" laparoscopic approach to cholelithiasis and choledocholithiasis in an attempt to decrease the need for multiple procedures and their associated morbidity and mortality. This is a preliminary experience aiming at evaluation of laparoscopic common bile duct exploration in a selected group of patients with choledocholithiasis to choose good selection criteria.

Patients / Material and Methods: From March 2011 to May 2013, fifty patients with common bile duct stones underwent laparoscopic CBD exploration in Gastro-enterology surgical center, Mansoura, Egypt.

Results: Fifty patients with CBD stones underwent laparoscopic CBD exploration, with successful procedure in 47 cases and the remaining 3 cases required conversion to open surgery; Two patients underwent laparoscopic trans-cystic approach with successful CBD clearance in both patients as they have small stones below 0.5 cm. Forty-five patients required laparoscopic choledochotomy. Hospital morbidity occurred in 2 (4%) patients; one with minor bile leak which managed conservatively and one with missed CBD stone that required endoscopic stone removal 5 days postoperatively. There was no operative mortality.

Conclusions: Laparoscopic CBD exploration is a feasible, safe and effective procedure that has a low morbidity and mortality rate. Patient selection is mandatory especially in the first few cases (during the learning curve) until experience is approached.

Keywords: Common bile duct stones, Laproscopic exploration, Non-experienced surgeons.

INTRODUCTION

Gall stones (Cholelithiasis) are a common health problem worldwide. Gall stones can occur anywhere within the biliary tree, including the gallbladder and the CBD. CBD stones are the second most frequent complication of Cholelithiasis and occur in 10% to 15% of patients.[1,2]

The management of CBD stones remains controversial. There is no standard algorithm and the disparity in laparoscopic skills among surgeons has perpetuated this lack of a standard.[3]

The big revolution in biliary surgery was the introduction of laparoscopic cholecystectomy (LC) in

1989.[4] The logical extension of this procedure was the introduction of laparoscopic CBD exploration (LCBDE) for suspected or proved ductal stones. Two approaches have been popularized for LCBDE: trans-cystic common bile duct exploration (TC-CBDE).[5,6] and laparoscopic choledochotomy (LCD).[7,8]

During the early development of LC, patients with the slightest suspicion of CBD stones underwent preoperative endoscopic retrograde cholangio pancreatography (ERCP) with a view that if stones were discovered they could be removed either using endoscopic sphincterotomy or operative CBD exploration. However, the use of preoperative ERCP is increasingly being challenged because it is a costy procedure; in the majority of cases;[9-11] there is a risk of life-threatening complications such as bleeding (3%), pancreatitis (2%), duodenal perforation (1%), and late papillary stenosis (10% to 33%);[12] and it has a failure rate that may require patients to return to the operating room to clear their CBD stones. Most laparoscopic surgeons therefore prefer the "single-stage" laparoscopic approach for cholelithiasis and choledocholithiasis in an attempt to decrease the need for the excessive number of negative ERCPs and their associated morbidity and mortality; to avoid damaging the ampulla of Vater, the physiological consequences of which are of legitimate concern; and to spare the patients multiple hospital admissions, to shorten the hospital stay, and lastly, to decrease the cost.[13-15]

Aim of the study: This is a preliminary experience aiming at evaluation of LCBDE in a selected group of patients with cholelithiasis and choledocholithiasis trying to establish good selection criteria.

MATERIAL AND METHODS

From Mars 2011 to May 2013, fifty patients with CBD stones diagnosed by history, physical examination, biochemical data, ultrasonography, or magnetic resonance cholangio-pancreatography (MRCP) underwent LCBDE in Gastro-enterology surgical center, Mansoura University, Egypt, with successful completion in 47 cases. Failure of completing the procedure laparoscopically in 3 cases that required conversion to open surgery with completion of the operation. Of the 47 successfully treated patients, 2 patients underwent laparoscopic trans-cystic stone extraction and 45 underwent laparoscopic choledochotomy. Our primary technique was laparoscopic trans-cystic CBD exploration (LTC-CBDE), and the indications for LTC-CBDE were stones smaller than 8 mm, fewer stones, and cystic duct lateral entrance to the CBD. The LCD technique is an alternative approach in patients with dilated common duct (diameter >10 mm), failure of trans-cystic duct exploration, or proximal ductal calculi.

Informed consent was obtained from all patients to be included in the study, after explaining the nature of the disease and operative steps and possible complications. This study was approved by the local ethical committee.

The exclusion criteria were:

1. Age below 20 or above 70 years.
2. Serum bilirubin level above 10mg/dl "neglected Obstruction".
3. Patients with liver cirrhosis.
4. History of previous upper abdominal surgery.
5. Severe acute cholecystitis (pyogenic or gangrenous).
6. Severe gallstone pancreatitis.
7. Acute pyogenic cholangitis.
8. Ampullary stenosis with multiple intra-hepatic stones, and
9. Suspected biliary tumor.

Surgical Procedure:

LC was performed by a standardized technique using a 45° video laparoscope placed through a 10-mm umbilical port and three additional laparoscopic sheaths: one 10-mm at the epigastrium, one 5- mm right flank, and one 5-mm inserted into the right upper quadrant. Intra-operative cholangiography (IOC) was a mandatory step. All IOC were typically performed by introducing a 14-gauge cholangio-catheter through a small puncture site in the right upper quadrant. The catheter was then inserted into a small incision in the cystic duct and secured in place with a clip. A half-strength contrast solution was injected under fluoroscopy for visualization of the biliary anatomy. Gentle instrumental compression was exercised on the CBD to ensure adequate filling of the sub-hepatic ducts and visualization of small calculi, and to eliminate false positive images due to air bubbles. Biliary anatomy as well as the number, size, and location of bile duct stones were considered in choosing a trans-cystic approach or a choledochotomy. After the decision was made, the bile duct was dissected and exposed, a longitudinal incision no longer than the largest stone was made in the anterior surface of the CBD and below the cystic duct, through which a 3 Fr-flat-wire basket was inserted through epigastrium sheath into the CBD and maneuvered both proximally and distally in the biliary tree. Also, a balloon catheter was used to retrieve the stones.

After complete clearance of the CBD, a latex rubber T-tube of appropriate size (14–16 Fr) was inserted into the CBD incision. After the tube had been positioned in place, the CBD incision was closed using interrupted sutures (4/0 Vicryl or Ethicon). Complementary T-tube cholangiogram was done to detect any residual stones. At the end of the procedure, a single infra-hepatic suction drain was placed, and this was removed after 48–72 h if there was no bile leak. Patients were discharged with their T-tubes opened in situ.

Discharge and Follow-Up: A T-tube cholangiogram was performed within about 10 days postoperatively, and if this was free the T-tube was clamped for one day then removed safely in the outpatient setting. If there were retained stones, the T-tube was left in place. ERCP was done for removal of missed stone/s once the diagnosis is made.

RESULTS

Fifty patients with CBD stones underwent LCBDE attempt, with successful completion in 47 cases and the remaining 3 cases required conversion to open surgery; thus the conversion rate in our study was 6%. The reasons for conversion were dense adhesions with unclear anatomy and impacted stone at the lower end of the CBD. (Table 1) shows the demographic characteristic and clinical presentations of all patients.

Table 1. Demographic characteristic and clinical presentation.

Age (years)	46 .6±15.4
Sex (male/female)	(14/36)
Biliay colic	30 (60%)
Jaundice	36 (72%)
Acute cholecystitis	5 (10%)
Dyspepsia	40 (80%)
Total number	50 cases

Two patients underwent LTC-CBDE with successful CBD clearance in both patients as they had small stones below 0.5 cm. Forty-five patients had LCD. T-tube confirmation cholangiogram at the end of the operation was done. The diameter of the CBD was 13.4± 2.3 mm, diameter of CBD stones was 13.5±2.1mm. Number of CBD stones was 3.1±2.4. Stone clearance obtained in 44 patients. The operative time was 115±29 minutes while the postoperative hospital stays was 5.3± 2.5 days. The median time to remove the drain was 2.4± 1.5 days.

Hospital morbidity occurred in 2 (4%) patients; one with minor bile leak (leakage <100 mL/ 24 h) that was managed conservatively and one with missed stone that required ERCP and stone removal 5 days post-operatively. There was no operative mortality.

DISCUSSION

Several different ways have been described for treating CBD stones, which are diagnosed during or before LC. It is logic that the best treatment should be a one stage technique, with the least discomfort for the patient and with lowest morbidity and the shortest hospital stay period.

Biliary endoscopic sphincterotomy "BES", since its introduction in 1974, has supplanted surgery as the standard therapy for bile duct stones. About 85% to 90% of bile duct stones can be removed by balloon/basket extraction following BES.[16]

Laparoscopic CBDE is more desirable due to several important reasons. Firstly, it removes the need and hence the risks of ERCP. Secondly, it reduces the inconvenience by offering a one-stage procedure in laparoscopic CBDE compared to a two-stage approach in ERCP followed by LC.[17] Laparoscopic CBD exploration is cost effective and permits early recovery with a reduced period of short-term disability.[18]

The results of a multi-center study reported by Cuschieri et al suggest that a single stage laparoscopic treatment is a better option.[19]

Laparoscopic exploration of the common bile duct could be done either by a trans-cystic approach or by a choledochotomy. In the trans-cystic technique, good results have been published with a clearance of 85% or more but the technique has limitations. The laparoscopic choledochotomy has no limitations in size of stones but carries a higher morbidity that could be due to the use of a T-tube when closing the incision in the common bile duct.[20]

In reported series there is a great difference between the results of feasibility of trans-cystic stone removal. In large reported series by Moore et al (21) trans-cystic CBD clearance was succeeded in 65% of cases while Lyass et al,[22] reported 85% success rate. The overall complication rate of trans-cystic exploration is reported as 5% to 10%, with a mortality rate of <1%.[23] In our study trans-cystic stone retrieval was achieved in 2 of 47 patients. (4%). Those patients fulfilled the criteria of such procedure which are small sized stone with the appropriate dilated and short cystic duct. Those 2 patients had smooth post-operative course without complications. However a larger number of patients are needed to judge the efficacy of that approach in comparison to the choledochotomy in terms of reducing complications or improving the outcome.

Comparing the various techniques in performing laparoscopic CBDE, trans-cystic CBDE has been associated with fewer complications compared to choledochotomy.[24]

The risk of retained stones following laparoscopic CBDE had been reported from 0 to 19% of cases. Retained stones continued to be a significant complication in CBDE, whether performed opened or laparoscopically.[25-27]

In our study Hospital morbidity occurred in 2 (4%) patients; one with minor bile leak (leakage <100 mL/24 h) who managed conservatively. And one case

with missed stone CBD (2%) who requires ERCP 5 days later with stone removal.

There always have been debates regarding primary closure of the choledochotomy and T-tube insertion. However, many recent studies have shown that primary closure may be better.[28]

In our study, the choledochotomy was closed over T-tube in all patients; one patient develop minor bile leak who managed conservatively. Our patients are allowed to go home with a functioning T-tube; this would shorten the hospital stay and decrease the total hospital expense. At outpatient clinic the T- tube was removed when T- tube cholangiogram was free.

The conversion to open surgery seems also to be variable between studies. Some authors reported a conversion rate up to (9.5%); on the other hand some reported a rate of conversion less than (1.5%),[29] in our study the conversion rate was 6% (3/50) due to marked adhesion and impacted stone at lower end CBD.

In conclusions clearly there is no single best approach for the management of choledocholithiasis. The optimal treatment is one that can be performed in the same setting. LCBDE is a feasible, safe and effective procedure that carries a low morbidity and mortality. The applicability of LCBDE will be dictated by the suitability of the patient to undergo a more prolonged procedure, the skill and training of the surgeon, the availability of more sophisticated equipment, and the availability of local expertise in ERCP if this failed. Patient selection is mandatory especially in the first few cases till the learning curve approached.

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ORIGINAL ARTICLE

ORIGINAL DISEASE RECURRENCE AFTER ADULT TO ADULT LIVING DONOR LIVER TRANSPLANTATION (A-ALDLT), SINGLE CENTER EXPERIENCE

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Abstract

Background and Aim: The recurrence of the original disease affects liver transplantation (LT) outcome. Recurrence of viral and non-viral liver disease results in graft failure. This study aimed to analyze the factors responsible for disease recurrence after A-A LDLT and the effect of disease recurrence and its management on the outcome of LT.

Subjects and Methods: After exclusion of 6 months mortality and pediatrics, thirty one alive transplanted patients were enrolled in the analysis in the follow up duration from 6 months to 60 months post transplantation. Univariate analysis and then multivariate analysis were done to detect the relationship between (demographic, preoperative, intraoperative and postoperative data) and overall recurrence and between recurrence variables and total survival in the follow up period.

Results: Sixty nine patients underwent LDLT in our institute from April 2003 until the end of December 2009. The present retrospective study included 31 patients in the follow up duration and the incidence of recurrence was 15/31(48.4%) of patients (10 hepatitis C virus (HCV), 3 hepatocellular carcinoma (HCC) and 2 primary sclerosing cholangitis (PSC)). On univariate analysis, there was no statistically significant predictors of recurrence regarding (demographic, Preoperative, intraoperative and postoperative data). The overall 1-, 3- and 5- year survivals of patients were 90.3%, 87.1% and 83.9% respectively, while the overall 1-, 3- and 5- year survivals of patients with and without recurrence were 86.7%, 80% and 73.3% and 93.8%, 93.8% and 93.8% respectively.

Conclusion: Recurrence of primary disease after LDLT is confirmed in our study with the highest incidence in HCV patients. On the other hand HCV recurrence was higher in the following patients (Cytomegalovirus (CMV) infections and with acute rejection). While HCC recurrence was higher in the following patients (Beyond Milan, with Alfa feto protein (AFP) >200 and patients with moderate tumor differentiation). Recurrence of primary disease after liver transplantation decreases post transplantation Survival. However its effective management improves survival.

Keywords: Living donor liver transplantation, Hepatitis C virus recurrence, HCC recurrence.

INTRODUCTION

Living related liver transplantation (LRLT) is a well-accepted therapeutic option for patients with end-stage liver disease caused by variable diseases like, chronic viral hepatitis, HCC and PSC.[1]

With improvement of surgical techniques, monitoring and immunosuppression, mortality and morbidity rates decreased after liver transplantation.[2] Recent studies indicated that 5-year survival after liver transplantation for HCV and HCC reached 60%[2] and for PSC reached 65%.[3]

Further, the recent development of LRLT decreased patients in waiting list and widened the spectrum of indications of LT with comparable results of cadaver LT.[4]

However, recurrence of primary disease is still a problem. Recent reports show that 99% recurrent viremia occur after transplantation for HCV and hepatitis B virus (HBV).[5] 46% clinical HCV recurrence occur after transplantation for HCV progressing rapidly to cirrhosis due to immunosuppressive,[6,7] less than 10% recurrence occur after transplantation for HCC[8] and between 10% and 27% recurrence occur after transplantation for (PSC).[9,10]

Many reports applied show that factors favoring HCV recurrence are coincident diseases destroying liver parenchyma; a high activity of the inflammatory process in the native liver, acute organ rejection, hepatocyte dysplasia[11] and CMV infection[12] and factors for tumor recurrence are pathological features, namely vascular invasion, more than three nodules, size larger than 5 cm and moderately to poorly differentiated tumors.[8] However treatment options of recurrent disease vary widely according to severity of recurrent disease and its effect on the recipient and his graft.[13]

The aim of this study was to analyze the factors responsible for disease recurrence after LDLT and the effect of disease recurrence and its management on the outcome of LT.

MATERIAL AND METHODS

After approval of institutional review board (IRB) and obtaining written informed conscent from both donors and recipients, we retrospectively analyzed liver transplanted patients in the department of hepatopancreatobiliary (HPB) surgery, National Liver Institute (NLI), University of Menoufiya in the period from April 2003 to December 2009. During the period, 69 patients underwent LDLT. After exclusion of early death (6 months mortality) and pediatrics, 31 alive transplanted adult patients were enrolled in the current analysis in the follow up duration from 6 months to 60 months. They were analyzed for the following data:

A- Preoperative variables:

Donor's variables: (Age, gender, blood group and body mass index (BMI), donor to recipient relation). Recipient´s variables: A- Demographic findings: (Age, gender, blood group and BMI) B- Indication of liver transplantation (primary disease). C- Scoring systems including:1- model for end stage liver disease (MELD) score[14] 3- Child-Pugh scoring system[15] 4- Milan criteria for HCC cases.[16] These criteria are a single tumor of less than 5 cm in diameter or, in patients with multiple tumors, no more than three tumors each of them less than 3 cm in diameter, no vascular invasion and no distant metastases. b- University criteria of San Francisco (UCSF) criteria (extended Milan criteria):[17] A solitary tumour less than 6.5 cm or with two or three nodules, the largest being less than 4.5 cm and a totaling 8 cm, no vascular invasion and no distant metastases. D- Pre transplant intervention therapy: 1- Medical: a- Supportive treatment specific to the primary disease - Antiviral (Ribavirine, immunoglobulines and interferones).[18] 2- Intervention:a- Endoscopic:- Endoscopic sclerotherapy or band ligation for haematemesis or melena or endoscopic treatment of PSC (19. b- Radiological: - Radiofrequency, alcohol injection or chemoembolisation for tumors. E- Co-morbidity (cardiac, DM, HTN,....) F- CMV co infection.

B- Intraoperative variables:

Duration of the operation per hours, graft weight (actual intraoperative weight), actual graft recipient weight ratio (GRWR), cold ischemia time per minute, warm ischemia time per minute and blood transfusion per unit.

C- Postoperative variables:

1- Immunosuppression protocol: the standard is combination of 3 drugs (calcineurin inhibitors (CNIs), steroids and mycophenolate mofetil (MMF). Tacrolimus (FK506) was prescribed at an initial dose of 0.05–0.1 mg/kg/day divided every 12 hours (9 a.m. and 9 p.m.) and adjusted over time to maintain levels of 10–15 ng/mL at 0–14 days, 6–10 ng/mL at 14–28 days, and 5–8 ng/mL thereafter. MMF was given at an oral dosage of 250-500 mg twice a day to be stopped 6 months later. The initial methylprednisolone dose was 500 mg intraoperatively with a brief taper of prednisone from 240 to 40 mg/d over 6 days followed by 5–20 mg/d maintenance treatment, with complete withdrawal at the end of 3rd month post LDLT. Cyclosporine (CsA) was used when neurotoxicty or nephrotoxicity developed with Tacrolimus. It was given at an oral dosage of 8-10mg/kg/day, where blood trough levels were maintained between 150 and 250 ng/ml in the 1st 6 months and between 100 and 150 ng/ml thereafter. When CNIs were contraindicated or their side effects halted their use, sirolimus (SRL) was given at an initial dose of 3 mg/m2 and adjusted over time to achieve blood trough levels of approximately 5–8 ng/mL.

Biopsy-proven acute rejection episodes were treated with steroid pulses (IV methylprednisolone 200 to 500 mg/d for 3 days), which were tapered over several days to the baseline dose.

2- Postoperative follow up protocol to detect recurrent disease: The follow up was done monthly during the 1st 6 months, then every 3 months till the end of the 1st year, then every 6 months till the end of follow up (60 months). (N.B. We have no backup (LRLT grafts or Cadaveric grafts) for those who had recurrence of the original pathology (cause for transplantation) and the plane for those who developed disease recurrence will be mentioned with each disease recurrence).

A- HCV recurrence:

a- Diagnosis: 1- Laboratory results (elevated alanine transaminase (ALT), aspartate transaminase(AST)) ≥2-fold over the normal upper limit. 2- Positivity of serum HCV RNA by reverse-transcription polymerase chain reaction (RT-PCR) 3- Core liver biopsies (The biopsy was performed with ultrasonographic guidance and a conventional automatic 16-gauge Tru-cut needle) to assess: a- Fibrosis: evaluated according to The METAVIR[20] and/or Ishak[21] scores. The fibrosis score was measured from 1 to 6 (Trichrome stain was used). b- The inflammatory grading (18 points) (infiltration of the portal tract with mononuclear inflammatory cells, interface hepatitis, spotty necrosis, confluent necrosis). c- The histological activity index (HAI): The sum of spotty necrosis score (from 1 to 4), a confluent necrosis score (from 0 to 6), interface hepatitis score (from 0 to 4) and a portal inflammation score (from 0 to 4) N.B. Other possible diagnoses (particularly cellular rejection was excluded by the followings: a- Absence of endothelialitis and centrilobular tissue damage. b- biopsies from patients with HCV infection contain macro or microvesicular steatosis, irregular limiting plates, lobular inflammations, hepatocyte necrosis and reactive changes of hepatocytes. C- The liver biopsy was analyzed by two expert pathologists to avoid inter-observer variation.

b- Treatment: Criteria for treatment of recurrent HCV were: staging >1 and grading >4. All treated patients received Pegelated interferon (PEG-IFN-α-2b) (PEG-Intron, Schering Plough, Kenilworth, NJ, USA) that was administered subcutaneously at a weekly dose of 1 μg/kg of body weight plus Ribavirin (Rebetol, Schering Plough, Kenilworth, NJ, USA) that was administered orally at the starting daily dose of 400–800 mg/day. Planned duration of treatment was 48 weeks. Patients who were HCV RNA-positive after 12 weeks of treatment were considered as non-responders and treatment was stopped. All patients were monitored monthly during and after therapy. Complete blood count, AST, ALT, bilirubin, creatinine and prothrombin time were checked monthly or more frequently if needed. Serum HCV RNA levels were checked by RT-PCR before therapy, at 12 and 24 weeks and at the end of therapy (Quantitative test: HCV Monitor; sensitivity >600 UI/mL.[12,18,22]

B- HCC recurrence:

a- Diagnosis: 1- Clinical findings: Abdominal pain, mass (hepatic recurrence), chest complaint (pulmonary recurrence), bone aches and fracture (bone recurrence). 2- Laboratory findings: persistent elevation of AFP, anaemia,….. 3- Radiology: Ultra sonography (Number, site and size of tumour, lymph nodes, ….), tri phasic C.T abdomen (Number, site and size of tumour and assessment of lymph nodes), metastatic work up (Bone scan, C.T chest, C.T brain and PET scan).

b- Treatment: The surgical treatment of recurrent HCC was the 1st option and the non-surgically fit patients were treated by palliative treatment in the form of radiotherapy for bone metastases, medical supportive treatment or administration of tyrosine kinase inhibitor (Sorafeneb) which also was given as adjuvant chemotherapy after resection.[23-26]

C- PSC recurrence:

a- Diagnosis: 1- Clinical: Jaundice, fever,….. 2- Laboratory findings: ''cholestatic'' liver tests (elevated gama glutamate transeferase (GGT), alkaline phosphatase (ALP) and bilirubin). 3- Radiological: The diagnosis of recurrent PSC was made primarily by showing multiple intra and extrahepatic biliary strictures with exclusion of other causes of nonanastomotic strictures (biliary infection, ischemia, hepatic artery thrombosis, ABO-incompatible graft, reperfusion injury). These strictures were shown by magnetic resonance cholangiopancreaticography (MRCP).[17] 4- Liver biopsy (fibro-obliterative cholangitis).

b- Treatment: Medical: Ursodeoxycholic acid at high doses (15-20 mg/kg/day) was the treatment of choice followed by endoscopic treatment of biliary strictures, symptomatic treatment of itching and radiotherapy, chemotherapy for cholangiocarcinoma.[27,9,10,25]

Statistical analysis: All data were tabulated and processed with SPSS software (Statistical Product and Service Solutions, version 21, SSPS Inc, Chicago, IL, USA) and Windows XP (Microsoft Corporation, Redmond, Washington, USA). Qualitative data were expressed in frequency and percentage and analyzed with the chi-square test. Quantitative data were expressed as the mean and standard deviation and were compared with the t test. The previous (preoperative, intraoperative and

postoperative) variables were descriptively studied. Univariate analysis and then multivariate analysis were done to detect the relationship between the previous data and (HCV and HCC) recurrence and between recurrence variables (Occurrence of recurrence and its management) and survival of patients in the follow up period after LDLT. The Kaplan–Meier method was applied for survival analysis and compared using log-rank tests. In all tests, a P value of <0.05 was considered significant.

RESULTS

I- Characteristics of patients and their donors:

They were classified as 27 (87.1%) males, and 4 (12.9%) females. Their mean age was 47.84years ±5.07. Their donors were classified as 22 (71%) males and 9 (29%) females; their mean age was 24.39 years ±6.44. They were classified according to Child-Pugh score into 2 (6.5%) class A, 9 (29%) class B, and 20 (64.5%) class C, and their mean MELD score was 15.5±4.4. (54.8%) of them had co morbidity in the form of Hypertension and DM, while the incidence of CMV infection was (16.1%) in them (N.B. CMVIgG was positive in all donors and recepients, 2 patients developed CMV viremia and invasive CMV. Both had elevation of the liver enzymes, bilirubin plus GIT symptoms e.g. nausea, vomiting, colics and diarrhea. One of them responded to 4 weeks ganciclovir IV therapy and the second unfortunately died with graft failure 6 months postoperatively). (87.1%) of them were given regimen including FK, MMF and steroids (2 patients were not given FK and another 4 patients were not given MMF). (19.4%) were given regimen including Cyclosporine, MMF and steroids (18 patients were switched from FK to cyclosporine and 2 patients were given cyclosporine from the start) and (16.1%) were given regimen including sirolomus, MMF and steroids (5 patients were shifted from FK to sirolomus and 1 patient was switched from cyclosporine to sirolomus). Acute rejection episodes occurred in 9 (29%) of patients and treated with single steroid bolus in 7 (77.8%) and multiple boluses in 2 (22.2%). (Table 1).

II- Indications of LT: The commonest indication for transplantation in adults was post HCV cirrhosis which represented 54.8% of indications. (Fig. 1).

III- Recurrence rate, timing, management and outcome

The incidence of recurrence was 15/31(48.4%) of patients. It was distributed according to the aetiology as follow: 10/17(58.8%) had recurrent HCV, 3/8(37.5%) had HCC recurrence and 2/2 (100%) had PSC recurrence. It was diagnosed at a mean of 17.44±12.9 months post transplantation. The recurrence in HCV patients was at the following months post LT (5, 6, 6, 7.8, 9, 12, 16.6, 18, 26, 40) and HCC recurrence was at (17, 19, 29 months post LT), while recurrent PSC was at (3.1, 44 months post LT).

The treatment in adults was as follow: 3/15 (20%) had no treatment, 10/15(66.6%) were treated medically and 2/15(13.3%) were treated surgically.

1- The medical treatment was distributed as follow:

a- Seven HCV patients were treated with peg-interferone, and viracure, they completed the course of treatment with SVR

b- Two sclerosing cholangitis: The 1st one had recurrent sclerosing cholangitis at 3.1 monthes post LT and treated with medical treatment (UDCA). The patient developed multiple cholangectitic abscesses and has been treated with pigtail drainage then followed by surgical drainage but did not improve and died. The 2nd one had recurrent sclerosing cholangitis at 44 months post LT, complicated with intrahepatic cholangiocarcinoma with intraabdominal LN metastasis and was treated with medical treatment (UDCA), radiotherapy and chemotherapy for cholangiocarcinoma but he did not improve and he is still a live.

c- One HCC patient: The patient had bone recurrence at 19 months post LT and was treated with radiotherapy but he did not improve and he is still a live.

2- The surgical treatment included 2 patients with HCC: The 1st one had hepatic recurrence at 17 months post LT, associated with intraabdominal L.N metastases, with a large L.N. in porta hepatis and died intraoperative from massive P.V.bleeding. The 2nd one had pulmonary and hepatic recurrence at 29, 35 months respectively and was treated with pulmonary lobectomy and resection of hepatic F.L, then he underwent adjuvant chemotherapy in the form of Nexavar but he did not improve after treatment and died. (Fig. 2) and (Table 2).

IV- Predictors of HCV recurrence:

On univariate analysis, it was found that HCV recurrence was higher with CMV infections and acute rejection but without statistical significance. (Table 3).

V- Predictors of HCC recurrence:

On univariate analysis, it was found that HCC recurrence was higher in the following patients (beyond Milan, with AFP >200 and patients with moderate tumor differentiation) but without statistical significance. (Table 4).

VI- Outcome of patients: 1-, 3- and 5- years survival of patients were 90.3%, 87.1% and 83.9% respectively, while 1-, 3- and 5- years survival of patients with and without recurrence were 86.7%, 80% and 73.3% and 93.8%, 93.8% and 93.8% respectively. (Table 5), (Fig. 3).

Table 1. Characteristics of patients and their donors.

Number of patients	31(100%)
Donor age(years) (Mean±SD)	24.39±6.44
Recipient age(years) (Mean±SD)	47.84±5.07
Donor gender	
Males	22 (71%)
females	9 (29%)
Recipient gender	
males	27 (87.1%)
females	4 (12.9%)
Child class	
A	2 (6.5%)
B	9 (29%)
C	20 (64.5%)
MELD score (Mean±SD)	15.5±4.4
Co morbidity	17 (54.8%)
CMV infection	5 (16.1%)
Actual Graft weight (Mean±SD)	880.8±124.4
Actual GRWR(Mean±SD)	1.09±0.15
Cold ischemia time (min) (Mean±SD)	91.6±66.7
Warm ischemia time (min) (Mean±SD)	58.03±22.3
Duration of operation (hours) (Mean±SD)	13.8±2.7
Immunosuppression and steroid regimen	
FK, MMF, steroids	27 (87.1%)
Cyclosporine, MMF, steroids	6 (19.4%)
sirolomus, MMF, steroids	5 (16.1%)
Acute rejection episodes	9 (29%)
Bolus steroids number-	
Single	7 (77.8%)
Multiple	2 (22.2%)

MELD: Model for End stage Liver Disease, **CMV:** Cytomegalovirus, **GRWR:** Graft Recipient Weight Ratio, **MMF:** Mycophenolate mofetil.

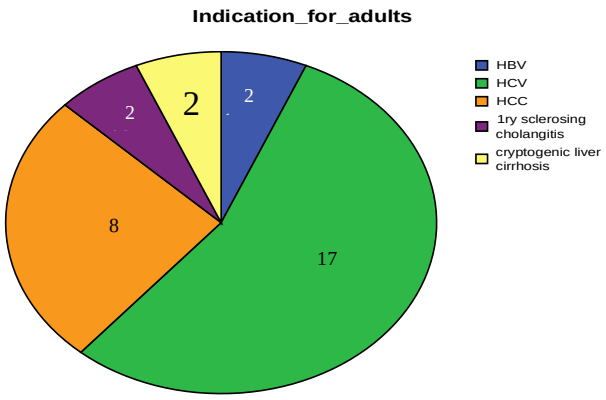
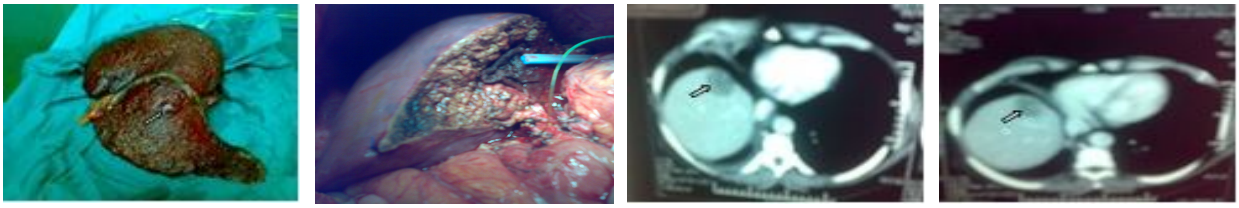


Fig 1. Indications of LT.



A B C D

Fig. 2. (A)- picture of a native liver of HCC patient (1 FL, 3.5 cm, within Milan), (B)- The picture of the graft after implantation to the patient.(C)- Triphasic CT abdomen of the previous patient, with HCC recurrence, in the form of hepatic recurrence, 35 months, post transplantation, he underwent surgical exploration. (D)- Another triphasic CT abdomen of the patient.

Table 2. Recurrence, rate, timing, management and outcome.

Aetiology	Frequency	Recurrence rate (%) No (%)	Mean±SD	Management of recurrence	Outcome of recurrence treatment
HCV	17	10 (58.8%)	14.64±11.2	No 3/10 (30%) Medical 7/10 (70%)	Improved 7/10 (70%) No improvement 3/10 (30%)
HCC	8	3 (37.5%)	21.66±10.5	Medical 1/3 (33.3%) Surgical 2/3 (66.6%)	Improved 0 No improvement 3/3 (100%)
HBV	2	0	0	----------	----------
PSC	2	2 (100%)	23.55±6.7	Medical 2/2 (100%)	Improved 0 No improvement 2/2 (100%)
Cryptogenic cirrhosis	2	0	0	----------	----------
Total number	31	15 (48.4%)	17.44±12.9	No 3/15(20%) Medical 10/15 (66.6%) Surgical 2/15 (13.3%)	Improved 7/15 (46.6%) No improvement 8/1(53.3%)

HCV: Hepatitis c virus, **HCC:** Hepatocellular carcinoma, **HBV:** Hepatitis B virus, **PSC:** Primary sclerosing cholangitis.

Table 3. Recipient and donor risk factors as predictors of HCV recurrence.

Characteristic	Recurrence No (%)	p-value
Number of patients	10 / 17 (58.8%)	
Child class		> 0.05
- A	0	
- B	1 / 2 (50%)	
- C	9 / 15 (60%)	
MELD score group		> 0.05
- < 16	4 / 8 (50%)	
- 16 – 24	6 / 8 (75 %)	
CMV infection	3 / 3 (100%)	> 0.05
Actual Graft weight Mean ± SD	935.5 ± 97.7	> 0.05
Actual GRWR		> 0.05
- 0.8 – 1	3 / 4 (75%)	
- > 1	7 / 13 (53.8%)	
Cold ischemia time per min. Mean ± SD	93.7 ± 30.9	> 0.05
Warm ischemia time per min. Mean ± SD	59 ± 14.5	> 0.05
Immunosuppresion and steroid regimen		> 0.05
FK, MMF, steroids	8 / 13 (61.5%)	
cyclosporine, MMF, steroids	1 / 3 (33.3%)	
sirolomus, MMF, steroids	2 / 2 (100.0%)	
Acute rejection episodes	6 / 7 (85.7%)	> 0.05
Bolus steroids number		> 0.05
Single	4 / 5(80%)	
Multiple	2 / 2 (100%)	

Table 4. Recipient and donor risk factors as predictors of HCC recurrence.

Characteristic	Recurrence No (%)	p-value
Number of patients	**3/8 (37.5%)**	
Milan criteria		> 0.05
- Within	1 / 6 (16.6%)	
- Beyond	2 / 2 (100%)	
Comorbidity	3 / 8(37.5%)	> 0.05
CMV infection	1 / 2 (50%)	> 0.05
AFP		> 0.05
- ≤ 200	1 / 4 (25%)	
- > 200	2 / 4 (50%)	
Actual Graft weight	833.3 ± 76.4	> 0.05
Actual GRWR		> 0.05
- 0.8 – 1	2 / 2 (100%)	
- > 1	1 / 6(16.6%)	
Cold ischemia time per min. (Mean ± SD)	73.3 ± 28.9	> 0.05
Warm ischemia time per min. (Mean ± SD)	66.7 ± 20.8	> 0.05
Immunosuppresion and steroid regimen		> 0.05
FK, steroids MMF	3 / 7 (42.8%)	
cyclosporine, MMF, steroids	1 / 3(33.3%)	
sirolomus, MMF, steroids	1 / 4 (25%)	
Tumor differentiation		> 0.05
- Well	1 / 3(33.3%)	
- Moderate	2 / 5 (40%)	

Table 5. Outcome.

Characteristic	All recipients	Non recurrent	Recurrent
	31 (100%)	**16 (100%)**	**15 (100%)**
Survival			
1 year	28 (90.3%)	15 (93.8%)	13 (86.7%)
3 years	27 (87.1%)	15 (93.8%)	12 (80%)
5 years	26 (83.9%)	15 (93.8%)	11(73.3%)
Disease specific survival			
HCV	16 / 17 (94.1%)	7 / 7 (100%)	9 / 10 (90%)
HCC	5 / 8 (62.5%)	4 / 5 (90%)	1 / 3 (33.3%)
PSC	1 / 2 (50%)	0	1 / 2 (50%)
Disease free survival			
1 year	22 (71%)	-	-
3 years	17 (54.8%)	-	-
5 years	15 (48.4)	-	-

HCV: Hepatitis c virus, **HCC:** Hepatocellular carcinoma, **PSC:** Primary sclerosing cholangitis.

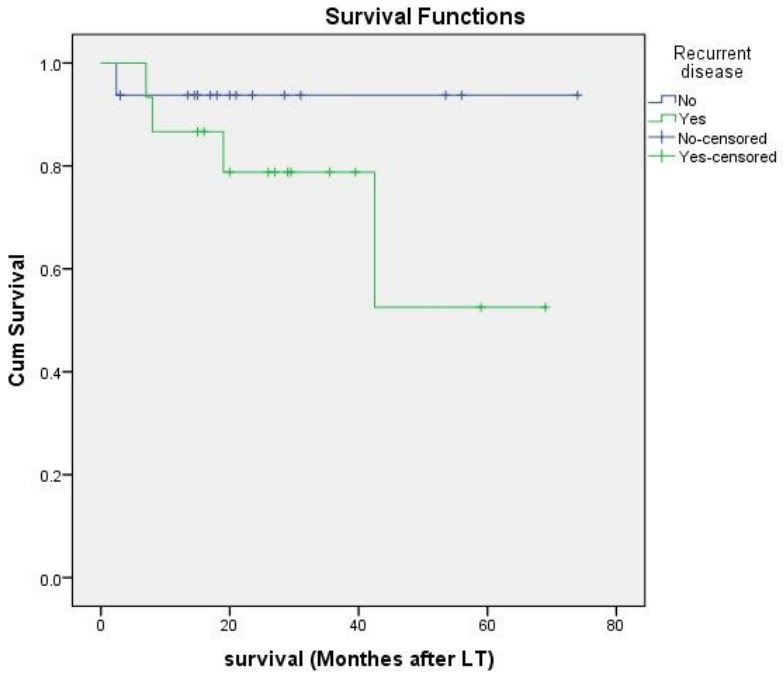


Fig 3. Kaplan-Meier survival curve of recurrent and non-recurrent patients: Log Rank test= .215 p- value: > 0.05.

DISCUSSION

The incidence of recurrence in the present study was (48.4%), while Abdullah and colleagues in 2005[28] detected (25%) recurrence of primary disease in their study. On the other hand, Tsochatzis, and others in 2007[29] found recurrence of the primary disease in (29.5%) of patients. The recurrence of our HCV patients was (58.8%), however, in a study by Francisco and colleagues in 2006,[30] histological recurrence was 92%. in contrast, in the studies by Yosry and colleagues in 2009[31] and Raffaella and colleagues in 2010,[32] HCV recurrence was found in (31.1%) and (46.2%) respectively.

On the other hand, the recurrence in HCC patients was (37.5%) (1/6 within Milan and 2/2 beyond Milan criteria) however, in literature studies, HCC recurrence develops in 8%–20% of patients.[33] As in the studies by Valdivieso and colleagues in 2010[34] and Kornberg and colleagues in 2010[23] who found 12.5% and (26.6%) recurrence of HCC respectively.

Regarding predictors of recurrence, we studied predictors of HCV and HCC recurrence.

I- HCV recurrence:

Cytomegalovirus (CMV) infection has been strongly associated with increased severity of HCV recurrence.[35,36] Inversely, in the current study there was no significant association between CMV infection and recurrence. Similarly, Doris and associates in 2010[37] concluded that CMV had no impact on HCV recurrence.

The current study did not show any significant correlation between graft size and GRWR and HCV recurrence, similarly Yosry and associates in 2009[31] did not find significant association between the graft volume or between GRWR of <1% or >1% and HCV recurrence despite the larger graft volume (836± 142 g) in non-recurrent group in their study.

Immunosuppressant is considered a main factor in the severity of recurrent HCV infection,[35,6,36] because of its effect on viral replication and its suppression of the systemic immune responses, both of which can lead to accelerated hepatocellular damage and fibrosis.[38] So, modifying immunosuppressant are the main means of preventing disease progression.[31] Doris and associates in 2010[37] found that patients in the Calcineurin inhibitors group showed a significant trend towards HCV recurrence as compared to patients on SIR therapy during their follow up period. Similarly, in the study done by Kornberg and associates in 2010,[23] there was significant association between tacrolomus based immunosuppression and HCC recurrence. In contrast in the current study, the regimen of immunosuppressant (tacrolomus based, cyclosporine based or sirolomus based) was not significantly associated with disease recurrence. The possible explanation for that finding is that steroids were administered to the study subjects for only 3 months and monotherapy was the standard immunosuppressive regimen in our center and the sample size was small.

While,[30,31] found no significant correlation between the regimen of immunosuppression, and HCV recurrence. Also, in the study done by Balbi and colleagues in 2009[38] and Jiménez-Pérez and colleagues in 2010,[39] there was no significant association between tacrolomus based, or cyclosporine based immunosuppressant, and SVR after treatment for recurrent HCV infection after LT.[30] found significant correlation between MMF and low HCV recurrence. On the other hand, several authors reported that MMF administration was not associated with low HCV recurrence.[40] Similarly, in the present study we did not show significant correlation between MMF administration and disease recurrence. Treatment with steroids for acute cellular rejection episodes has been reported to be a risk factor for the severity of HCV recurrence.[41] In the studies by Francisco and colleagues in 2006[30] and Doris and colleagues in 2010[37] there was significant correlation between pulse steroids and HCV recurrence. In contrast we did not find a significant association between acute rejection episodes and recurrence despite the trend towards recurrence, similarly,[31] found no significant correlation between the administration of pulse steroid therapy and the development of clinically recurrent HCV.

II- HCC recurrence:

Concerning Milan criteria as a predictor of HCC recurrence, it was found that patients beyond Milan criteria had a higher recurrence (100%) with a trend towards significant recurrence, similarly, Marco and colleagues in 2005,[42] Marubashi and colleagues in 2006[43] and Kiyici and colleagues in 2008[44] did not find significant association between Milan and HCC recurrence. Inversely, Satoru and Hiroyuki, 2004[45] and Kornberg and colleagues in 2010[23] found significant association between Milan out status and recurrence.

An increase in AFP concentration might reflect tumor aggressiveness including differentiation degree and vascular invasion and consequently lead to a higher risk of tumor recurrence.[46] Hwang and colleagues in 2007,[47] Kondili and colleagues in 2007[48] and Kornberg and colleagues in 2010[23] found significant correlation between high AFP and HCC recurrence. Inversely, AFP >200 was not a significant predictor of HCC recurrence in the present study.

We found no association between tumor differentiation and HCC recurrence, similarly, Kiyici and colleagues in 2008[44] and Marubashi and colleagues in 2006[43] found no correlation between differentiation and recurrence, inversely Kondili and colleagues in 2007,[48] Hwang and colleagues in 2007[47] and Kornberg and colleagues in

2010[23] found correlation between poor differentiation and HCC recurrence.

In the present study overall adults survival was 83.9%, similarly, in the studies by Abdullah and colleagues in 2005[28] and Gruttadauria and colleagues in 2007,[49] the overall patient survival rate at 3 years was 85%. In our study, non-recurrent and recurrent adults survival were 93.7%, and 73.3% respectively, also, in study by[28] that included 20 patients, non-recurrent and recurrent patients survivals were (86.8%) and (80%) respectively.

Antiviral treatment in transplant patients is feasible and does not induce severe immunological effects, so, it is recommended in recurrent HCV to use antiviral in the form of PEG plus RBV with good SVR and survival.[38] In the current study, we found that survival was better (100%) in patients who underwent management of their recurrent HCV (Peg-interferone and viracure) than who did not undergo management (66.6%) with trend towards significant survival, Also in a study by Raffaella and colleagues in 2010,[32] it was found that long term maintenance RBV monotherapy was associated with reduced fibrosis progression in recurrent HCV patients and better survival.

The survival rate of recurrent HCC patients in this study was 33.3% while in Kiyici and colleagues in 2008,[44] Kornberg and colleagues in 2010[23] and Valdivieso and colleagues in 2010[34] studies the 5-years survival rates in their recurrent HCC patients were 25%, 41.7% and 48% respectively. In contrast, survival of our non-recurrent HCC patients was 90% that was similar to survivals in non-recurrent HCC patients in (Kornberg and colleagues in 2010[23] and Valdivieso and colleagues in 2010[34] studies where they were 89.3%, and 83.5% respectively.

In a study by Marubashi and colleagues in 2006,[43] surgical treatment was done in 3/9 of their recurrent HCC patients with good survival also, in Kornberg and colleagues in 2010[23] study, the surgical treatment of their recurrent HCC was the 1st option, and it was independent predictor of post recurrence survival and the non-surgically fit patients were treated by palliative treatment in the form of radiotherapy for bone metastases, administration of tyrosine kinase inhibitor (Sorafeneb) or medical supportive treatment. While, in Valdivieso and colleagues in 2010[34] study, surgical resection was performed in 11/23 patients, Sorafeneb in 2/23 and medical supportive treatment in 10/23, they found that surgical treatment prolonged survival. On the other hand, in the present work, surgical treatment of recurrent HCC was our 1st option where 2/3 of patients were treated surgically, and one of them was given adjuvant therapy in the form of Sorafeneb, but none of them survived and the 3rd non surgically fit patient (bone metastases) was given radiotherapy and he is still a live. The survival of PSC patients (recurrence (100%)) was 50%, however, Jeyarajah and associates in 2000[50] reported 5-year graft survival rate of 65% in recurrent PSC and 76% in non-recurrent. On the other hand, Alonso and associates in 2002(51) detected 1-, and 5-year survivals of their PSC patients of 85% and 70% respectively.

In Conclusion: Recurrence of primary disease after LDLT is confirmed in our study with the highest incidence in HCV patients. On the other hand HCV recurrence was higher in the following patients (CMV infections and with acute rejection). While HCC recurrence was higher in the following patients (beyond Milan, with AFP >200 and patients with moderate tumor differentiation). Recurrence of primary disease after liver transplantation decreases post transplantation Survival. However its effective management improves survival.

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ORIGINAL ARTICLE

INFRAPOPLITEAL BALLOON ANGIOPLASTY FOR CRITICAL LIMB ISCHEMIA

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Abstract

Background: Lower extremity peripheral arterial disease (PAD) is a major cause of morbidity and mortality. Percutaneous endovascular therapy is an alternative to surgery for the treatment of PAD. While infrapopoliteal PTA was restricted to patients with short stenotic lesions or poor candidates for bypass, recently it has been used preferentially over bypass surgery by some groups due to the advent of new devices and techniques. The growing experience with endovascular therapy justifies an assessment of crural PTA. The aim of this study is reviewing our results **in** infrapopliteal angioplasty stratifying patients by anatomic characteristics according to the TASC classification.

Patients and Methods: This study was conducted at Arab Contractors Medical Center and Mansoura University Hospital on 80 patients during the period from Jan 2009 till April 2013. Inclusion criteria were rest pain, ulceration and tissue necrosis. Exclusion criteria were life threatening infection, Burger's disease and multilevel lesions. All patients were investigated by colour duplex scan, C.T.Aor M.R.A. The TASC "I" classification for tibioperoneal occlusive disease was done. All procedures were done with local anesthesia, sometimes sedation was needed for irritable patients.

Cases were performed preferentially through antigrade ipsilateral femoral access and rarely through retrograde contralateral access. All patients were anticoagulated with 10,000 IU heparin after initial angiography.

We used 6F sheaths for ipsilateral antigrade access and 8F sheath for retrograde contralateral access, 4F vertebral catheters were used with 0.035 floppy angled giudewire (Terumo, Somerest, ND), 0.018, 0.014 hydrophilic wire (Boston Scientific, Natick, Mass) or glide wire. Five cases had direct tibial vessel puncture using fluoroscopic guidance had been done. Angioplasty was performed with low profile balloon (Amphirion Deep, Invatec, Italy) 2.5 to 3F. Balloon was inflated for 1 to 3 minutes.

If vasospasm occurred; administration of 50-400 mcg of nitroglycerin was helpful.

After the procedure, patients were given 600 mg loading dose of clopidogrel, if the patient didn't receive it preoperatively, maintained on 75 mg daily dose for 3 months to one year, along with aspirin and statins.

Results: During the study period, 80 patients underwent PTA [14 (17.5%) for rest pain and 66 (82.5%) for tissue loss] after exclusion of five cases from the study due to failure of guide-wire passage. Antigrade access was used in 73 cases (91.25%) and seven cases (8.75%) retrograde access was performed due to difficult puncture. Primary patency was 58.75% at first year and 48.75% at second year.

First year primary patency for TASC A through D was 83.3%, 87.5%, 45%, 34.6% respectively. And for Second year was TASC A through D was 72.2%, 68.75%, 40%, 26.9% respectively. Limb salvage at 1 year: 81%, and at 2 year: 75%.

Conclusion: PTA is recommended as first line of treatment for TASC A, B, C lesions and TASC D patients who are not candidate for bypass. But more studies are needed to compare long term follow up between PTA and bypass in TASC D lesions.

Keywords: Peripheral arterial disease, percutaneous endovascular therapy, TASC, Angioplasty.

INTRODUCTION

Lower extremity peripheral arterial disease (PAD) is a major cause of morbidity and mortality. Symptoms range from claudication to critical limb ischemia (CLI), which is presented by rest pain, ulceration, and gangrene. Surgery is reserved for CLI.(1)

Surgical approaches are associated with an increased risk for systemic and local complications due to comorbidities that characterize patients with PAD. So, percutaneous endovascular therapy is an alternative to surgery for the treatment of PAD.(2)

Early studies of percutaneous angioplasty (PTA) of the tibioperoneal vessels reported 1-year patency rates of <15%, leading the authors to conclude this was suboptimal therapy that should be reserved for patients with no other options of treatment.(3) Indeed, for patients with CLI, surgical bypass grafting with autogenous conduit remains the gold standard, with 5-year limb salvage rates > 80%.(4) However, many patients who require arterial revascularization for CLI do not have an adequate saphenous vein, so alternate conduits with inferior patency and limb salvage rates must be used.(5,6)

In contrast to femoropopliteal PTA, infrapopoliteal PTA has been less frequently used and still controversial due to heterogeneous results so offered predominantly to patients with CLI.(7) Although infrapopoliteal "crural" PTA was restricted to patients with short stenotic lesions or poor candidates for bypass;(8) crural PTA recently has been used preferentially over bypass surgery by some groups due to the advent of new devices and techniques. The growing experience with endovascular therapy justify an assessment of crural PTA.(9,10)

Recently, the bypass versus angioplasty in severe ischemia of the leg (BASIL) study suggested that if the anatomy is conductive for angioplasty, primary PTA might be an appropriate first therapy even if the patient is a good candidate for bypass. However, ideal anatomy was not well defined in BASIL.(11)

The Transatlantic Intersociety Consensus (TASC) "I" criteria represents a standardized definition for lesion characteristics.(12,13) Outcomes of tibial PTA are difficult to predict from the existing literature owing to a lack of details regarding indications for intervention and lesion characteristics.(14-18)

The primary goal in treating CLI is limb salvage and maintenance of quality of life, not patency.(19,20)

The purpose of this study is reviewing our results in infrapopliteal angioplasty stratifying patients by anatomic characteristics according to the TASC classification.

MATERIAL AND METHODS

This study was conducted at Arab Contractors Medical Center and Mansoura University Hospitals on 85 patients during the period from Jan 2009 till April 2013.

Inclusion criteria were rest pain, ulceration and tissue necrosis. Exclusion criteria were life threatening infection, Burger's disease and multilevel lesions. {66 patients (82.5%) presented by ulceration and tissue necrosis, and 14 patients (17.5%) presented by rest pain}.

All patients were subjected to thorough history taking for any comorbidity, general examination and routine laboratory investigations including complete blood picture, kidney function tests, liver function tests, fasting blood sugar, coagulation profile and lipid profile.

All patients were investigated by colour duplex scan, C.TA., and MRA in cases of severe renal impairment.

The TASC "I" classification for tibioperoneal occlusive disease is detailed as follows:

TASC A: a single stenosis < 1 cm long.

TASC B: multiple focal (<1 cm) stenosis of tibial or peroneal arteries, including up to two focal stenosis at the tibial trifurcation or short tibial or peroneal stenosis in conjunction with femoropopliteal disease.

TASC C: longer stenosis of 1 to 4 cm, occlusion 1 to 2 cm or extensive stenosis involves the trifurcation.

TASC D: occlusion > 2 cm long or diffuse disease.

All procedures were done with local anesthesia, sometimes sedation was needed for irritable patients.

Cases were performed preferentially through antigrade ipsilateral femoral access and rarely through retrograde contralateral access. All patients were anticoagulated with 10,000 IU heparin after initial angiography.

We used 6F sheaths for ipsilateral antigrade access and 8F sheath for retrograde contralateral access, 4F vertebral catheters were used with 0.035 floppy angled giduewire (Terumo, Somerest, ND), 0.018, 0.014 hydrophilic wire (Boston Scientific, Natick, Mass) or glide wire. Five cases had direct tibial vessel puncture using fluoroscopic guidance Angioplasty was performed with low profile balloon (Amphirion Deep, Invatec, Italy) 2.5 to 3F. Balloon was inflated for 1 to 3 minutes.

If vasospasm occurred; administration of 50-400 mcg of nitroglycerin was helpful.

After the procedure, patients were given 600 mg loading dose of clopidogrel, if the patient didn't received it preoperatively, maintained on 75 mg daily dose for 3 months to one year, along with aspirin and statins.

Angiographic success was considered when all technically accessible lesions were treated with < 30% residual stenosis. Hemodynamic success was defined:ABI increase of at least 0.1[21] Clinical success was defined as at least one upward clinical categorical shift, improvement of rest pain, improvement of wound or ulcer healing.

Follow up: Patients were followed up weekly for one month, and then every 3 months for 1 year, and every 6 months thereafter, or more frequently if stenosis were detected or to monitor wound healing. Patency was assessed with duplex ultrasound. Ankle brachial pressure index is measured.

Salvage was defined as freedom from major amputation (below or above knee). Toe, ray or transmetatarsal amputations were considered minor amputations, not any higher amputations.

Statistical analysis: The statistical analysis of data done by using excel program and SPSS program statistical package for social science version 10.

The description of the data done in form of mean (+/-) SD for quantitative data .And Frequency & proportion for Qualitative data.

The analysis of the data was done to test statistical significant difference between groups.

For quantitative data student t-test was used to compare between two groups. Chi square test was used for qualitative data.

N.B: P is significant if < or = 0.05 at confidence interval 95%.

Patency and limb salvage was done using Kaplan –Meier curve.

RESULTS

During the study period, 80 patients underwent PTA {14 (17.5%) for rest pain and 66 (82.5%) for tissue loss} after exclusion of five cases from the study due to failure of guide wire passage (one of failed cases needed urgent femorotibial bypass, another one improved clinically, post procedure, due to opening of new collaterals spontaneously during the procedures, the other three cases needed below knee amputation). Demographic data, comorbidities, clinical presentation and hospital stay are summarized in (Table 1). The median hospital stay was 5.1 days (range 3 – 16 days). Most of cases stay for one day before intervention and 2 days after except if there is periprocedure morbidity, complications or the need for amputation (either minor or major).

Antigrade access was used in 73 cases (91.25%) and seven cases (8.75%) retrograde access was performed due to hostile anatomy from previous surgery or due to high femoral bifurcation.

Intraprocedural complications: Flow limiting spasm occurred in 5 patients (6.25%) had been treated by nitroglycerin injections. Thrombosis occurred in 6 patients (7.5%), two of them had been treated by aspiration and four patients had been treated by thrombolytic therapy.

Post procedural complications: (Table 2): One patient (1.25%) died 3 weeks after discharge of unknown cause. Two patients (2.5%) developed transient contrast nephropathy. Three patient (3.75%) developed groin hematomas treated conservatively. Two patients developed pseudoaneurysm, one treated by ultrasound guided compression and the other expanding pseudoaneurysim treated by surgical repair. One patient developed symptomatic microembolism to the big toe and inner aspect of the second toe improved with

antiplatelet and analgesics.

Mean follow up was 14 months with a range of (6–28 months). Primary patency was 58.75% at first year and 48.75% at second year (Table 3).

First year primary patency for TASC A through D was 83.3%, 87.5%, 45%, 34.6% respectively. And for Second year was TASC A through D was 72.2%, 68.75%, 40%, 26.9% respectively. Limb salvage at one year was 81% and at 2 years was 75%.

Two patients (2.5%) needed major amputation inspite of successful primary patency one because of severe life threatening infection of the foot (below knee amputation) and the other developed skin necrotic patches14 months after intervention, that was rapidly progressive diagnosed as vasculitis (above knee), this patient was diabetic and dialysis dependent, he died 3 weeks after amputation.

Failure of primary patency occurred in 41 patients (51.25%) of these 4 patients underwent major amputation and 25 patients (31.25%) were managed by repeated balloon angioplasty, resulting in 16 arteries remain patent for more than one year and 9 patients failed, and the remaining 12 patients treated conservatively by cilostazol, naftidrofuryl and oral anticoagulant. {5 patients underwent surgical bypass grafting using saphenous graft leading to limb salvage in 3 patients and eventual amputation in 2 patients, and the other 4 patients (two of them underwent below knee amputation and 2 patients died without more intervention)}. Wound completely closed or improved in 42 patients (63.6%) (Out of 66 patients presented by tissue loss), stable in 14 patients (21.2%), and worse in 10 patients (15.2%). The remaining 14 patients were presented by rest pain (9 patients (64%) improved, 3 patients (21.5%) were stable, 2 patients (14.5%) worse.

Table 1. Demographic Data and patients characters.

	Tasc A (n = 18)	**Tasc B (n = 16)**	**Tasc C (n = 20)**	**Tasc D (n = 26)**
Age	65.57 ± 5.49	64.50 ± 10.35	64.10 ± 1.74	67.69 ± 8.63
Sex:				
Male	10 (55.6%)	12 (75%)	12 (60%)	14 (53.8%)
Female	8 (44.4%)	4 (25%)	8 (40%)	12 (46.2%)
Smoking	12 (66.7%)	10 (62.5%)	8 (40%)	16 (61.5%)
DM*	14 (77.8%)	10 (62.5%)	14 (70%)	16 (61.5%)
HTN*	16 (88.9%)	16 (100%)	16 (80%)	22 (84.6%)
Hyperlipidaemia	16 (88.9%)	10 (62.5%)	12 (60%)	12 (46.2%)
Renal insufficiency	4 (22.2%)	8 (50%)	6 (30%)	12 (46.2%)
Dialysis	0 (0%)	2 (12.5%)	6 (30%)	4 (15.4%)
Congestive Heart failure	0 (0%)	2 (12.5%)	8 (40%)	10 (38.5%)
Prior MI*	0 (0%)	2 (12.5%)	8 (40%)	8 (30.8%)
Cerebrovascular	4 (22.2%)	2 (12.5%)	6 (30%)	4 (15.4%)
Rest pain	6 (43%)	2 (14.3%)	2 (14.3%)	4 (28.4%)
Tissue loss	12 (66.7%)	14 (87.5%)	14 (70%)	26 (100%)
Hospital stay	3.67 ± 1.28	4.63 ± 2.0	5.50 ± 3.32	6.08 3.65

DM: Diabetes mellitus, **HTN:** Hypertension, **MI:** Myocardial infarction.

Table 2. Complication.

Post procedure	Tasc A (n = 18)	Tasc B (n = 16)	Tasc C (n = 20)	Tasc D (n = 26)	P value
Died	0 (0%)	0 (0%)	1 (33.3%)	0 (0%)	
Microembolism	0 (0%)	0 (0%)	1 (33.3%)	0 (0%)	
Hematoma	0 (0%)	1 (33.3%)	0 (0%)	2 (100%)	0.369
Pseudoaneurysm	0 (0%)	1 (33.3%)	1 (33.3%)	0 (0%)	
Nephropathy	1 (100%)	1 (33.3%)	0 (0%)	0 (0%)	

Table 3. Primary patency rate.

Primary patency	Tasc A (n = 18)	Tasc B (n = 16)	Tasc C (n = 20)	Tasc D (n = 26)	P value
1st y	15 (83.3%)	14 (87.5%)	9 (45%)	9 (34.6%)	< 0.001
2nd y	13 (72.2%)	11 (68.8%)	8 (40%)	7 (26.9%)	0.007

DISCUSSION

There is marked shift in primary management of infrainguinal occlusive disease from surgical bypass to percutaneous revascularization. Recently newly developed devices and techniques improved outcome and increased interest in infrapopoliteal PTA with lower complication rates.[23]

This study demonstrates that outcome of PTA depends on TASC classification. Outcome of TASC D lesions were significantly worse than other lesions. Also many patients may be not candidate for bypass; they should be treated by PTA.

Tibial artery interventional therapy has been proven to lead to limb salvage with low morbidity and mortality in patients with critical limb ischemia and should be used as a first line treatment modality in the majority of patients, especially in those with significant medical comorbidities.[24] However, differences in outcome between available devices are unknown and ways to increase long term patency remain poorly defined.[1] there are great difficulties in comparing results of infra-popliteal angioplasty as different studies have different outcome variables, lacks uniformity regarding procedural indication .also there are discrepancy regarding lesions characteristics segmental and multi-level disease pattern. Nevertheless reports by Kudo et al (2005) and by Haider et al (2006) found Tasc D lesions to have worse prognosis, and this is also reported by our study.

Intra-procedural complication rate (13,75%) in our study was equal as reported by Lyden (2009). All intra-procedural complications were managed in an endovascular fashion. No patient required emergency surgery to correct a procedural complication.

Two settings exist where operative therapy should be used first with tibial bypass over interventional modalities. The first is when a total occlusion continuously includes the superficial femoral artery, popliteal artery, and tibial arteries. Interventional therapies are generally not durable enough to achieve wound healing in this setting. The second setting is for patients when the extent of tissue loss necessitates extended forefoot amputation or debridement, where interventional therapy may not restore enough flow to achieve limb salvage.[3,24]

Conrad et al (2009) said that, the use of PTA of the infrapopliteal vessels as a primary treatment when anatomically feasible bypass have voiced the concern that failure could result in the need for a more distal bypass or endovascular injury of target vessels could

result in the inability to identify a distal target artery for bypass. This was not identified in this study, where surgical crossover was undertaken in primary and secondary failure. However, Sanford et al. (2007) detailed 66 patients who underwent surgical bypass for failed PTA including 16 tibial vessels (24%), and reported a 12 month primary patency of 61%. They noted that 21% of patients in the PTA failure group required a bypass more distal than the original artery treated, emphasizing that the percutaneous procedure should always be undertaken with consideration of backup surgical options should the initial PTA fail.[21]

Hyeon et al (2012) found that the minimally invasive nature of infrapopliteal PTA has obvious appeal, it also has potential disadvantages: conversion of an elective to emergency procedure, loss of bypass targets or making them more distal, a less durable solution, lengthy procedures with hazards of radiation exposure, and the rising costs of care if multiple interventions are needed.

In our study the primary patency rate was 58.75% in first year, and 48.75% in second year which is similar to the results of Haidar et al. (2006).

Limb salvage rate reported by Sadek et al. (2009) was 84 % after two years which is higher than our results (75%).

In conclusions PTA of infrapopliteal vessels can be performed safely, with low morbidity and mortality. PTA is recommended as first line of treatment for TASC A, B, C lesions and TASC D patients who are not candidate to bypass. But more studies are needed to compare long term follow up between PTA and bypass in TASC D lesions whose are candidate to bypass.

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ORIGINAL ARTICLE

MULTICENTER COMPARATIVE STUDY BETWEEN ENDOVENOUS RADIOFREQUENCY ABLATION AND ENDOVENOUS LASER THERAPY IN MANAGEMENT OF PATIENTS WITH PRIMARY VARICOSE VEINS

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Abstract

Background: The treatment of varicose (GSV) reduces the symptoms and the complications of venous insufficiency and increases the quality of life (2). Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) of the great saphenous vein (GSV) have been introduced as alternative and minimally invasive techniques for the treatment of truncal vein incompetence

Purpose: This prospective comparative study was conducted to evaluate the effectiveness of endovenous treatment of symptomatic varicose veins using the endovenous Laser therapy (EVLT) or radiofrequency ablation (RFA) and to describe the complications and short term outcome of patients follow up.

Methods: This is a multicenter, non-randomized, non-blinded prospective comparative study, was conducted in both the Zagazig university hospital as well as Elhoussein university hospitals between June 2010 and June 2012. The patients were divided into two groups; 60 patients in each group. The 1st group underwent endovenous Laser therapy while the 2nd group underwent endovenous radiofrequency ablation. Both procedures were performed under duplex scan guidance with foam sclerotherapy of incompetent perforators and superficial varicosities. The outcome of both groups was compared as regard pain and bruising and other complications, returning to normal activity, health related quality of life, and recurrence. Follow up will continue for at least 6 months.

Results: The number of treated patients was 120 patients 60 in each group with mean age 29.2 ± 5.8 in the 1st group (EVLT) and mean age 31.1 ± 8.5 in the 2nd group (RFA). There were 64 % females and 36 % males in the 1st group and there were 69% females and 31% males in the 2nd group. In the 1st group there were 68 limbs (11 bilateral and 57 unilateral, 65 GSV disease and 3 limbs with both GSV and SSV), while in the 2nd group there were 65 limbs (12 bilateral and 53 unilateral, with GSV disease in 61 and 4 limb showing both GSV and SSV disease). The overall number of complications encountered in the 1st group (EVLT) was 41%, while the overall number of complications encountered in the 2nd group (RFA) was 24%. 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 65 limbs (95.5%) in 1st Group and 61 limbs (93.8%) in 2nd Group.

Conclusion: Endovenous ablation in occluding incompetent GSV is a new effective and safe option in the treatment of varicose GSV.

Keywords: Endovenous, Radiofrequency, laser therapy.

INTRODUCTION

Ligation of the great saphenous vein (GSV) and small saphenous vein (SSV) at their junctions with the deep venous system, stripping and removing the tributaries has been the standard of care for treatment of symptomatic varicose veins for many decades. However, this approach has a recurrence rate up to 40% at 5 years; 20% of all varicose vein operations are performed for recurrence.[1] The treatment of varicose (GSV) reduces the symptoms and the complications of venous insufficiency and increases the quality of life.[2]

Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) of the great saphenous vein (GSV) have been introduced as alternative and minimally invasive techniques for the treatment of truncal vein incompetence.[3] These procedures were designed to ablate the (GSV) through a percutaneous approach to minimize the discomfort and complications associated with conventional stripping.[4] The RFA catheter delivers radiofrequency energy to achieve heat – induced venous spasm and collagen shrinkage, whereas EVLT releases thermal energy both to the blood and to the venous wall, causing localized tissue damage.[5]

Aim of the work: This prospective comparative study was conducted to evaluate the effectiveness of endovenous treatment of symptomatic varicose veins using the endovenous Laser therapy (EVLT) or radiofrequency ablation (RFA) and to describe the complications and short term outcome of patients follow up.

MATERIAL AND METHODS

This is a multicenter, non-randomized, non-blinded prospective comparative study in which we evaluated short term results of both endovenous radiofrequency ablation & endovenous laser therapy in management of truncal varicosities in patients with lower extremity primary venous insufficiency. This study was conducted in both the Zagazig university hospital as well as Elhoussein university hospitals between June 2010 and June 2012.

The patients were divided into two groups; 60 patients in each group. The 1st group underwent endovenous Laser therapy in the form of 980nm wave length diode laser, powered up to 90 w and with pulse mode operation (Diod 90 w, LISA®, Germany) under duplex scan guidance. An adjunctive procedure associated at the time of treatment is foam sclerotherapy of incompetent perforators and superficial varicosities.

The 2nd group underwent endovenous radiofrequency ablation using the VNUS® radiofrequency generator and the closure fast® catheter (VNUS Medical Technologies, San Jose, CA) under duplex scan guidance. An adjunctive procedure associated at the time of treatment is foam sclerotherapy of incompetent perforators and superficial varicosities.

Post procedural crepe bandage then compression stockings for several weeks were systematically proposed. All procedures are ambulatory, and patients do not have any physical activity restrictions. Non-steroidal anti-inflammatory drugs and analgesics were provided to the patients as needed.[7]

Pre-operative and post-operative duplex scans were assessed by two vascular technologists. Patients were matched in each group using the same inclusion and exclusion criteria. Inclusion criteria include; primary GSV incompetence confirmed by duplex scan, physical condition allowing ambulation after the procedure, patient able to give informed consent, requirement for intervention agreed between patient and the surgeon, availability of patients for all follow up visits.

Exclusion criteria are varicose veins without GSV or SSV incompetence on duplex scan, recurrent varicose veins, associated deep venous incompetence on duplex scan below common femoral vein, presence of an aneurysmal vein segment or tortuous GSV above the knee felt to be unsuitable for catheterization, GSV diameter <3 mm or >13mm in the standing position, thrombus in the GSV, patients with a pacemaker or internal defibrillator, patients on anticoagulants, concomitant peripheral arterial disease (ankle-brachial pressure index of <0.9), patient has a serious systemic disease or pregnancy.

Pre-operative: Before the procedure each patient was evaluated by taking full history, clinical examination of the limb, the CEAP classification and the venous clinical severity score (VCSS) were assigned by a surgeon skilled in the management of venous disease.

The VCSS is composed of 10 parameters (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers, compressive therapy) that escalate in severity with increased area of the limb involved and are graded 0 to 3 (absent, mild, moderate, severe). In order to generate a dynamic score, VCSS categories are scored individually,

which adds emphasis to the most severe sequelae of venous disease that are likely to show the greatest response to therapy.[8] The VCSS has been evaluated in clinical practice and validated as an important instrument for longitudinal research to assess outcomes after treatment with low variability.[9] The VCSS has been demonstrated to increase with higher CEAP clinical class in a strong linear relationship.[10]

Duplex ultrasonography was undertaken in all patients preoperatively to assess the extent of venous disease. Reflux was assessed by response to a Valsalva maneuver in a reverse Trendelenburg position or with manual limb compression and release; with the patient in a standing position. The mean vein diameter was recorded in both groups.

In addition, each patient completed the 20-question Chronic Venous Insufficiency Questionnaire (CIVIQ2) quality of life questionnaire that has been validated for use in patients with chronic venous disease after being translated to Arabic.

The CIVIQ comprises 20 questions in four quality-of-life domains: physical (items 5, 6, 7 and 9), psychological (items 12–20), social (items 8, 10 and 11), and pain (items 1–4).[11] All questions have a 5-point response category, with higher scores reflecting more severe impairment. Higher scores represent lower health related quality of life (HRQOL) due to CVI or varicose veins.[12]

Before surgery, accurate mapping (cartography) should be done using the duplex-scanning method from the groin to the ankle to highlight tortuous veins stretches, ectasia areas, and incompetent, perforator, and varicose veins.

Procedure: The patient was placed in trendelenburg position after marking the varicosities in the standing position. Venous access was obtained with Seldinger technique just below the knee because of its relative larger diameter, less tortuous course and the smaller risk of nerve injury. After the entrance to the vein was established, a 7 fr 11 cm long sheath was introduced. (Fig. 1).

Tumescent anesthesia was given before the ablation procedure. We used a spinal anesthesia needle to administer tumescent anesthesia solution. The solution of tumescent anesthesia included 500 ml saline, 25ml 2% lidocaine, 10 ml 8.4% Sodium Bicarbonate and 1 ml adrenaline (1:1.000). Using ultrasound guidance the solution is infiltrated percutaneously below the saphenous fascia and above the deep fascia to surround the vein concomitant to a dose of 35 mg/kg is safe and effective. Some patients refused tumescent anesthesia thus spinal anesthesia was the alternative type of anesthesia used. All patients who had spinal anesthesia tumescent fluid were administered with the exception of lidocaine.

In EVLT: a catheter was inserted with its tip positioned to be 2 cm distal to the sapheno-femoral junction (SFJ), and a 600 mm laser fiber was inserted into the catheter, which was then withdrawn by 2.5 – 5 cm distal to the SFJ to allow the laser fiber to be protruded from the catheter tip. All the persons in the treatment room advised to wear the protective laser goggles, then Laser is activated the device used was a 980 nm wave length diode laser, high power up to 90 w, and pulse mode operation (Diod 90 w, LISA®, Germany). Depending on personal performance, pulse laser therapy was delivered from 2.5 – 5 cm below the SFJ and the fiber was drawn back 5mm every 3 pulses. At the end of the procedure, the laser was deactivated before withdrawal of the fiber from the sheath. Under duplex guidance closure of the vein was documented. (Fig. 2).

In RFA the closure fast catheter was inserted and by duplex US positioned to be about 2 cm distal to SFJ we used RFG2 generator which uses power ranged from 15 – 40 watts to reach the pre-established treatment temperature (120 c) during 20 seconds cycles. The closure fast catheter treats a 7 cm vein segment in every cycle (20 seconds). 2 cycles were done in the position 2 cm below SFJ, and then every 7cm distal segments were ablated by 1 cycle. In areas with vein-ectasia an additional cycle was advised. Venus closure system seen in Fig. 3.

Post-operative: All patients received a standard postoperative regimen; dressings were placed over the wounds and crepe bandages wrapped around the treated limbs. Patients were instructed to remove all dressings on the 3rd postoperative day, to shower and then to apply class II full length compression hosiery for 2 weeks.

Evaluation was done after 72hrs, one week, one month, and 6 month. Items to be evaluated will be: pain and bruising and other complications, returning to normal activity, health related quality of life, and recurrence. Follow up will continue for at least 6 months.

A 10 cm visual analogue scale (VAS) was used for self-assessment of pain with patients filling out a VAS for each leg treated. Scores were measured in centimeters. The respondents are asked to assess their pain intensity between the end-points of no pain to worst possible pain on the scale. They were asked to return to normal activity as soon as they wished.[13] During each patient's visit a standard set of information was collected. Physicians assessed patient's signs and symptoms utilizing VCSS classification and the patient were asked to complete another 20-question CIVIQ2 quality of life questionnaire.

We assessed patients' limbs for the presence of recurrent varicose veins. In cases where varicose veins were present, the question of whether varicosities were new or pre-existing was considered. New varicose veins below the knee were classified as recurrent varicosities.

Ultrasound examination included characteristics of outflow and reflux. Special attention was paid to visualization of the GSV to detect recanalization of this vein and whether there was any residual flow in the GSV.

Efficacy of vein obliteration was categorized as follows: Totally occluded (TO) veins were defined as those with no evidence of flow. Partially occluded (PO) veins were defined as less than or equal to 3 cm segment of flow within the SFJ or an otherwise occluded vein trunk. Inefficiently occluded (IO) veins were defined as greater than 3 cm of flow in any treated vein segment.[14]

Reflux was defined as any evidence of reverse flow for more than 0.5 s in any treated vein segment or at the level of SFJ or SPJ.

The presence of neovascularisation in the groin was assessed by duplex ultrasound examination. This was defined as multiple small vessels in the groin reconnecting more proximal vein or its tributaries and the distal patent vein below the site of occlusion.

RESULTS

Statistical Analysis: Data collected throughout history, clinical examination, DUS examinations, scores and questionnaires was coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis.

According to the type of data, the following tests were used to test differences for significance;. Differences between frequencies (qualitative variables) in groups were compared by Chi-square test. Differences between means (quantitative variables) in two groups were compared by Student's t-test, paired two groups by paired t test. P value was set at <0.05 for significant results.

Demographic Data of Patients: The number of treated patients was 120 patients 60 in each group with mean age 29.2 ± 5.8 in the 1st group (EVLT) and mean age 31.1 ± 8.5 in the 2nd group (RFA). There were 64 % females and 36 % males in the 1st group and there were 69 % females and 31 % males in the 2nd group. Body mass index (kg/m2) was 24.3±2.1 in the 1st group and in 26.9±2.3 the 2nd group.

In the 1st group there were 68 limbs (11 bilateral and 57 unilateral, 65 GSV disease and 3 limbs with both GSV and SSV), while in the 2nd group there were 65 limbs (12 bilateral and 53 unilateral, with GSV disease in 61 and 4 limb showing both GSV and SSVdisease).

The distribution of CEAP classification in the 1st group was C2 13.2%, C3 55.1%, C4 27.4% and C5 4.3%. In the 2nd group the distribution was C2 17.6%, C3 53%, C4 29.4% and C5 0%. The mean vein diameter was 7.9±2.8 mm in the 1st group and 8.3±2.2 mm in the 2nd group.

Operative Data of Patients: Spinal anesthesia was used in 45% of cases and tumescent anesthesia in 55% of cases in the 1st group, while in the 2nd group only 34% of the cases took spinal anesthesia and 66 % took tumescent anesthesia. All patients who had spinal anesthesia Tumescent fluid was administered with the exception of lidocaine. The average treated length in the 1st group 39.5±9.7 cm and the average treated length in the 2nd group 40.4±10.7 cm.

Post-operative Complications: The overall number of complications encountered in the 1st group (EVLT) was 41(%), while the overall number of complications encountered in the 2nd group (RFA) was 24 (%) .This is collected in Table 1.

Short-term technical success is defined as the successful occlusion of the vein lumen. Immediate vein occlusion with lack of spontaneous and augmented flow demonstrated by duplex ultrasound and vein wall thickening was achieved in 100% of the treated veins in our series. No cases of failure of closure were identified at the time of the procedure by the completion of a duplex ultrasound scan.

In the 2nd group there was one case (1.5%) of a perforation of the GSV 1 cm from the SFJ immediate exploration of the SFJ was done and ligation of the junction, the GSV and after closure of the wound RFA was completed as usual.

In both groups there was no incidence of Endothermal Heat Induced Thrombosis (EHIT) which is a thrombus protruding into the common femoral vein. There was no incidence of Deep vein thrombosis (DVT). There was no incidence of pulmonary embolism in our study.

In the both group; no cases of lignocaine toxicity occurred. Close observation of the patients was done, talking to the patient throughout the procedure to notice any suspicious symptoms of toxicity arising.

1st Group: At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 65 limbs (95.5%). DUS follow-up of the other 3 limbs showed that 1 limb (1.4%) showed veins related to missed anterior accessory saphenous in one case and in 1 limb (1.4%) an incompetent thigh perforator connected to a superficial vein connected to the SFJ. 1 limb (1.4%) recanalization of the vein was found.

2nd Group: At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 61 limbs (93.8%). DUS follow-up of the other 4 limbs showed that

2 limbs (3%) showed partially occluded (PO) veins related to missed anterior accessory saphenous. 2 limbs(3%) had inefficiently occluded (IO) vein related to recanalization of the vein.post operative results are concluded in Table 2.

In the 1st (EVLT) group there were 35 limbs (51.4%) presented with bruises and ecchymosis (without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy) 2 limbs (2.9%) showed prolonged ecchymosis and local edema for one month, and 5 limbs (7.4 %) of paraesthesia. In the 2nd (RFA) group there were 12 limbs (18.5%) cases of bruises (without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy), and 7 limbs (10.8 %) of paraesthesia.

Skin burn occurred in the form of mild erythema in 9 limbs (13.2%) in the first group and in 8 limbs (12.3%) in the second group which might be due to insufficient tumescent anesthesia and very superficial veins. All cases improved with conservative management.

Table 1. Complications of both groups.

Complications	G1%	G2%
Perforation of SFJ	0	1.5
Bruises and Ecchymosis	51.4	18.5
Nerve injury	7.4	10.8
Erythema	13.2	12.3
DVT	0	0
Pulmonary embolism	0	0
Recurrence	4.2%	6%

Table 2. Post-operative findings are concluded in the following.

Length of hospital stay (hour)	6.9±2.3	6.2±1.5	1.9	NS
Return to activities (d)	5.6±2.4	3.5±2.1	5.1	<0.001
Pain (VAS)	7.9±2.2	4.7±1.5	9.3	<0.001
VCSS	6.4±2.4	6.3±2.7	0.2	NS
6 m VCSS	2.7±2.1	2.6±2.1	0.26	NS
CIVIQ2	49. 2±21.9	45±20.2	1.1	NS
6 m CIVIQ2	19.4±2	20.3±2.3	2.28	<0.05

DISCUSSION

Endovenous techniques of saphenous vein ablation have been introduced as minimally invasive alternatives to high ligation and open surgical stripping of the incompetent saphenous vein. Stripping can lead to painful and prolonged post-operative recovery in some patients, with risks of infection, hematoma and nerve injury.[15] Conventional treatment generally entails general or spinal anesthesia. In many centers patients undergoing the operation are admitted at least 1 day.[16] The mechanism of action of EVLT and RFA are different. With laser energy, there is uniform, complete occlusion from intimal thermal damage caused by the steam bubble.[17] Some of the researches feel that adequate vein wall contact with the laser fiber is necessary to accomplish this intimal damage.[2] Radio frequency energy causes collagen shrinkage and fibrosis.[18] Published data give reliable occlusion rates for EVLT (97% to 100%)[2] and RFA (84% to 100%).[19] Successful occlusions of the GSV at the rate of over 90% immediately after EVLT were reported.[20] Heating the collagen of the venous walls results in contraction and destruction of the endothelium, the thickness of the wall increases and therefore, resulting in fibrosis of the veins.[22] We did not find any variability in occlusion rates with either EVLT & RFA techniques, as was seen in Mayo clinic study.[23] We emphasized the importance of performing these procedures under tumescent anesthesia, collapsing the vein, and minimizing the trauma by not introducing the RFA or EVLT catheter into the common femoral vein. This is our opinion as surgeons, of course, but there are many physicians performing these ablation who are not vascular surgeons or interventionists.[23] In our study, performed by vascular surgeons immediate closure of the vein is reported as reported in all reviewed literature. In our 6 months follow up, the success rate was 95.5% in the EVLT group and 93.8 in th RFA group. Our findings are comparable with the previous studies. In min et al., who used a similar techniques for GSV varicosities, reported that 93% of 499 GSV were occluded 2 years after therapy.[2] An Italian work group reported a success rate of 97% in 1000 patients with a follow up of 3 years.[24] Another large study with more than 1250 limbs treated showed, a success rate of approximately 95%.[25] Sharif et al., reported long saphenous vein occlusion in 100% and 96% at 3 and 12 months after EVLT.[26] Absence of neovascularity in the groin with the presence of physiological drainage is an added advantage of

endovenous treatment. Avoiding the ligation of all the tributaries in the groin and performing high ligation of the GSV prior to stripping contributes to the neovascularity and recurrence seen with conventional ligation and stripping.[27] Technical problems such as difficult access, problems in advancing the catheter or a tortuous GSV may also lead to recurrence. Lohr and Kulwicki stated that neovascularization, though less frequent with endovenous ablation than surgery, is also considered a cause and has been seen in 2.8 – 7% of cases.[28] However, it seems that it could protect against neovascularization by preserving physiological drainage of the abdominal wall.[29]

There were no significant differences between the RFA & EVLT techniques in our study. It is possible GSV thrombi caused by laser energy have different characteristics from those occurring after RFA.[23] Deep vein thrombosis (DVT) after endovenous ablation is extremely rare and indeed most case series and trials show no evidence of DVT at all.[30]

For safety, the manufactures recommended the tip of the ablation catheter should be at least 2 cm from the saphenofemoral junction. In our series the catheter tip is positioned to be 2 cm distal to SFJ in EVLT and 2 cm distal to SFJ in RFA. Thrombosis of GSV was expected but was at least 3 cm away from the SFJ.[30]

Concomitant SSV or transluminal occlusions of perforators with endovenous ablation have been considered risk factors for calf DVT[31] although it is not evident in our study.

Studies have reported low rates of skin staining, to avoid and decrees incidence of skin burns and pigmentation is the very generous use of tumescent fluid under duplex ultrasound guidance and making sure that at least 1 cm of fluid is surrounding the treated vein all around. Also it is wise to manage very superficial veins by other modalities rather than endovenous ablation.[32]

The most common self-limited or minor complications included slight pains minor burning, bruising and abnormal skin sensation.

Using of A 10 cm visual analogue scale (VAS) for self-assessment of pain showed that pain is more significant postoperative in the EVLT Group than the RFA group. Bruising was more evident in the EVLT group in comparison with the RFA group most due to vein perforations by the laser beam.

The serious complications of endovenous ablation are few saphenous nerve injury following endovenous ablation is rare.[33] Our patients had none of the serious complications.

In conclusion endovenous ablation in occluding incompetent GSV is a new effective and safe option in the treatment of varicose GSV. Selection of endovenous ablation as a treatment alternative to conventional surgery depends on the cost of equipment and disposables and operator experience. The advantages of endovenous ablation are far greater than its associated risks. Tumescent anesthesia should be instilled below the saphenous fascia and confirming by duplex that at least 1 cm of fluids is surrounding the treated vein to avoid unpleasant minor complications. Catheter tip must be at least 2cm from SFJ to avoid extension of the thrombi to deep venous system. After endovenous ablation, patients can immediately return to their daily routine life works.

Further long term follow up studies are needed to confirm absence of recurrence and to more establish the techniques.

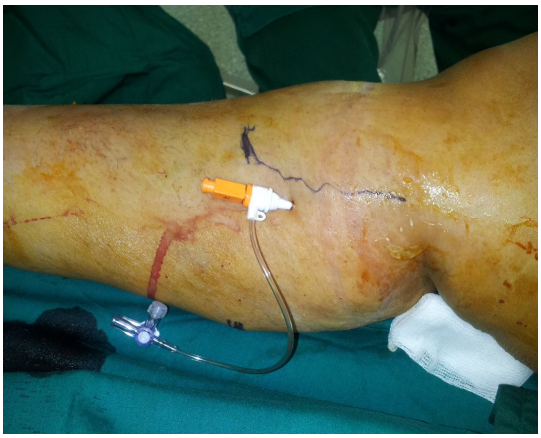

Fig 1. Sheath N. 7 inside the GSV by seldenger tech.

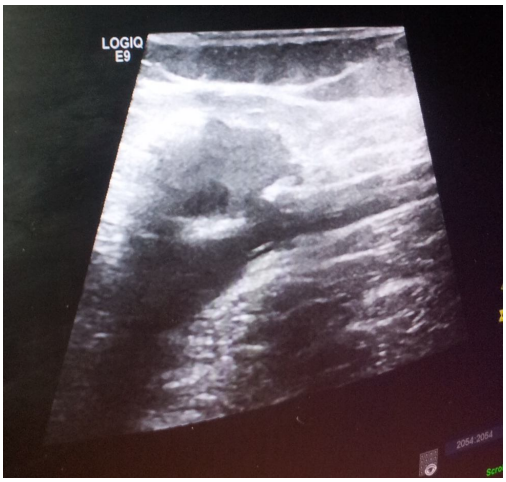

Fig 2. Duplex U/S showing the catheter inside the GSV.

Fig 3. Venus closure system for V.V.

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ORIGINAL ARTICLE

MANAGEMENT OF EXTREMITY VASCULAR INJURIES IN UPPER EGYPT DURING THE EGYPTIAN REVOLUTION

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Abstract

Aim of work: To evaluate the pattern of clinical presentation, diagnosis and management outcome of different techniques of extremity vascular repair.

Materials and Methods: This prospective study was conducted at Sohag University Hospitals from February 2011 to July 2013 and involved 162 patients with extremity vascular injuries who underwent various surgical interventions. Patients were evaluated for the mechanism of trauma, site and type of injury, associated injuries, methods of vascular repair and their outcomes.

Results: Firearm injury and stab penetrating injuries were the most common causes (45.7%, 28.4%) respectively. Lower extremities were affected more commonly (53.75%) and superficial femoral artery (SFA) was the most common injured one (37.65%). Combined arterial and venous injuries were present in 50 patients (30.9%). Forty-eight patients (29.6%) had associated fractures. Interposition autogenous reversed saphenous vein graft was the most common method of repair (74.7%). Synthetic graft was used only in 6 patients (3.7%). Wound infection was the commonest complication (17.3%). 14 patients (9.25 %) had secondary amputation and 11 patients (6.8%) died due to associated head, chest and / or abdominal injuries. Vascular reconstruction was successful in 136 cases (84%).

Conclusion: Early detection and proper management of vascular injuries save the vast majority of limbs with vascular injuries.

Keywords: Extremities, vascular injuries, management, Egyptian revolution.

INTRODUCTION

The Egyptian Revolution of 2011 was part of the Arab Spring that took place after the Tunisian revolution following a popular uprising that began on 25 January 2011.[1] Vascular injuries occur mainly in young male population all over the world[2] and they comprise 2-3% of all cases of trauma.[3] Extremity arterial injuries account for 50% of all arterial traumas caused by penetrating injuries in 64 %-82 %.[4] Vascular injuries in the extremities can result in limb disability, limb loss, and even death. These unfortunate outcomes resulted from delayed recognition or inappropriate assessment of the injured limb.[5] Although penetrating arterial injuries are usually diagnosed immediately, diagnosis of blunt vascular injuries may be delayed.[6] It may be explained by the relatively asymptomatic patients or the presence

of additional life threatening injuries that take priority in the resuscitation process. So, prompt assessment and treatment are mandatory to avoid unpleasant results for the patient's limb and life.[7] With improvement in vascular repair techniques, early referral of patients to experienced health care hospitals concerning with vascular surgery, limb salvage reaches to more than 90% and amputation rate has gone down to less than 10%.[8,9]

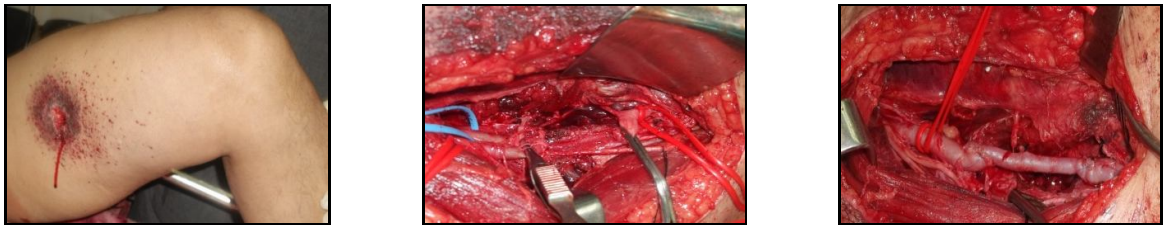
The aim of this study was to find out the pattern of vascular injuries and to detect the outcome of different techniques of vascular repair and related complications.

MATERIAL AND METHODS

This prospective study was carried out from February 2011 to June 2012 on 162 patients (149 males, 13 females) with a mean age of 28.4 years (range from 13 - 45 years) in Sohag University Hospitals. All patients with vascular trauma involving upper or lower extremity were included in the study. Patients with late vascular injuries or those with Mangled Extremity Severity Score (MESS) ≥ 7 points were excluded from the study.

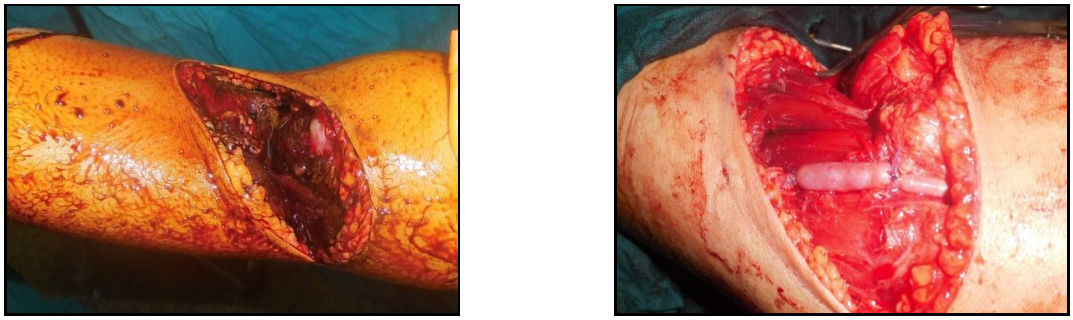
All patients were assessed by the surgeon on duty in trauma unit and then by vascular surgeon. Patients were resuscitated according to the guidelines of Advanced Trauma Life Support protocol. Patients were reassessed clinically after resuscitation with special concern to time interval between the occurrence of injury and arrival to hospital, mechanism of injury (penetrating, blunt or road traffic accidents), associated injuries and applying the MESS as a standard protocol for deciding on primary amputation for severe limb injuries and excluded those with score of ≥7 points. Clinical examination included hard and soft signs of vascular injuries, hand held doppler and pulse oximetry of the affected limbs. Duplex ultrasound was done in all cases. CT angiography was done in 21 patients (13%) only. Complete blood picture, blood grouping with cross-matched blood and x-rays of the affected region were advised before transfer to the operative theatre. Broad spectrum antibiotics was started before surgery and continued postoperatively. All patients were operated under general anaesthesia, spinal anaesthesia or epidural block. Both lower limbs in case of lower extremity injury or injured upper limb and one lower limb in case of upper extremity injury were sterilized and draped. All injuries were explored through a longitudinal incision extending both proximally and distally. Proximal and distal control was achieved first before exploring the injury site. Extension and type of vascular injury were assessed and method of repair was decided. Associated venous injury if present was assessed and planned for its treatment. In need for autogenous saphenous vein graft, it was prepared from the contralateral limb. Associated injuries; nerves, muscles and tendons were assessed. Debridement of surrounding non-viable soft tissue was done and the injured nerves were marked with polypropylene suture before repair of the vascular injury. Associated fractures were fixed by orthopedic surgeon. Both proximal and distal ends of the injured vessels were cleared from any residual thrombus with Fogarty catheter and flushed with heparinized saline. Method of repair depended upon the extent and type of injury. Reversed autogenous saphenous vein graft was the commonest type of repair performed in this study. Repaired vessels were irrigated with saline and covered with muscles and soft tissue after placing of suction drain. Prophylactic fasciotomy were performed in 46 patients (28.4%), when ischemia time exceeded more than 6-8 hours, patients had combined arterial and venous injury or those with extensive musculoskeletal injuries. If conditions allowed, intraoperative heparin (5000 IU) was administered followed postoperatively by daily subcutaneous low molecular weight heparin (LMWH) (40 mg) to prevent thromboembolic event followed by oral warfarin therapy.

Immediately in the post-operative period, patency of repaired vessel was assessed by regaining intact distal pulses, hand-held doppler and capillary refill in cases of inability to feel pulse. Post-operatively all patients were followed up and monitored for manifestations of complications e.g. wound infection, compartment syndrome and secondary hemorrhage. Patients were discharged after satisfactory wound healing and advised to follow-up in vascular outpatient clinic.



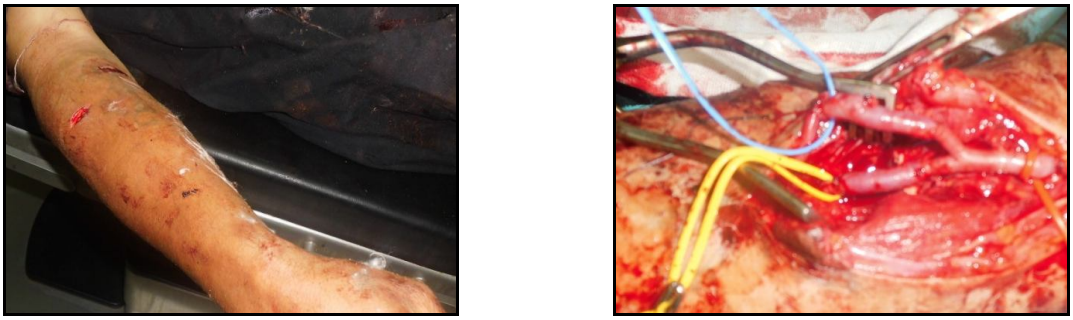
A B C

Fig 1. (a) Shows firearm injury in left thigh, (b) shows complete cut of superficial femoral artery (SFA) with segment loss, (c) shows repair with reversed interposition vein graft.



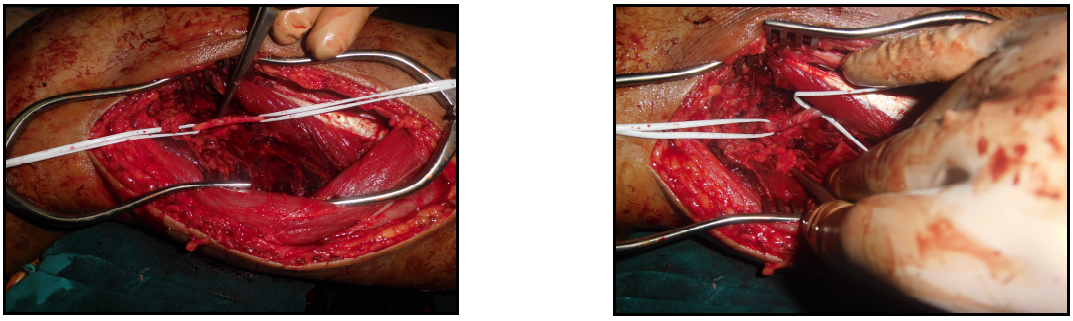
A B

Fig 2. (a) Shows cut wound injury in right upper limb following road traffic accident, (b) shows repair of brachial artery with vein graft.



A B

Fig 3. (a) Shows multiple stab wound injury in right forearm, (b) shows primary repair of both radial and ulnar artery.



A B

Fig 4. (a) Shows incomplete cut of lower SFA following firearm injury in right thigh, (b) shows repair with venous patch.

RESULTS

Firearm injuries and stab wound penetrating trauma were the most common causes of injury (45.7%) and (28.4%) respectively followed by blunt trauma (17.3%). (Table 1) Time interval between occurrence of injury and presentation in our hospital ranged from 4 - 12 hours. Lower limb was more commonly affected (53.75%) and superficial femoral artery (SFA) was the most frequently involved artery (37.65%). (Table 2) 50 patients (30.9%) had Combined arterial and venous injury. Incomplete transection was the commonest type of vascular injury (54.94%) (Table 3). Interposition reversed autogenous saphenous vein graft was the most common type of repair (74.7%) (Table 4). Fasciotomy was performed in 46 patients (28.4 %). Wound infection was the most common complication (17.3%) (Table 5). 11 patients (6.8%) developed secondary hemorrhage due to anastomotic blow-out that were treated by reexploration of the site of repair, control of bleeding but rebleeding occurred few days later and ended by ligation of vessels as life-saving measure that followed later by limb amputation. Graft thrombosis occurred in 8 cases (4.9%) who underwent reexploration. Thrombectomy was performed while re-thrombosis occurred in 3 patients who finally ended by limb amputation. 11 patients (6.8%) died due to associated other major injuries in head, chest or abdomen.

Table 1. Mechanism of vessel injury.

	No. (%)
Firearm injury	74 (45.7%)
Stab penetrating injury	46 (28.4%)
Blunt trauma	28 (17.3%)
Road traffic accident	14 (8.6%)

Table 2. Type of injured vessel.

	No. (%)
Superficial femoral artery (SFA)	61 (37.65%)
Popliteal artery	12 (7.4%)
Common femoral artery	5 (3.1%)
Anterior tibial artery	3 (1.85%)
Posterior tibial artery	2 (1.25%)
Brachial artery	37 (22.8%)
Axillary artery	12 (7.4%)
Subclavian artery	6 (3.7%)
Radial artery	13 (8%)
Ulnar artery	3 (1.85%)
Venous injuries	8 (4.9%)

Table 3. Type of vascular injury.

	No. (%)
Complete transection	41 (25.3%)
Incomplete transection	89 (54.94%)
Thrombosed vessel	18 (11.1%)
Contusion and spasm	14 (8.64%)

Table 4. Technique of vascular management.

	No. (%)
Saphenous vein graft	121 (74.7%)
Primary repair	3 (1.9%)
End-to-end anastmosis	11 (6.8%)
Venous patch repair	13 (8%)
Synthetic graft	6 (3.7%)
ligation	5 (3.08%)

Table 5. Complications.

	No. (%)
Wound infection	28 (17.3%)
Limb edema	21 (13%)
Secondary hemorrhage	11 (6.8%)
Graft thrombosis	8 (4.9%)
Amputation	14 (9.25%)
Death	11 (6.8%)

DISCUSSION

Increasing terrorist activities and operations against terrorism led to increase in the incidence of vascular injuries. Majority of our patients were victims of penetrating injury and were young adult males as reported in other series worldwide.[9,10]

Although the number of patients in this study was relatively small, it was noted that other studies were also similar in number of patients such as Yavuz et al,[3] who performed his study on 158 patients. However other series were smaller than this study such as Siddique and Ahsin,[11] Rozycki et al,[7] and Jawas et al,[12] who studied 54, 62 and 36 patients respectively.

Firearm injury and stab penetrating injury were the most

common mechanisms and occurred in (45.7%, 28.4%) respectively. This might be attributed with increased frequency of terror attacks and violence during fighting the terrorism. Similar results were obtained by other studies.[13-15] Blunt trauma occurred in (17.3%) in this study while Cargile et al, recorded (12%) percentage of blunt trauma. Conversely, in developed countries, such as the Northern European countries, Oller et al,[16] had reported that blunt trauma was the most common reason for vascular injuries.

We applied the Mangled Extremity Severity Score (MESS) during patient assessment. It allocates points to 4 parameters of the injury named degree of skeletal or soft-tissue injury, limb ischemia, the degree of shock and patient age.[17] Also, Yavuz et al,[3] had reported in his study that the rate of poor outcomes was significantly higher in patients with higher MESS scores (>4) compared to those with lower MESS scores ($p < 0.001$). Starnes et al, had published on his series regarding injuries on the battlefield that saving a life comes before saving a limb in decision making of vascular injuries and the decision for limb amputation is more difficult than it seems. So sometimes, early amputation is the best solution for saving life.[18]

Superficial femoral artery was the commonest arterial injury in this study and accounted for (37.65%). Makins et al,[19] had reported on a British review during World War I that the incidence of femoral artery injuries was (31%). De Bakey and Simeone[20] had reported less percentage of femoral artery injuries during World War II which was (21%). Also Weaver et al,[21] recorded (35.1%) according to the data based on the Vietnam War. On the contrary, Yavuz et al,[3] and Feliciano et al,[14] had reported that femoral artery injuries occurred more frequently and accounted for (70%) and (65%) respectively of all the peripheral vascular injuries. Presence of hard signs of vascular injury (pulsatile bleeding or increasing hematoma, presence of thrill or bruit and distal ischemia) is the indication of immediate exploration without any diagnostic investigation.[22]

Feliciano et al,[14] and Cargile et al,[13] had reported higher percentages of preoperative angiography (63% and 45%) respectively because the majority of patients were admitted with soft signs e.g. significant hemorrhage by history, diminished pulse compared to contralateral extremity. On the contrary, Asensio et al,[15] used angiography in (15%) only. In this study, preoperative CT angiography was done in 21patients (13%) only as it was not available during the whole day and diagnosis was dependant mainly on physical examination, hand held doppler and duplex ultrasonography in assessment of most of vascular injuries and this was approved by Meissner et al,[23] who recommended combination of physical examination, doppler and duplex ultrasonography examinations as optimum screening methods for assessment of vascular injury. On the other hands, Peng et al,.[24] had reported that CT angiography could replace conventional arteriography in assessing extremity vascular trauma in stable patients with equivocal clinical finding.

Time interval between the onset of injury and intervention ranged from 4 -12 hours. Sfeir et al,[25] had reported that time interval had a significant effect on the outcome of limb salvage and complications. However Hafez et al,[26] had argued that there was no correlation between arrival time after trauma and the treatment outcome. Also, he reported that the severity of tissue ischemia depended on many factors rather than time interval alone e.g. state of the arterial injury, efficiency of collateral circulation and extent of tissue damage.

Technique of vascular injury repair depends upon the mechanism of injury, type and extent of injury and associated injuries. Reversed autogenous vein graft was the commonest method used for vascular repair in this study. Saphenous vein graft is the best choice because it has a high rate of long-term patency and less incidence of infection.[15] It was noted that other series were also similar in their use of the same graft.[27-30] However end-to-end anastomosis was the preferred method in cases without segmental loss of the blood vessel.[3]

Polytetrafluoroethylene (PTFE) graft could be used when the autogenous vein graft was not appropriate, but it was known by its poor patency and increased incidence of infection than the native one.[26,29,31,32] In this study, PTFE was used in 3.7% of cases. Similar series reported nearly equal results such as Yavuz et al, Asensio et al, and Cargile et al,.[3,13,15]

Ligation of arterial injuries was a good option only in selected vessels e.g. radial, ulnar and tibial arteries in unstable patients and in polytraumatized patients with poor general conditions. In this study, ligation occurred in 5 arterial patients (3.08%), Three ulnar arteries and two posterior tibial arteries. ligation did not induce ischemia in involved limbs. Franz et al, agreed with this series who performed arterial ligations primarily in tibial vessels.[33]

Management of venous injury is controversial and challenging. Surgeon must consider whether to ligate or reconstruct the injured vein. Several factors must be considered in taking the decision; general condition of the patient, associated injuries and their treatment protocol and the complexity of venous reconstruction. Venous reconstruction has multiple advantages e.g. a return pathway is kept opened so enhances improving limb salvage especially in the presence of combined arterial and venous injuries or in cases of single venous return conduit such as the popliteal vein. It is also reasonable that open return venous conduit prevents acute venous hypertension and chronic venous insufficiency subsequently.[34] The merits of ligation rather than reconstruction of venous injury claim that a considerable percentage (30%–70%) of venous

reconstructions will thrombose within a week postoperatively.[35] and this is confirmed by the high incidence (approximately 60%) of DVT after major trauma.[36] Timberlake GA and Kerstein[37] also had reported that no extremity was lost after ligation of injured veins and the permanent sequelae of venous hypertension is quite rare. In this series, six venous injuries were ligated; one cephalic vein, two basilic veins, three superficial femoral veins while the remaining two veins (superficial femoral veins) was repaired primarily. DVT occurred in one of them causing limb edema.

Surgical treatment of combined vascular and orthopedic injuries is one of the most difficult problems in management of traumatized patients. The duration of ischemia is critical to the outcome so arterial repair should be performed first to restore circulation to the limb before the orthopedic stabilization is addressed. Sometimes, massive musculoskeletal trauma makes the limb unstable that external fixation must be placed before the vascular procedure.[38] In such cases, intraluminal shunts and rapid installation of external fixator minimize limb ischemia, thus allowing an unhurried orthopedic and vascular repair.[39]

Fasciotomies have been considered a useful adjunct to the repair of vascular injuries especially with prolonged ischemia time and associated injuries to prevent compartment syndrome.[40] Also, Field et al,[41] confirmed that prophylactic fasciotomy reduced the risk of limb loss in patients with prolonged ischemia time longer than 6 hours or those who had combined arterial and venous injury. On the contrary, Kluger et al,[42] and Yavuz et al,[3] had limited fasciotomy to the necessary cases only following vascular repair.

Wound infection was the most common complication. We believe that the incidence of wound infection can be decreased by performing adequate debridement of unhealthy and non-viable tissues, frequent irrigation of the wound by saline, starting antibiotics preoperatively and continued postoperatively, adequate hemostasis minimize hematoma formation and subsequent wound infection. Once occurred, early drainage and debridement was done, swab from contents for culture and sensitivity, frequent dressing till the wound became clean to be closed later. Hood et al,[43] had reported that unexplained fever and leukocytosis are assumed to be due to deep tissue infection until proved otherwise so re-exploration of the wound and debridement of necrotic tissue or hematoma evacuation are essential for minimizing septic sequelae, secondary hemorrhage and subsequent amputation rate. In this study, wound infections occurred in (17.3%) of cases. Similar series reported nearly equal results such as Yavuz et al,[3] who recorded (11%) incidence ,Muhammad et al,[44] who noticed that wound infection occurred in (18.2%).

In this study 11 patients (6.8%) died during the hospital stay while 14 limbs (9.25%) were amputated. Most of cases died due to associated head, chest and/or abdominal trauma. All of amputations in this study were due to secondary hemorrhage in 11 patients and thrombosed graft with failed thrombectomy in 3 patients. Yavuz et al,[3] and Jawas et al,[12] had reported (5.7%, 14%) death rate respectively. Also, Yavuz et al,.[3] had reported (5.1%) amputation rate while Jawas et al,[12] reported (14.3%) amputation rate.

Conclusion: Early detection and proper management of vascular injuries save the vast majority of limbs with vascular injuries.

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ORIGINAL ARTICLE

FEASIBILITY OF LEFT LOBE GRAFT IN ADULT LIVING DONOR LIVER TRANSPLANTATION

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Abstract

The objective: of this study is to assess the feasibility of LLG as an option in the Adult Living Donor Liver Transplantation. The study aims to consider the anatomical advantages of the Left Lobe Graft, the safer Donor's hepatectmy and to innovate criteria for Left Lobe Graft selection. Data on 34 consecutive LL LDLTs, including two retransplants, were retrospectively compared with those of 34 RL LDLTs, in terms of survival, complications and donor morbidity. The mean GRWR of LL grafts was 0.71% whereas that of RL grafts was 0.88%. The 1-year patient survival rates of LL LDLT were 85.3%,, which were comparable to those of RL LDLT (85.3%). The incidence of small-for-size syndrome was higher in LL LDLT (11.8%) than in RL LDLT (5.9%). The overall donor morbidity rates were comparable between LL (20.5%) and RL (14.7%), whereas postoperative liver function tests and hospital stay were significantly better in LL donors. **Conclusion:** Adult LL LDLT has comparable outcomes to that of RL LDLT. To minimize the risk to the donor, LL-LDLT could be an ideal option in adult-to-adult LDLT.

INTRODUCTION

Living donor liver transplantation (LDLT) was first initiated in children in 1989 in response to a severe organ shortage from pediatric donors.(1) At the start of adult LDLT, left lobe (LL)-LDLT was the only option available because of the potential risk for the donor in right lobe (RL)-LDLT. However, the use of LL grafts for adults was severely limited due to their size limitation. Generally, a LL graft can provide only 30–50% of the required liver volume for an adult recipient, and has been thought to be too small for adult recipients to sustain their metabolic demand.(2) During this process, the graft type has shifted from the left side of the liver to the right side of the liver to overcome the problems encountered with "small-for-size grafts," that is, a <1.0% graft-to- recipient body weight ratio (GRWR). The use of "small-for-size grafts" leads to "small-for size syndrome," including poor bile production, delayed synthetic function, prolonged cholestasis and intractable ascites, with subsequent septic complications and higher mortality.(3)

Graft size plays a role in determining outcomes after liver transplants, but it is not the only factor. The likelihood of small-for size syndrome is influenced not only by the size of the graft but also likely by other factors such as the degree of portal hypertension, MELD score, and spleen size. Perhaps a better term than small-for-size to describe this syndrome is small-for-need.(4) The crucial prerequisite to performing LDLT is a minimal morbidity and mortality risk to the healthy living donor. Unfortunately, sporadic donor deaths associated with RL donations have been reported in the United States(5) and Europe,(6) as well as in Japan.(7) It is

reported that operative mortality for the RL donor is estimated to be as high as 0.5–1%.[8]

MATERIAL AND METHODS

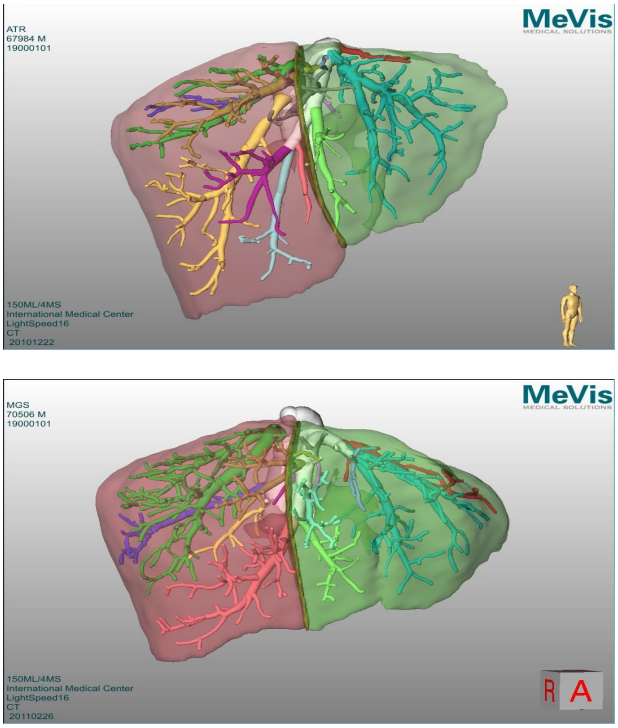
The study was retrospectively done in the period between June 2009 and December 2012, including 68 LDLT cases performed at the International Medical Center (IMC, Cairo) and Kumamoto University Hospital (Kumamoto, Japan). This Comprised 68 adults (aged ≥ 18 years). Of the 68 adults, a total of 34 patients (50%) underwent LDLT using Left Lobe grafts all without the caudate lobe, whereas 34 patients (50%) received Right Lobe grafts all without middle hepatic vein (MHV). The relation of the donors to recipients was Son (n =15), Daughter (n = 8), Brother (n = 8), Wife (n = 5), Sister (n = 4), Husband (n = 4), Mother (n = 2), Cousin (n = 2), Aunt (n = 1) and others (n = 20). The indications for liver transplantation in LLG recipients were HCV cirrhosis (n = 12), HCC (n = 9), Cryptogenic cirrhosis (n = 3), Biliary Atresia (n = 2), Primary Biliary Cirrhosis(PBC) (n = 2), Alcoholic cirrhosis (n = 1), Familial Amyloid Poly neuropathy(FAP) (n = 1), Fulminant Hepatic Failure (FHF) (n = 1) and Retransplantation (2 cases due to chronic rejection with prior indications of Allagile syndrome and Biliary Atresia respectively). While the indications for RLG recipients were HCC (n = 16), HCV cirrhosis (n = 8), HBV cirrhosis (n = 4), AutoImmune Hepatitis (AIH) (n = 1), FHF (n = 1), Primary Sclerosing Cholangitis(PSC) (n = 1), Multiple Developmental Liver Cysts (n = 1), and Retransplantation (2 cases due to chronic rejection with prior indications of FAP and Biliary Atresia respectively). The preoperative characteristics of the donors and the recipients in the 2 groups are described and compared in Table 1.

Table 1. Patient characteristics.

	Left Lobe(n=34)	Right Lobe(n=34)	p-Value
Recipient			
Age (years)	51.1 ± 12.6	51.6 ± 12.1	NS
(Range)	(18-69)	(22-65)	
Sex (M / F)	21 / 13	19 / 15	NS
Body weight (kg)	64.7 ± 13.2	70.1 ± 16.2	NS
Etiology (n)			NS
Cirrhosis	16	12	
HCC	9	16	
Cholestatic	5	1	
FHF	1	1	
Retransplant	2	2	
Others	1	2	
Child-Pugh	8.3 ± 1.8	8.9 ± 2.5	NS
A / B / C	5 / 23 / 6	7 / 11 / 16	
MELD score	14.9 ± 6.6	16.7 ± 6.9	NS
<10 (n)	6	4	
≥ 10, <20	21	23	
≥ 20, < 30	5	5	
≥ 30	2	2	
Graft			
Estimated GW (g)	503.5 ± 100.8	738.6 ± 166.5	<0.0001
Estimated GRWR (%)	0.79 ± 0.11	1.08 ± 0.22	<0.0001
Actual GW (g)	455.4 ± 109.9	619.7 ± 151.6	<0.0001
Actual GRWR (%)	0.71 ± 0.10	0.88 ± 0.22	0.0003
<0.6% (n)	4	0	
≥0.6, <0.8%	25	8	
≥0.8, <1.0%	4	18	
≥1.0%	1	8	
Donor			
Age (years)	33.6 ± 12.1	39.2 ± 14.1	NS
(Range)	(20-66)	(21-63)	
Sex (M / F)	29 / 5	18 / 16	0.0034
Blood type compatibility(n)			NS
Identical	14	16	
Compatible	15	11	
Incompatible	5	7	

Graft Selection Criteri

The volume of the graft had to satisfy a minimum graft-to-recipient weight ratio (GRWR) of 0.7% for recipients with low Model for End-Stage Liver Disease (MELD) scores (<15) and a GRWR of 0.8% for recipients with high MELD scores (>15). RL graft could be selected when the volume of the left lobe plus the caudate lobe (LLI or RLV) was >30%. In this study we were relatively obliged to select LLG in some cases due to the very complicated anatomy of the right hepatic system in the absence of alternative donor even the MELD score of the recipients was >15 but fortunately the LLG volume could satisfy GRWR of 0.7 or more . Figure 5.2,5.3 shows two examples of these cases showing very complicated right hepatic venous system that would cause an outflow reconstruction problem if RLG without MHV was selected and not to mention the risk for the donor if RLG with MHV was selected where LLG could provide a very accepted alternative to RLG (Figs. 1,2).



Figs 1,2. Complicated Right Hepatic venous system.

Operative Procedure (LLG without Caudate lobe).

Donor Hepatecomy

An upper midline incision is made(could be extended to right subcostal region)Fig.3. This is followed by mobilization of the liver. Then cholecystectomy & cholangiograpgy is done for proper identification and confirmation of prior imaging of biliary anatomy, thus identifying left Hepatic Duct(s) and marking of cutting point for later transaction. Hilar Dissection starts afterwards, the left hepatic artery is dissected free from the surrounding tissue. The middle and right hepatic arteries and the left and right main branches of the portal vein are dissected free and encircled with vessel loops. To start Parenchymal Transection at first identification of middle hepatic vein using intraoperative US, then the transaction plane would be 1cm to the right of the vein or without US by shifting 1 or 2 cm to the cantlie's line. In some cases we may depend on demarcation line (fig.4)after identification of it by Pringle's Maneuver. Transection is done with the aid of Cavitron Ultrasonic Aspirator (CUSA), Harmonic Scalpel, Irrigation monopolar or bipolar electrocautery and Coagulation monopolar electrocautery. Graft is then removed to backtable then all stumps are closed (Fig. 6).

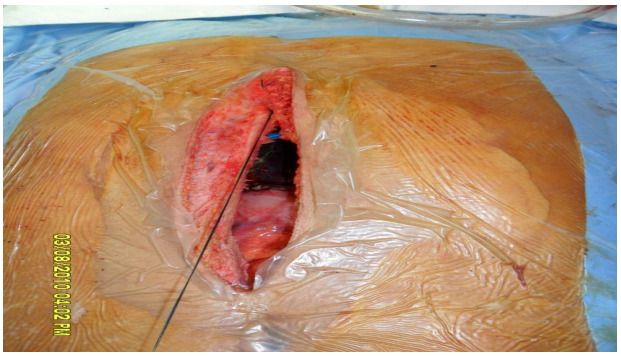


Fig 3. Midline incision.

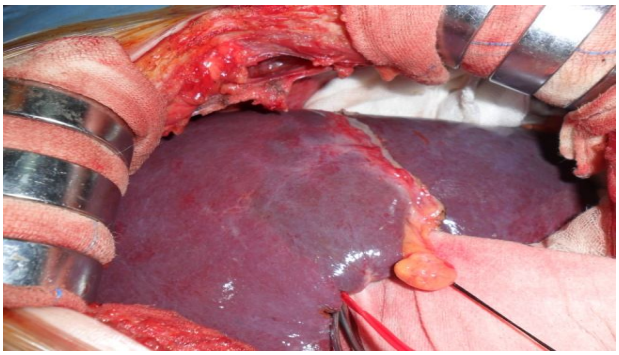


Fig 4. Demarcation line.

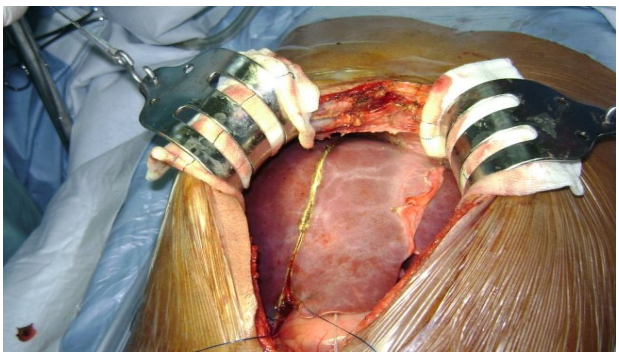


Fig 5. Transiction Line.

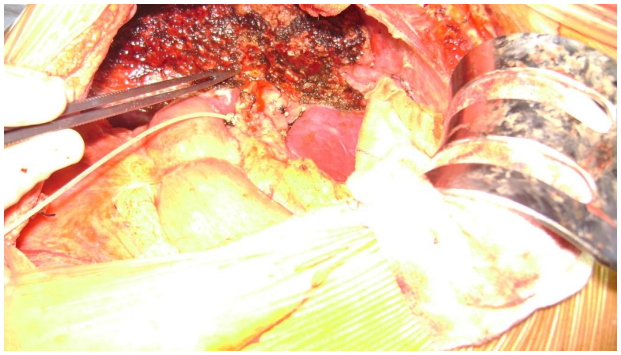


Fig 6. After Graft removal.

Graft Implantation:

The recipient native hepatectomy is performed in a standard fashion. After bleeding is controlled, vascular and biliary stumps are prepared for anastomosis. The common stump of the MHV and LHV is elongated, with removal of the diaphragmatic crus and the inferior phrenic vein(fig.7). In this series, Outflow modulation is done as the RHV stump is clamped horizontally together with the MHV / LHV stump, and its border is cut open to make a large, common hole in line with the graft hepatic vein. This modulation is to minimize Ischemia Reperfusion Injury specially with small grafts as a strategy against development of Small For Size Syndrome (SFSS). Portal vein reconstruction done between Left Portal branch of graft to the main portal trunk of recipient or one of the main branches according to the size. Hepatic Artery reconstruction done between graft artery and either of recipient branches of hepatic artery. None of grafts with more than one artery required 2nd anastmosis based on backflow stream(Fig. 8). Bile duct reconstruction done in duct to duct fashion as a rule unless the case requires Roux- Y Hepatico-Jejunostomy as in Biliary Atresia or in some cases with more than one bile ducts.

Measurement of Portal Pressure:

In case of the presence of portal hypertension specially in HCV patients (in both groups), the continuous portal pressure was monitored by cannulation of the inferior mesenteric vein The readings of the portal pressure were taken at 3 time points: before total hepatectomy, during the anhepatic phase, and after all the vascular anastomosis and prior to closure of the wound. Portal pressure <20mm / Hg was accepted, While >20mm / Hg was considered high considering modulation to lower the pressure. No inflow modulation was done in this series. Temporary portocaval shunt was done in two cases in anhepatic phase to minimize bowel congestion.

Immunosuppressive drugs:

The immunosuppressive regimen consisted of a combination of calcineurin inhibitor (Tacrolimus Prograf or Cyclosporine: Neoral) and steroids with or without mycophenolate mofetil (MMF; CellCept). Currently, the triple regimen including calcineurin inhibitor, steroids and MMF has been the standard protocol for HCV patients. Steroids were basically tapered off by 6 months after LDLT. MMF 1000–2000 mg / day was started from postoperative day 1 and maintained for 3–6 months. For ABO incompatible LDLT, the protocol consisted of a single dose (375 mg / m2) of Rituximab (Rituxan) 2–4 weeks before LDLT. The immunosuppressive dose was adjusted on daily bases guided by trough level.

Definition of small-for-size syndrome:

The definition of SFSS was as reported by Kyushu University group. Briefly, SFSS is defined as having prolonged functional cholestasis (total bilirubin>10 mg / dL at postoperative day 14) and intractable ascites (daily production of ascites of >1 L at postoperative day 14 or >500 mL at postoperative day 28).

Statistical analysis: Continuous variables were compared using a two-tailed, unpaired Student t test for independent samples. All values are expressed as mean ±standard deviation. p-Values ≤ 0.05 were considered significant. All statistical analyses were done using GraphPad software.

Follow Up Period

This study involved follow up of 1 year for Recipients and for 3 months for Donors postoperatively.

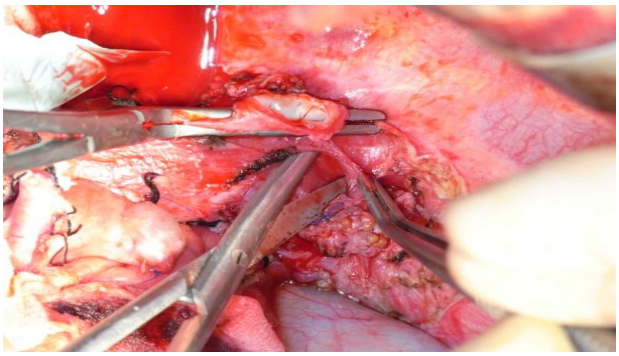


Fig 7. IVC Preparartion.

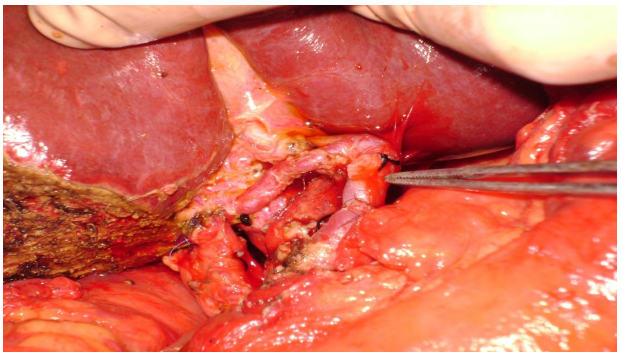


Fig 8. Double Artery Graft (Single Anastmosis).

RESULTS

Patient characteristics

Detailed demographic data for the recipients and donors are presented in Table 1. There were no significant differences in patient age and MELD score between RL and LL groups. The mean Actual Graft Weight of LL grafts was 455 g (range 280–680 g), which was significantly smaller than that of RL grafts (620 g, range 360–1020g, $p < 0.0001$). The mean Actual GRWR was 0.70% (range, 0.50-1.01%) in LL grafts, which was, again, significantly smaller than those of RL grafts (0.88% range 0.65-1.20%, $P<0.0003$). Twelve LL grafts were extremely small, namely, GRWR<0.7%, although the preoperative predicted GRWR was >0.7%.

Donor operative outcomes

Table 2 shows the comparison of operative outcomes between LL and RL donors. The mean operative time was comparable whereas blood loss was significantly less in RL donors (242 mL vs. 375 mL). However, no donors of either group needed blood transfusion. Postoperative liver function tests including peak total bilirubin, peak aspartate aminotransferase and alanine aminotransferase were significantly better in LL donors. Furthermore, lengths of hospital stay were significantly shorter in LL donors (11.9 days vs. 18.2 days), whereas overall morbidity rates were comparable. These data suggest that LL donation is potentially safer than RL donation, although there was no procedure-related mortality in either group. One LL donor developed loss of appetite and depression. Two LL donors and one RL donor developed wound sequelae (Clavian I). Two LL and four RL donors developed bile leakage/biloma where the two LL donors required US guided drainage and Endoscopic Naso-Biliary Drainage tube(ENBD), while the four RL donors required US drainage only (Clavian IIIa). Two LL donors developed bile leakage at closure stump site and required surgical intervention (Clavian IIIb). In terms of procedure-related complications, we have not experienced any Clavien's grade IV and V complications so far.

Table 2. Donors Operative Outcomes.

	Left Lobe(n=34)	Right Lobe	p-Value
Donor			
Operative time (min)	430 ± 91	403 ± 69	NS
Blood loss (mL)	375 ± 336	242 ± 168	0.051
Blood transfusion (%)	0	0	NS
Postoperative LFTs			
Peak T.Bil (mg/dL)	1.8 ± 0.4	3.0 ± 0.7	<0.0001
Peak AST (IU/L)	217 ± 117	308 ± 76	0.0001
Peak ALT (IU/L)	253 ± 156	313 ± 90	0.053
Morbidity (%)	20.5	14.7	NS
Clavien I	8.8	5.9	
Clavien II	0	0	
Clavien IIIa	5.9	8.8	
Clavien IIIb	5.9	0	
Clavien IV	0	0	
Clavien V	0	0	
Hospital stay (days)	11.9 ± 8.0	18.2 ± 7.0	0.001

Overall patient and graft survival rate

The overall 1- year patient survival rates were 85.3% for both LL & RL grafts, i.e. comparable results. Figure 9 shows patient survival in LL grafts according to the GRWR. To investigate the impact of the graft size, the GRWR was classified into four subgroups as follows: (GRWR <0.6%), (GRWR ≥0.6, <0.8%), (GRWR ≥0.8, <1.0%), (GRWR ≥1.0%). There was no significant difference in overall survival rates between these subgroups. Furthermore, 29 (85.3%) out of 34 LL grafts in this series were GRWR <0.8%. The 1-year survival rates of this group of patients were 85.7%, which were comparable to those of patients with LL grafts of GRWR ≥0.8 (80%). Also to be considered that 4 patients of LL graft were <0.6% and all of them survived the 1st year post transplant.

Recipient operative outcomes

Table 3 shows a comparison of operative data between LL and RL recipients. The mean operative time was comparable in both groups. Only one case of each group (3%) required temporary Porto-caval shunt because of small for size graft in LL case and because of intestinal congestion in RL case. No additional measures were done for all for small for size grafts <0.8% (29 LL cases & 8 RL cases). Figure 10 compares the 1-year graft survival rates between LL and RL LDLT according to the MELD scores. In all categories, the LL group revealed comparable results with the RL group. However, in patients with a MELD score ≥20, the LL group (n = 7) tended to show better outcome than RL group (n = 7) 100% & 57.1% Subsequently. Three cases of RL group with MELD score ≥20

because of Sepsis (n=2), and Chronic rejection(n=1), this explains that the relatively better LL results is this subgroup is not related to the high MELD score.

The overall complications were comparable in both groups (35.3% in LL group vs. 38.2% in RL group). Complications of LL group included SFSS (n = 4), Bile Leak"Relaparotomy" (n = 1), HCC Recurrence (n = 1), Prolonged Ascites (n = 2), Prolonged Cholestasis (n = 1), Infection (n = 1), Acute Tubular Necrosis (n = 1), and Diaphragmatic Hernia (n = 1). While RL complications included SFSS (n = 2), Massive Intra-abdominal Bleeding "Relaparotomy" (n = 1), Hepatic Artery Thrombosis (n=1), Acute Cellular Rejection (n = 2), Bile Leak (n=1), Prolonged Ascites (n=2), Infection (n=4).

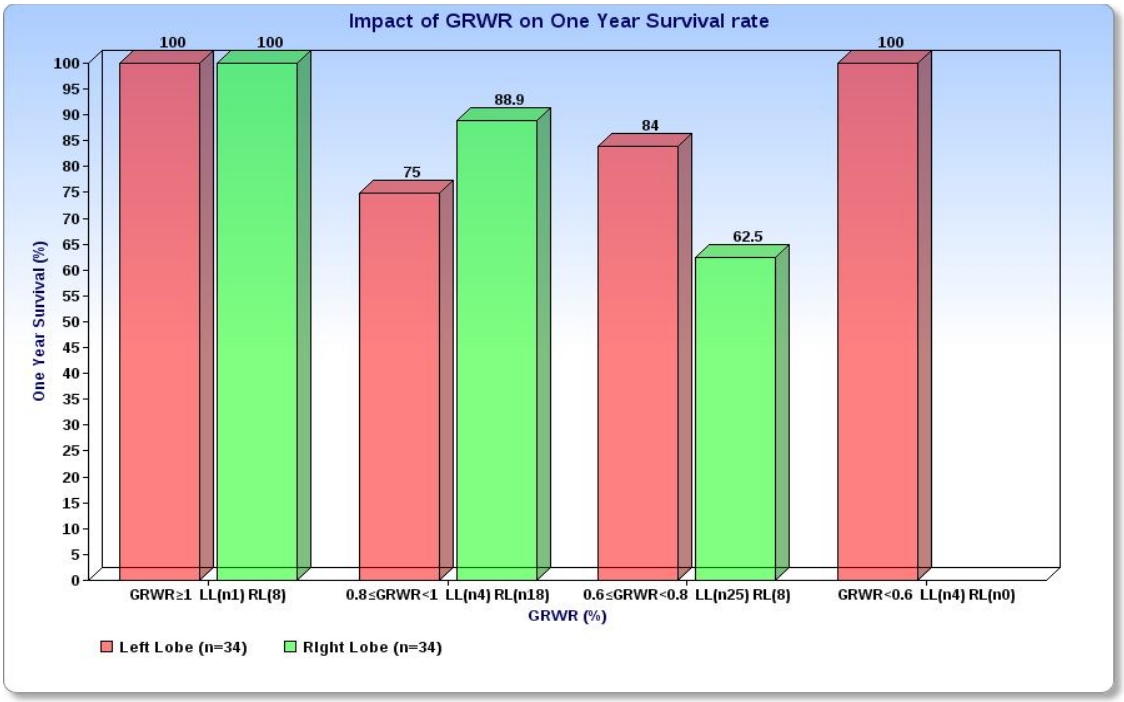


Fig 9. The impact of GRWR on One year survival rates.

Table 3. Recipients Operative Outcomes.

	Left Lobe(n=34)	Right Lobe	p-Valu
Recepient			
Cold Ischemia Time	92.4 ± 81	135.7 ± 77.3	0.0376
Warm Ischemia Time	47.4 ± 7	50.5 ± 8	NS
Operative Time (min)	777.8 ± 202	811.2 ± 110	NS
Temporary PC Shunt (%)	3.0	3.0	NS
Complications (%)			
Over All	35.3	38.2	NS
SFSS	11.8	5.9	NS
HAT	0	3.0	NS
ACR	0	5.9	NS
Bile leak	3.0	3.0	NS
Prolonged Ascites	5.9	5.9	NS
Prolonged Cholestasis	3.0	0	NS
Intra-abdominal Bleeding	0	3.0	NS
Infection	3.0	11.8	NS
HCC Recurrence	3.0	0	NS
Others	5.9	0	NS
Relaparotomy (%)	3.0	3.0	NS
In-hospital mortality (%)	8.8	14.7	NS

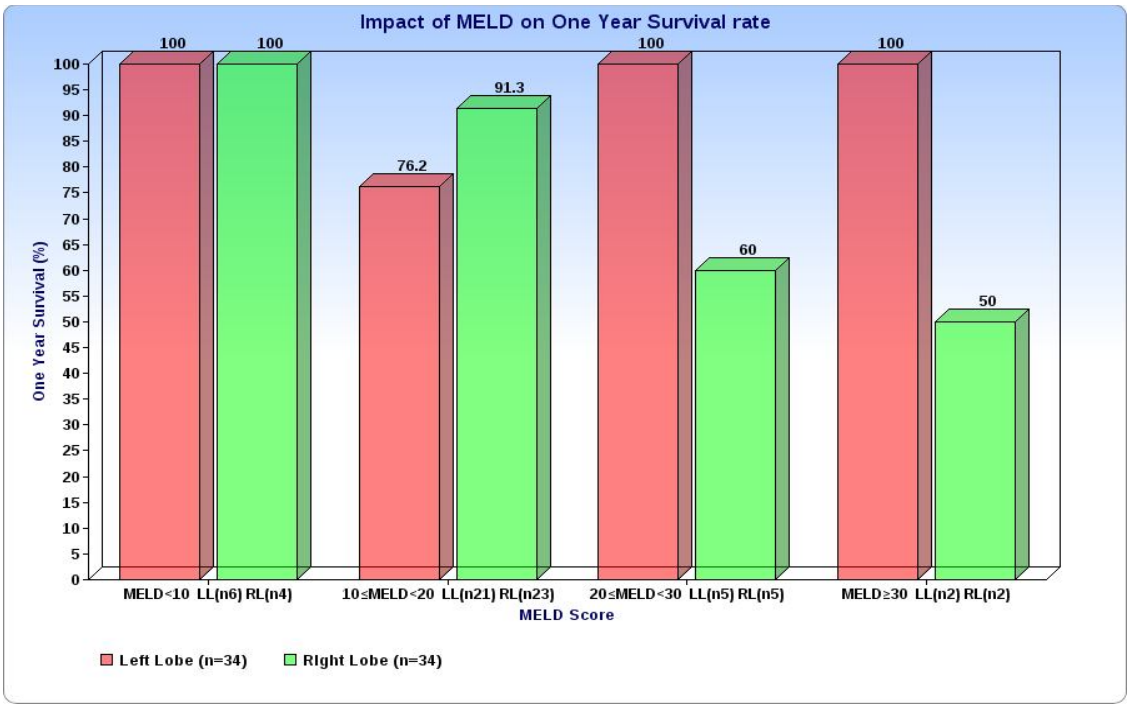


Fig 10. The impact of MELD score on one year survival rates.

Incidence of small-for-size syndrome

The incidence of SFSS was higher in LL LDLT (11.8%) than in RL LDLT (5.9%). Development of SFSS is multifactorial, but parameters to be considered are Graft Quality " donor age", graft size "GRWR", Metabolic Load "MELD" in Relation to Portal Hypertension". Therefore, graft size is not the sole determinant to develop SFSS in this series. Only one case died directly as a sequence of SFSS (LLG case), while the other five cases recovered completely conservatively.

Causes of Graft loss

Within the 1st year posttransplant, in LL group 5 patients died from: Bile Leak/Sepsis (n=1, POD 67), SFSS/Sepsis (n=1, POD 54), Recurrent HCC (n=1, POD 267), Chronic Rejection (n=1, POD 243), Acute Tubular Necrosis (n=1, POD 6). In Hospital Mortality "directly post-transplant" was 2 out of 5. In RL group 5 patients died from: Hepatic Infarction (n=1, POD34), Multiple Hepatic Abscesses (n=1, POD 63), Chronic Rejection (n=1,PoD 297), Sepsis (n=2, POD 55,70). All deaths were In Hospital Mortality.

DISCUSSION

This study clearly showed that the outcomes of LL LDLT were comparable with those of RL LDLT, although SFSS occurred more often in LL LDLT. However, this does not necessarily lead to graft loss. In this series, only one patient lost his graft directly as a result of SFSS.

SFSS is characterized clinically by a combination of prolonged functional cholestasis, intractable ascites and a delayed recovery of both prothrombin time and encephalopathy. The mechanism of SFSS remains unknown but is probably multifactorial. Excessive portal perfusion and pressure to the small graft is suggested to be one of the most important factors.[9]

Therefore, in this series we modulated the outflow of the graft during caval drainage by making one big oval vein opening on recipient side by opening the three hepatic veins together or at least increasing Left & Middle hepatic vein caliber by snipping on IVC thus, minimizing graft congestion and decreasing the perfusion injury specially in the presence of high portal pressure/flow as in high MELD score cirrhotic patients which was very effective. Intraoperatively, it was proved both clinically and radiologically as graft was soft, portal pressure <20 mmHg and venous outflow signal was excellent. This suggests that with proper venous drainage, relatively smaller grafts can tolerate high portal flow/pressure.

Yamada et al., selectively used HPCS for LL grafts with GWRW between 0.6 and 0.8 and showed 100% patient survival.[10] Botha et al. also reported excellent results in patients with small LL grafts (the median GWRW was 0.67%) with HPCS: the 1-year patient and graft survival were 87% and 81%, respectively.[11] They all concluded that a small LL graft with modulation of

portal flow by HPCS may prevent SFSS while at the same time providing adequate liver volume. Furthermore, the Kyoto group showed that portal venous pressure <15 mmHg was the major factor for a better outcome.[12]

The current approach in managing the problem of SFSS of Kyushu group is to perform splenectomy aggressively In terms of the usefulness of splenectomy for low GRWR (<0.8) patients, the 1-year graft survival rates in patients with splenectomy were 93.4%, which was significantly better than those without splenectomy (79.2%). Therefore, they believe concomitant splenectomy is very useful especially for patients with a small graft to control the portal flow and platelet count, thereby improving the overall results.[9]

Focusing on the ''flow'' rather than in the ''size'' may improve our understanding of the pathophysiology of the ''small-for-size'' syndrome and ''post-hepatectomy liver failure'' and it would have important implications for the clinical management of patients at risk. First, hepatic hemodynamic parameters would have to be measured in hepatic surgeries. Second, these parameters (in addition to liver mass) would be the principal basis for deciding the ''safe'' threshold of viable liver parenchyma. Third, the hepatic hemodynamic parameters are amenable to manipulation and, consequently, the ''safe'' threshold may also be manipulated. Shifting the paradigm from ''small-for-size'' to ''small-for-flow'' syndrome would thus represent a major step for optimizing the use of donor livers, for expanding the indications of hepatic surgery, and for increasing the safety of these procedures.[13]

By analysis of the 6 cases that developed SFSS in this study, The GRWR was significantly smaller in LL patients (<0.8%) than RL patients (>0.8%) this should drive us to think about the functional volume rather than the actual volume, also the donor age was relatively old in both groups denoting bad compliance or quality of the graft. The only case that died from SFSS was a LLG case and the recipient was quite old 69 years, while all cases recovered even with grafts <0.6%, so, SFSS is multifactorial.

Regarding graft size, this series suggests that small for size grafts " <0.8% GRWR" function very well with rapid recovery even with extremely small grafts "<0.6% GRWR" patient can survive with smooth postoperative coarse. 37 patient received small for size grafts "29 LLG & 8 RLG" with survival rate of 81%. These results suggest that graft size is not the only determinant of successful LDLT and also that smaller grafts could be used safely if carefully selected. Actually LLG provides an ideal option for many cases thought to be inconvenient previously with great attention paid to size only.

Regarding donor safety, LL donation is safer than RL donation if we consider shorter operative time, better liver functions postoperatively, rapid recovery, less hospital stay and not to mention the quite larger remnant liver volume. With the innovation of "Midline Incision", both cosmetic and pain wise has improved which give more advantages for LL donation.

Based on understanding the results of this study and recent studies concerned with improving the outcomes of SFSG, an algorithm could be proposed for proper graft selection without controlling the portal pressure by dividing the patients into Cirrhotic group and Non-Cirrhotic group, in Cirrhotic group the portal hypertension is usually prominent even the MELD score is not relatively high. In this case we select LLG if MELD score is ≤ 15 and estimated GRWR is 0.7% or more. While in Non-Cirrhotic group portal hypertension is not so prominent so we select LLG with any MELD score and estimated GRWR is 0.7% or more (Fig. 11).

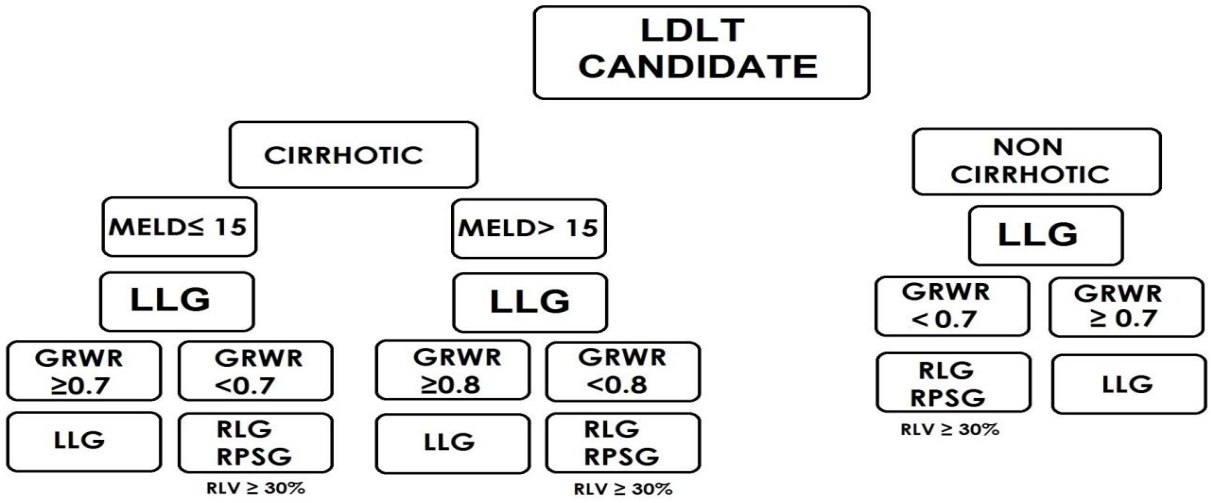


Fig 11. Innovated Graft Selection Algorithm RLV (Remnant Liver Volume), RPSG (Right Posterior Segment Graft).

In conclusion, with proper recipient & donor selection and refinement of surgical procedures, postoperative management LLG can provide a good option for LDLT with minimal burden for donors with very good overall results that could be compared to RLG with many advantages on LLG side regarding anatomical and technical points of view.

Abbreviations: GRWR, graft-to-recipient weight ratio; MELD, Model of Endstage Liver Disease HPCS, hemiportocaval shunt; LDLT, living donor liver transplantation; LL, left lobe; MHV, middle hepatic vein; PCS, portocaval shunt; RL, right lobe; RPS, right posterior segment; SFSS, small-for-size syndrome.

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ORIGINAL ARTICLE

PREVENTION OF SEROMA FORMATION AFTER OPEN VENTRAL HERNIA REPAIR WITH MASSIVE SKIN AND SUBCUTANEOUS RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

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Abstract

Introduction: Seroma and wound breakdown are commonest post-operative complication after open ventral hernia repair with massive skin and subcutaneous reconstruction. Following open ventral hernia, these occur in 12-20% and increase to 17-34% when combined with massive skin and subcutaneous reconstruction. This study evaluates a novel technique of applying talc powder to subcutaneous flaps to prevent seroma formation.

Patients and Methods: Sixty one patients of ventral hernia with skin and subcutaneous reconstruction were admitted to surgery department in Zagazig University Hospital. They were randomly divided into two groups .The PRE group did not receive talc therapy, and the POST group received talc therapy in the subcutaneous dissection. A prospectively collected surgical outcomes database was accessed identifying all patients. Demographics, peri-operative data, and outcomes were analyzed.

Results: PRE group consisted of 31 patients and POST group consisted of 30 patients. Complication rates for PRE / POST goups were: cellulitis or oral antibiotics 35.5%-13.3%, intravenous antibiotics 9.7%-3.3%, operative / radiologic intervention for wound infection 19.4%-13.3%, seroma intervention 19.4%-3.3%, wound breakdown12.9%- 3.3% and hernia recurrence 9.7 %- 0%. Of these, seroma intervention and hernia recurrence were significantly decreased in the POST group (p0.013, p0.032). Mean drain duration was 27.4 days for PRE and 16.3 days for POST (p0.004). Mean follow-up was 5.6 months for PRE and 2.5 months for POST (p0.032).

Conclusion: The addition of talc powder made a dramatic difference in patient outcomes. We found a decreased percentage of wound complications, with a significant reduction in seroma formation, recurrence, and drain duration. The use of talc powder is simple and easy for high risk patients to avoid post-operative complications especially seroma and wound break.

Keywords: seroma, ventral hernia, Talc powder.

INTRODUCTION

Hernioplasty with prosthetic mesh is currently the treatment of choice for ventral hernia, with lower recurrence rates than classical herniorrhaphies. Nevertheless, the use of prosthetic meshes is associated with postoperative complications such as increased rates of seroma and hematoma formation, chronic

inflammation, infection, chronic pain and mesh migration.[1]

A seroma is defined as a clinically identifiable collection of serous fluid in any tissue, potential space, or cavity after an operation. Seroma etiology remains unknown, but it seems to be due to a local inflammatory response to a mechanical injury incurred by tissue aggression during surgery and the presence of foreign bodies.[2]

The use of drainages does not decrease the frequency of seroma formation,[3] and a direct relationship exists between the amount of mesh in contact with subcutaneous tissue and the incidence of seroma.[4]

When seroma becomes symptomatic, percutaneous or surgical drainage is required and this procedure is associated with high risk of infection. When a seroma persists despite successive drainages, it becomes a difficult to solve problem and an important impairment to the patient's quality of life.

Talcum powder was first used in 1935 to produce pleurodesis before carrying out a lobectomy. After this report, intrapleural talcum powder application has been demonstrated to be one of the most effective, simplest, and with the highest cost-benefit ratio, procedures for the treatment of recurrent pleural effusions. Talcum powder induces a strong fibrotic reaction in the pleural cavity due to the activation of polymorphonuclear neutrophils, interleukin 8 and fibroblast growth factor.[5] Complications related to talcum powder pleurodesis are not frequent; the most common adverse effect is pyrexia secondary to the inflammatory process, and major systemic complications are exceptional.

MATERIAL AND METHODS

The study was conducted in gastrointestinal unit of surgery department of Zagazig University Hospital. Ethic approval was granted by the institutional ethics committee. The study was designed as randomized trial.

Sixty one adult patients seen in the surgical outpatient clinic with ventral hernias were scheduled for elective on-lay prolene mesh repair. Informed consent was obtained from all eligible patients. Patients with complicated hernias and immuno-compromised patients were excluded. The data were collected prospectively identifying all patients undergoing these operations.

Patients were divided into two groups based on receiving talc therapy. The PRE group (31 patients) did not receive talc therapy, and the POST group (30 patients) did receive talc therapy in the subcutaneous dissection (Fig. 1). Patient demographics, peri-operative data, and outcomes were analyzed using standard statistical methods. Patient demographic and peri-operative data, including patient age, comorbidities, the type and extent of subcutaneous procedures, size of hernias, operative time, and others factors were collected. We performed a study evaluating a novel intra-operative technique of applying talc to the subcutaneous flaps created during panniculetomies, tummy tucks and hernia repair to prevent seroma formation. Following the operative dissection and otherwise completion of the operation except for wound closure, talc is sprayed into the wound in volumes from 4 grams to 8 grams (Fig. 2).

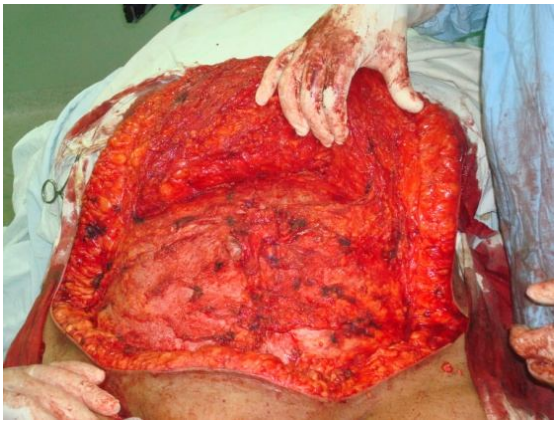

Fig 1. Subcutaneous dissection.

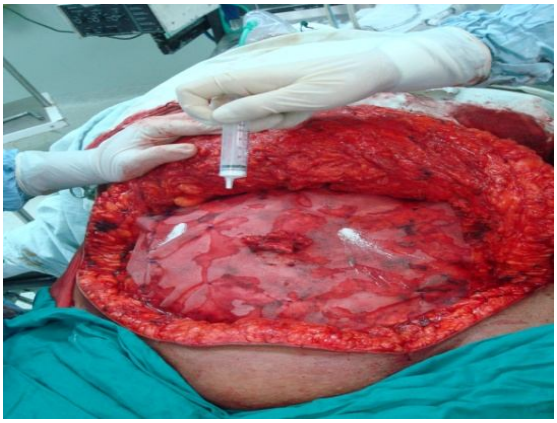

Fig 2. Talc powder application.

Surgical treatment of very large ventral hernias with concomitant panniculectomies or massive subcutaneous dissection were performed. The typical operation included a wide skin and subcutaneous incision with significant subcutaneous dissection with and without skin resection. The ventral abdomen was entered, and the intestinal content of the hernia were reduced back into the abdomen. The hernia was repaired with on-lay prolene mesh which was fixed by (2/0 prolene sutures)

(Fig. 3). The subcutaneous tissues were irrigated and either closed or talc was sprayed or instilled in the wound prior to closure.

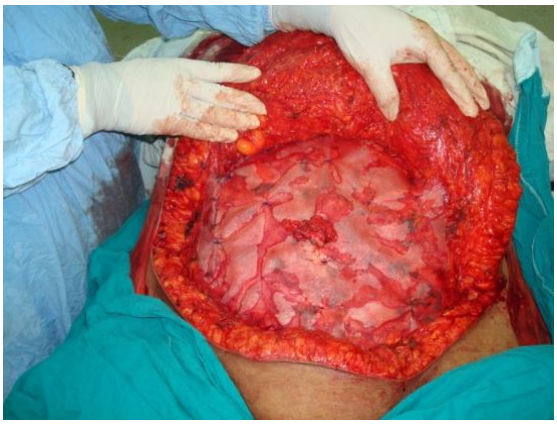

Fig 3. Application of prolene mesh.

Closure of the abdomen (Fig. 4) was performed in the same manner in all patients regarding the sutures used and drains placed. Tow limbs suction drain were placed through the skin and into the subcutaneous space. It was left in place until less than 30 cc of fluid was drained over 24 hours. When the drain collected less than 30 cc of fluid, the drain was removed.

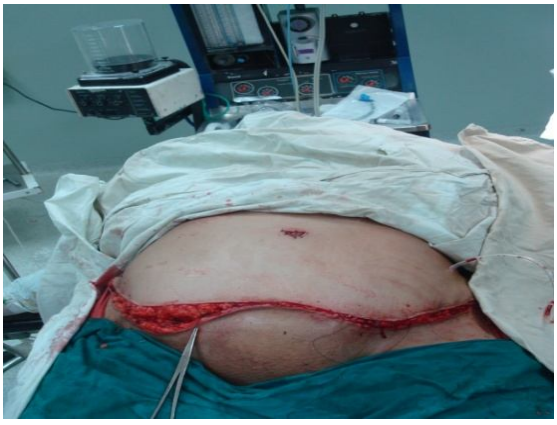

Fig 4. Wound closure.

Descriptive studies were performed with SPSS version 11.5.and group characteristics were compared using Student t test (Table 1). The nonparametric Mann–Whitney U test was used to assess the statistical significances of the differences between the 2 groups.

Chisquare and Fisher exact tests were applied to analyze categorical variables. Continuous variables are presented as the median (interquartile range); categorical variables are presented as incidences and percentages. Statistical significance was evaluated at the conventional α=.05 level.

RESULTS

From June 2011 to September 2013, a total of 61 patients underwent ventral hernia repair with skin and subcutaneous reconstruction were randomly divided into two groups. The PRE group did not receive talc therapy, and the POST group received talc therapy in the subcutaneous dissection.

(Table 1) describe the demographic data and comorbidities of the patients included in the analysis.

Outcomes data are shown in (Table 2). The laparotomy size in the pre group was (16±7 cm) while, in post group was (15±6 cm) without any significant effect on the incidence of post-operative seroma incidence. All cases needed post-operative suction drain, which left in place until less than 30 cc of fluid was drained over 24 hours. The post group shows significant decrease in suction drain duration (16.3days) in comparison to pre group (27.4days). On pain assessment of both group, the post group showed high pain scale (8.1) with prolonged duration of analgesic therapy (5.2±2.6 days) in comparison to pre group (6.6) & (4.8±1.5) most probably due to local subcutaneous inflammation in the post group , but it was not significant especially with regular post-operative analgesic. Regarding post-operative complications, the pre group showed significant incidence of post-operative of seroma, cellulitis and hernia recurrence, while the post group showed limited post-operative complication.

The pre group needed significant intervention for collected seroma in the form of repeated aspiration or even surgical drainage under cover of oral antibiotic which was limited in post group. Other complications like wound infection and breakdown showed insignificant difference between both groups. Although both group were similar in post-operative I.V antibiotic and hospital stay duration but the pre group showed prolonged postoperative mean of follow up(5.6 months) in comparison of post group (2.5 months).

Table1. Demographic and comorbidities.

Characteristics	Pre group(31)	Post group(30)	P value
Sex, No (%) Women	24 (77.4%)	25 (83.4%)	
Men	7 (22.6%)	5 (16.6%)	0.13
Age, mean(range)	49.8 (18-63)	47.1 (21-68)	0.45
BMI, mean (range)	36 (17-65)	37 (24-82)	0.4
Wall defect size(cm)	12.6±9.2	11.4±9.7	0.45
Incarcerated hernia	7 (22.6%)	10 (33.3%)	0. 6
Diabetes mellitus	8 (25.8%)	7 (23.4%)	0.6
Pulmonary disease	4 (12.9%)	3 (10%)	0.62
Operative time(min)	105±27	106±24	0.4

Demographic characteristics (including sex, age, body mass index (BMI), wall defect size, comorbidities and operative time) are summarized in (Table 1).

Table 2. Outcomes of the study.

	Pre group	Post group	P value
Laparotomy size (cm)	16 ±7	15±6	0.4
Duration of drain (days)	27.4	16.3	0.004*
Post-operative pain (vas pains scale)	6.6	8.1	0.45
Analgesic therapy (days)	4.8±1.5	5.2±2.6	0.61
Hematoma	2 (6.45%)	1 (3.3%)	0.62
Seroma	10 (32.3%)	2 (6.67%)	0.012*
Cellulitis or oral antibiotics	11 (35.5%)	4 (13.3%)	0.031*
Intravenous antibiotics	3 (9.7%)	1 (3.3%)	0.35
Intervention for wound infection	6 (19.4%)	4 (13.3%)	0.43
Wound breakdown	4 (12.9%)	1 (3.3%)	0.45
Seroma intervention	6 (19.4%)	1 (3.3%)	0.013*
Hernia recurrence	3 (9.7%)	0 (0%)	0.032*
Hospital stay(days)	5.6±1.2	5.1±1.2	0.4
Mean follow-up (months)	5.6	2.5	0.032*

DISCUSSION

Seroma is a frequent complication after open repair of hernia, with a variable incidence reported by different groups due to it being underreported. Most seromas are asymptomatic and inconspicuous on inspection, and diagnosis is based on the clinical finding of a palpable fluid collection in the subcutaneous tissue.[6]

Most seromas resolve spontaneously without any intervention. Fabozzi et al.[7] suggest that a seroma should be considered a complication only if it persisted for more than six weeks, presents continuous growth, or becomes symptomatic. If an underlying complication is suspected, such as infection or recurrence, then ultrasonography is the initial technique to confirm the nature of the swelling.[8]

Nowadays there is no consensus on the management of symptomatic seroma: it varies from percutaneous aspiration to surgical drainage or the instillation of sclerosing substances.[6]

Percutaneous seroma aspiration is the most widely used technique for symptomatic seroma management. This technique of repeated needle aspiration and mild application of external pressure was first described in 1971,[9] but it is associated with a higher risk of seroma

infection and a high recurrence rate.[10,11]

A more aggressive 3-trocar laparoscopic approach was described by Lehr and Schuricht[12] for treatment of persistent seromas after post incisional hernia repair. The technique described consists of evacuating both the serous fluid and the fibrinous debris followed by argon beam scarification of the seroma cavity lining. When seroma develops a thick surrounding capsule then it is considered a cystic seroma, and capsule removal might be the only curative option.[13]

In our study, the demographic and preoperative data of both pre group and post group were similar without any significant difference. This was the same of the study groups of Rita et al.[14]

In the ventral hernia the incidence of fluid collections following surgery has been reported at between 0 and 17%.[15] They are usually the result of surgical trauma or accumulation of fluid in the empty hernial sac and generally do not require treatment, unless they give rise to symptoms or persist for more than 6–8 weeks, in which case drainage is necessary.[16] The previous study is matching our results although; there were significant decrease in the incidence of seroma among post group patients whom received talc powder (6.67%) (p=0.012).

The post group patients show significant decrease in duration of post-operative wound drain (16.3 days)in comparison to pre group (27.4days) (p=0.004) as we used it to evaluate usage of talc powder to reduce post-operative seroma formation and need to post-operative drain which was denied by Willy et al.[17] Our results are matching Rita et al[14] series as they used post-operative drain as a rule in their procedure and nearly for same duration.

As stated by Fabozzi et al[7] in their study regarding seroma management, we managed our complicated cases but there was significant decrease in seroma intervention of post group in comparison to pre group.

Although we used IV antibiotic as prophylactic treatment of wound infection in our study following the study of Aufenacker et al[18] but the rate of post-operative wound infection is still high in our series (13.3-35.5%) in relation of series of other studies like Finan et al[19] and Taylor et al[20] which vary from(1-10%). This is explaining use of oral antibiotic in infected cases with significant decrease in post group in relation to pre group.

The hernia recurrence in post group was absent while in pre group the recurrence rate was 9.7%. This shows the significant role of talc powder in hernia recurrence reduction which is matching the studies of Rita et al[14] and Shell et al.[21]

We observed no significant difference between both groups regarding other postoperative complications like (pain, hematoma and wound break) which was reflected on patients need to analgesia and duration of hospital stay. Although of previous observation the post group appreciated short duration of post-operative follow up which was significantly prolonged in pre group , most probably related to use talc powder but it was within normal range of post-operative follow up for such cases according to study of Rita et al.[14]

In conclusion many studies had been done to evaluate use of talc powder in surgery especially treatment of malignant pleural effusion and treatment of postoperative seroma. Our study concentrates on use of talc powder in prophylaxis of postoperative seroma formation after ventral hernia repair and massive skin reconstruction. We found a decreased percentage of wound complications, with a significant reduction in seroma formation, recurrence, and drain duration. This suggests talc will provide a mean to decrease wound complications in massive ventral hernias.

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ORIGINAL ARTICLE

SEROMA FORMATION AFTER MASTECTOMY FOR BREAST CANCER

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Abstract

Background: Seroma formation after modified radical mastectomy (MRM) is a frequent complication which predisposes to other complications. Different surgical strategies have been practiced looking for its prevention. We aimed with this study to analyze the different methods of dissection that participate in seroma formation after MRM and accordingly standardizing the best operative technique with the least incidence of seroma formation.

Patients and Methods: A prospective randomized study included females who had MRM for early breast cancer from April 2011 to August 2013, at Sohag University Hospital. Patients were classified into 3 groups according to breast dissection with electrocautery, conventional scalpel, and harmonic scalpel to analyze its effects in seroma formation. Also timing of drain removal, postoperative use of pressure garment, and timing of postoperative shoulder exercise were analyzed for the same purpose.

Results: The study included 50 females with 16% incidence of postmastectomy seroma. All were treated with aspiration, but drain replacement was necessary in one case (12.5%) with axillary seroma. The use of electrocautery, early removal of drains, and early active shoulder exercise, all were highly significant factors (P= 0.001) in development of postmastectomy seromas and proved to be independent factors. Neglection of the wear of pressure garment was nonsignificant (P= 0.25).

Conclusion: Prevention of seroma or decreasing its incidence after MRM can be achieved by the use of ordinary scalpel or far better harmonic scalpel in breast dissection, delayed removal of drains, use of pressure garment postoperative, and also delayed active shoulder exercise.

Keywords: Harmonic scalpel, Axillary dissection, Needle aspiration, Breast cancer

INTRODUCTION

Breast cancer, the second cause of cancer deaths among women, is treated with either modified radical mastectomy (MRM) or breast conservation depending on the disease stage.[1] This entails creation of large axillary dead space and much dissection in creation of skin flaps.

Seroma after mastectomy is a collection of serous fluid under the skin flaps or in the axilla after axillary dissection.[2] Being the commonest complication after mastectomy, it occurs in 2.5% to 51% of cases.[3] It begins on the seventh day post-surgery, reaching a peak on the eighth day and slows continuously until the sixteenth day when it generally resolves.[4] It is responsible for

patient discomfort, prolongation of hospital stay, multiple physician visits, delay of adjuvant therapy,[5] and sometimes, a fibrous encapsulated seroma forms which is resistant to aspiration and requires surgical excision.[6]

The factors contributing to seroma formation are poor adherence of flaps to chest wall, division of several larger lymph trunks, large dead space / large raw area in the axilla, pump action of upper limb increasing lymph flow, local inflammatory mediators, irregular shape of chest wall and axilla, and shear forces during respiration.[7] The most probable cause for seroma formation is disruption of lymphatic channels in the axilla.[8] Although, laboratory studies have shown conflicting evidence, some determined the fluid to be lymph-like in quality,[9] and others showed an inflammatory exudate.[10] Ligation of lymphatics before cutting during axillary clearance leads to reduction of incidence of seroma formation by reduction of axillary lymph drainage postoperative.[11] Also dissection of breast skin flaps during mastectomy using ordinary scalpel has low incidence of seroma formation than using electrocautery but blood loss is much more. Use of harmonic scalpel is reported to be associated with reduced blood loss and drainage volume.[12]

Several methods have been developed to overcome this problem but none of them could be used successfully in practice.[13] It is managed by repeated needle aspiration to seal the skin flaps against the chest wall.[14] However, the use of needle aspiration in an edematous breast can produce additional inflammation and edema.[15] So the best method of management of seroma formation should be focused in how to avoid its formation from the start.

Aim of the work: The aim of this study was to analyze the different methods of dissection that participate in seroma formation after MRM and accordingly standardizing the best operative technique with the least incidence of seroma formation.

MATERIAL AND METHODS

This study was done prospectively in the period between April 2011 to August 2013 on female patients with early breast cancer admitted to General Surgery department, Sohag University Hospital and managed with MRM by surgeons with an extensive experience in breast cancer surgery.

Fifty female patients were eligible for inclusion in this study and were randomized into 3 groups (using randomly ordered sealed opaque envelops, which were opened immediately before mastectomy).

Patients were excluded if they were ASA (American Society of Anesthesiologists) classes > 2, those undergoing bilateral mastectomy or immediate reconstruction, those who had undergone more than 1 previous surgical procedure related to the presenting pathology, those with voluminous breasts, and those who were known to have bleeding diatheses, or were on anticoagulant medication.

Ethical approval was obtained from the local ethics committee and an informed consent was obtained from each participant. Patients were subjected to complete preoperative evaluation through history and examination to assess breast lump and axillary lymph nodes and also to exclude the presence of advanced breast cancer. Preoperative laboratory investigations included coagulation profile, complete blood count, blood sugar level, liver function tests, renal function tests, total proteins, serum albumin, and serum electrolytes. Preoperative radiological assessment included bilateral breast mammography, ultrasound in addition to chest plain x-ray and abdominal ultrasound to exclude metastases. Invasive diagnostic techniques included Tru-cut needle biopsy followed by histopathology.

After preoperative assessment MRM was done. The breast dissection was done by three different tools; electrocautery (Valley Lab., USA®), conventional scalpel and harmonic scalpel (Johnson & Johnson, Ethicon_Endo®). After operation drains were removed either within 3-5 days postoperative, whatever their daily output, or after 5 days; when their daily output was less than 30 cc.

Due to the unavailability of pressure garments, they were replaced by multiple large sized crepe bandages which surrounded the chest wall and the axilla over the wound dressing as early as possible after the operation (before the anesthesia recovery). Also soft objects were put over the axillary region and under the crepe bandage (e.g. multiple dressings and towels).

Active shoulder exercise from the first postoperative day was done with some patients and was postponed till 5-10 days postoperative in some of them (chosen randomly) and only the simple daily activities of the upper limb were allowed in that period.

Follow up for 1-2 months of all patients in this study was done postoperatively every week to assess the wound and to detect the cases of seroma formation and other complications. A seroma was defined as a postoperative fluid collection requiring one or more aspirations or subsequent drain placement.[16]

Statistical Analysis: Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS 16.0 for Windows, SPSS INC., Chicago, USA).

The association of different clinical and operative factors and risk of occurrence of seroma formation was evaluated by Binary Logistic regression analysis. The cut-off for significance of all used statistical analyses was

rated as P ≤ 0.05, P value = 0.001 was rated as highly significant, and P value > 0.05 was rated as not significant.

Categorical variables were expressed as number of cases and percentages, mean with standard deviation (SD) and median and range, as appropriate. The 95% confidence interval was calculated for the main outcome measure.

RESULTS

At this study, there were 50 female patients of early breast cancer. The age of the included patients ranged from 28 to 70 years with a mean age = 47.26 ±1.3 and the median was 43 years.

Breast dissection was done by conventional scalpel in 20 patients, electrocautery in 20 patients, and harmonic scalpel in the remaining 10 patients.

There were 8 cases (16%) of postmastectomy seroma detected 9-16 days postoperative, 7 cases of them were detected in outpatient follow up and the last case was detected during hospital stay at the 9th postoperative day. There were associated complications e.g. wound infection and flap necrosis in 3 cases of postmastectomy seroma. Five seromas were in the axilla and the other 2 cases had combined location both in the axilla and in the breast wound site. All seromas were treated with aspiration initially, with a mean of 2.7 aspirations (range 2 to 7 aspirations). But drain replacement was necessary in one case (12.5%) with axillary seroma.

Breast dissection was done by electrocautery in 20 cases (40%), of them 7 cases developed postoperative seroma (35%), which was a highly significant factor in the development of postmastectomy seroma (P= 0.01) (Table 1& 2).

Breast dissection was done by conventional scalpel in 20 cases (40%), and there was only one case developed postoperative seroma with percentage = 5%. The usage of conventional scalpel in the breast dissection is an important factor in the prevention of postmastectomy seroma, but was not a significant factor (P= 0.12) (Table 1& 2).

Harmonic scalpel was used in breast dissection in 10 cases (20%) without seroma formation in any; this means a percentage of 0% postoperative seroma formation. Although it is inferred from the previous results that the use of harmonic scalpel is an important factor in prevention of postmastectomy seroma, but P value could not be calculated as there were no cases of postmatectomy seroma detected (Tables 1, 2).

Wound drains were removed 3-5 days postoperative in 12 cases with development of postmastectomy seroma in 7 cases (58%), while in the other 38 cases the drains were removed later and there was only one case of seroma within those (2.6%). So, early drain removal 3-5 days postoperative was a highly significant factor in the development of postmastectomy seroma (P= 0.001) (Tables 1, 2).

Pressure garment was used in 22 patients (chosen randomly) postoperatively, of whom 2 cases developed postmastectomy seroma (9%), while in cases pressure garment was not used there were 6 cases of postmastectomy seroma (22%). So its use was associated with less incidence of postmastectomy seroma, but was insignificant (P= 0.25) (Tables 1, 2).

Active shoulder exercise was delayed 5-10 days postoperative in 38 patients chosen randomly, in whom there was development of postmastectomy seroma in only one case (2.6%). In those patients who had early active shoulder exercise (12 cases), there were 7 cases of postmastectomy seroma (58.3%). From these results it is inferred that early active shoulder exercise is a highly significant factor in the development of postmastectomy seroma (P= 0.001) (Tables 1, 2).

As regard Univariate logistic regression analysis of factors affecting occurrence of seroma we found the following results:

Univariate analysis

Usage of electrocautery was associated with high incidence of development of postmastectomy seroma with an incidence of (35%), an Odds ratio= (15.62) which means that the incidence of seroma in cases utilized electrocautery in dissection was higher 15.62 times than cases done without the use of electrocautery and P= 0.01. Also early drain removal had higher incidence of development of postmastectomy seroma than late removal with an incidence of (58.3%), an Odds ratio= 51.8 and P= 0.001. And in the same study early shoulder exercise had higher incidence of development of postmastectomy seroma with an incidence of (58.3%), an Odds ratio= 51.8 and P= 0.001 (Table 2).

Multivariate analysis

According to Multivariate logistic regression of factors affecting occurrence of seroma, including significant factors identified in Univariate analyses, we got the following results; seroma was significantly associated with the usage of electrocautery (P value = 0.02, hazard ratio= 28.40, with 95% confidence interval 1.55- 520.44). Add to this removal of wound drains 3-5 days postoperative was a significant factor in seroma formation (P value= 0.03, hazard ratio= 24.5, with 95% confidence interval 1.43– 498.87). Also Active shoulder exercise 5-10 days appeared to be a significant factor in seroma formation (P value= 0.03, hazard ratio= 24.5, with 95% confidence interval 1.43 – 498.87). All these factors appeared to be independent factors (Table 3).

Table 1. Comparison between factors that participate either in the prevention or formation of postmastectomy seroma

	Total number	Seroma Number 8 (16)	No seroma Number 42 (84)
Ordinary scalpel	20	1 (5)	19 (95)
Electrocautery	20	7 (35)	13 (65)
Harmonic Scalpel	10	0.0 (0)	10 (100)
Drains removed 3-5 days postoperative	12	7 (58.3)	5 (41.7)
Pressure garment	22	2 (9)	20 (91)
Delayed active shoulder exercise 5-10 days	38	1(2.6)	37 (97.4)

Table 2. Univariate logistic regression of factors affecting occurrence of seroma

Factors affecting seroma	Odds ratio	(95% confidence interval)	P value
Age ≥45y vs. age<45	0.56	(0.12 – 2.55)	0.45
Cautery vs. no Cautery	15.62	(1.34 -140.21)	0.01
Ordinary vs. no ordinary scalpel	0.17	(0.02 – 1.53)	0.12
Harmonic scalpel vs. no	Can't calculated as all seroma occurs in those with no harmonic scalpel		
Drain removed 3-5 days postoperative versus drain removed later	51.8	(5.22 – 513.56)	0.001
Pressure garment vs. no pressure garment	0.37	(0.07 – 2.03)	0.25
Active shoulder exercise vs. Delayed shoulder exercise 5-10 days vs.	51.8	(5.22 – 513.56)	0.001

- Factors with bold letters were significant.

Table 3. Multivariate logistic regression of factors affecting occurrence of seroma (including significant factors in univariate analysis)

Factors affecting seroma	Odds ratio	(95% confidence interval)	P value
Cautery vs. no Cautery	28.40	(1.55 -520.44)	0.02
Drain removed 3-5days postoperative vs. later removal	24.5	(1.43 – 498.87)	0.03
Active shoulder exercise vs. delayed shoulder exercise 5-10 days	24.5	(1.43 – 498.87)	0.03

DISCUSSION

Postmastectomy seroma development is a common event with rates ranging from 3% to 85% after breast or axillary surgery,[17] its treatment usually necessitates repeated aspiration,18 but often seroma needs replacement of a drain or even surgical intervention.6 Several factors have been investigated as the cause of seroma formation. These include age, obesity, duration of wound drainage, use of pressure garment, post-operative arm activity, preoperative chemotherapy, and use of electrocautery.[14,17]

We had a collectively seroma incidence rate as 16% because electrocautery was used in 40% of cases for dissection with an incidence of postmastectomy seroma formation as 35% which was a significant factor affecting development of seroma (P= 0.01). This may be due to increased thrombosis of subdermal vessels which lead to relative ischemia of the flaps and lymph spillage from inadequately sealed lymphatics might predispose the wound to seroma. Also the thermal effect of electrocautery on subcutaneous fat leads to lipolysis which is another underlying cause of seroma formation.[19]

The current study revealed that the use of conventional scalpel in MRM was associated with less incidence of seroma formation postoperatively (5%) than with electrocautery use, which may be due to the avoidance of the unwanted effects of electrocautery which lead to higher incidence of seroma formation.[19] This study matches with other studies.[19,20]

Harmonic scalpel causes breakdown of hydrogen bonds and forms a protein coagulum to occlude the vascular and lymphatic channels. So we can get a least incidence of seroma formation. It is important to cut all tissue only with the harmonic scalpel because it ensures the perfect sealing of lymphatic and blood vessels and causes lesser thermal injury and inflammatory reaction, in addition there is no use of sutures.[21,22] This study revealed that the use of harmonic scalpel in MRM was an important factor in prevention of postoperative seroma formation as there was no cases of seroma developed after its use, so it is better than electrocautery as regard seroma formation and also the use of harmonic scalpel is far better than conventional scalpel or in other word the use harmonic scalpel during MRM is the best for prevention of postoperative seroma formation which comes in accordance with other studies.[22,23]

Our study proved that early drains removal 3-5 days postoperative (independent on the daily output) was a highly significant factor (P= 0.001) in the occurrence of postmastectomy seroma, this is in accordance with other study.[24] As during axillary dissection and axillary lymph node dissection there is cut of the axillary vessels with continuous extracellular fluid leak from upstream tissues through afferent lymphatic vessels and some weeks are necessary for draining lymphatic network reconstitution.[25] Meanwhile 8-day drainage after MRM has less incidence of seroma formation than 5-day drainage.[26] The hazards of delayed drains removal can be avoided by early discharge of the patients from hospital with wound drains and good frequent follow up for them in output clinics with good care of drains (to avoid occlusion or infection) till their removal when daily output is acceptable (less than 30- 50 cc).

Our study showed that the use of pressure garment after MRM decrease the incidence of breast seroma formation (9%), but this was not a significant factor in preventing postmastectomy seroma formation (P= 0.25). This decrease in incidence of breast seroma formation, accordingly decrease other wound complications. This can be explained by early obliteration of the dead space by pressure garment (the dead space between the chest wall muscles and the skin flaps developed after the operation) that may decrease the amount and period of drainage. So, it decreases incidence of wound complications especially breast seroma formation.[27]

This study proved that the delayed active shoulder exercise (5-10 days postoperative) could decrease the incidence of breast seroma (2.6%) and this was a highly significant factor in prevention of postmastectomy seroma development (P= 0.001). This matches other studies which can be explained by enhancement of adherence of skin flaps after dissection and obliteration of dead space that occurs as a result of delay of active shoulder exercise.[28]

It was concluded from this study that the prevention of breast seroma formation after MRM can be achieved by the following strategies; the use of ordinary scalpel or far better harmonic scalpel in breast dissection, delayed removal of the wound drains, the use of pressure garment early postoperative, and also delayed active shoulder exercise at the side of operation 5-10 days postoperative with only daily activities of upper limb in this period. All these can help in prevention of seroma formation or even decrease its postoperative incidence.

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ORIGINAL ARTICLE

IS COLONIC DIVERTICULOSIS RARE IN NIGERIANS?

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Abstract

Introduction: Diverticula are bulging pouch-like herniations that can occur anywhere in the gastrointestinal tract including the colon. Colonic diverticula are said to be rare in black Africans. We therefore undertook to determine the occurrence of colonic diverticula in Nigerians.

Aims and Objectives: To determine the occurrence of colonic diverticula in Nigerians using Colonoscopy.

Methodology: This was a hospital-based cross-sectional study carried out at the Endoscopy suite of Crescent hospital, Ilorin from January 2010 to April, 2013. The endoscopy register was reviewed, and the biodata, indications and colonoscopic findings were recorded on a proforma.

Results: A total of 174 patients had colonoscopy carried out on them. One hundred and seven (61.5%) were males while 67(38.5%) were females. The age ranged from 4 to 90 years with a mean of 52.8+/-17.6 years. The indications for colonoscopy were rectal bleeding 78(44.8%); suspected colon cancer 52(29.9%); chronic constipation, and chronic diarrhoea 11 each (6.3%); suspected ano-rectal cancer 6(3.4%); abdominal pain 4(2.3%); anal pain, bloody stool, faecal incontinence and entero-cutaneous fistula 2 each (1.1%); anaemia, post-colostomy for Hirschprung disease, and colon cancer, and polyposis syndrome 1 each (0.6%). Endoscopic findings were Normal findings 43(24.7%); haemorrhoids 35(20.1%); diverticulosis 27(15.5%); rectal cancer 23(13.2%); colitis, and colonic polyps 13 each(7.5%); angiodysplasia 12 (6.9%); colon cancer 10(5.7%); anal cancer, and rectal polyps 6 each (3.4%); anal warts 4 (2.3%); proctitis 3(1.7%); caecal cancer 2(1.1%), rectal ulcer, and rectal prolapse 1 each (0.6%). Diagnostic yield was 75.3%. Colonic diverticulosis is positively correlated with age, and male gender ($p<0.05$), while rectal bleeding is the commonest presentation.

Conclusions: Colonic diverticulosis is common in Nigerians, and is positively correlated with increasing age, and male gender. Rectal bleeding is the commonest presentation.

Keywords: Diverticulosis, Colon, Rare, Nigerians.

INTRODUCTION

Diverticular disease of the colon is a herniation of the mucosa and submucosa through weak points in the muscular walls of the colon to form narrow-necked pouches.(1) It is well recognised in western countries.(2) The true incidence of diverticulosis of the colon is not known. But comparison of the earliest and most recent

autopsies and barium enema studies have indicated that the world prevalence is increasing over time.[3] It has been reported that diverticular disease is on the increase in Africa.[4,5] They are most common in the sigmoid colon which are the areas of highest intra-luminal pressures, as it has the smallest diameter and less compliant than the other parts of the colon.[6] It is commoner in individuals over 60years of age.[7] Both genders are affected equally.[7] The most significant risk factors for colonic diverticula include highly refined low fibre diet, ageing, high intra-luminal pressure, increase in type III collagen and deposition of elastin.[8]

Most people with uncomplicated diverticula are asymptomatic and it has been estimated that only 20% of individuals harbouring diverticula will present with symptoms and signs of the disease.[9] However those who are symptomatic may experience abdominal discomfort and pain, bloating, change in bowel habit, bleeding and fever. Complications include diverticulitis, lower gastrointestinal (GI) haemorrhage, hypertrophy and obstruction, pericolic abscess, perforation and vesico-colic fistula formation, and peritonitis.[5,7] There is no evidence that diverticular disease predisposes to malignancy.[5] Endoscopic examination (colonoscopy) may be necessary to diagnose and treat this condition especially when complicated by bleeding. Other diagnostic modalities include barium enema, and computerized tomography scan.[8] Management of uncomplicated symptomatic individuals include bowel rest, antibiotics and pain control and dietary advice. Surgery is reserved for complicated diverticular disease.[10]

There is a paucity of data on the occurrence of colonic diverticulosis using colonoscopy in Nigerians. Alatise et al[11] working in Ile-ife, south west Nigeria found 40 cases of colonic diverticulosis over a period of 5 years using colonoscopy, barium enema and or computerized tomographic scan. Similarly, Olokoba et al[12] in Ilorin, north central Nigeria made use of colonoscopy in diagnosing colonic diverticulosis. However, other Nigerian workers such as Ogunbiyi,[13] and Ihekwaba[14] in Ibadan, south west Nigeria used radiological methods such as Barium enema to determine the occurrence of colonic diverticulosis. Furthermore, Omojola and Mangete[15] in Port-Harcourt, south south Nigeria used Barium enema to diagnose colonic diverticulosis.

We therefore undertook to determine the occurrence of colonic diverticula in Nigerians using colonoscopy.

MATERIAL AND METHODS

The setting of the study was Crescent Hospital, Ilorin. It is a private hospital that runs a specialist gastroenterology clinic and GI endoscopic services. It receives referrals for gastroenterology consultations and lower GI endoscopy mainly from the University of Ilorin Teaching Hospital(UITH), Ilorin, other government-owned primary and secondary health facilities, and other private hospitals in Ilorin and its environs. This is because this procedure is not available elsewhere in Ilorin. This was a hospital based cross-sectional study carried out at the Endoscopy suite of Crescent hospital, Ilorin from Jan 2010 to April, 2013. The endoscopy register was reviewed, and the biodata, and the indications and colonoscopic findings were noted, and recorded on a proforma. A written informed consent was obtained from all participants.

All consenting patients who required colonoscopy as part of their management were recruited. All colonoscopies were performed with a Pentax video colonoscope with a light source EPM 3300. The patients usually had a 3-day bowel preparation through the use of laxatives comprising Bisacodyl (Dulcolax), Magnesium sulphate (Epsum) salt, and lactulose syrup. They were also placed on liquid diet during the period. The patients had intravenous lines, and analgesia and sedation was carried with 10 mg of diazepam and 100mg of tramadol. A digital rectal examination was done, and thereafter the Colonoscopy was carried out according to standard protocol. The study protocol was approved by the Ethics and Research committee of UITH, Ilorin.

RESULTS

A total of 174 patients had colonoscopy carried out on them. One hundred and seven (61.5%) were males while 67(38.5%) were females giving a male to female ratio of 1.6:1. Their ages ranged from 4 to 90 years, with a mean age of 52.8 +/-17.6years. There was a steady increase in the age of the patients till the sixth decade ie 51-60 years, thereafter there was a decline.(Fig. 1).

The indications for colonoscopy were rectal bleeding 78(44.8%); suspected colon cancer 52(29.9%); chronic constipation, and chronic diarrhoea 11 each (6.3%); suspected ano-rectal cancer 6(3.4%); abdominal pain 4(2.3%); anal pain, bloody stool, faecal incontinence and entero-cutaneous fistula 2 each (1.1%); anaemia, post-colostomy for Hirschprung disease, and colon cancer, and polyposis syndrome 1 each (0.6%).(Fig. 2)

Endoscopic findings were Normal findings 43(24.7%); haemorrhoids 35(20.1%); diverticulosis 27(15.5%); rectal cancer 23(13.2%); colitis, and colonic polyps 13 each(7.5%); angiodysplasia 12 (6.9%); colon cancer 10(5.7%); anal cancer, and rectal polyps 6 each (3.4%); anal warts 4 (2.3%); proctitis 3(1.7%); caecal cancer 2(1.1%), rectal ulcer, and rectal prolapse 1 each (0.6%).(Fig. 3)

Diagnostic yield was 131 out of 174(75.3%).(Fig. 4).

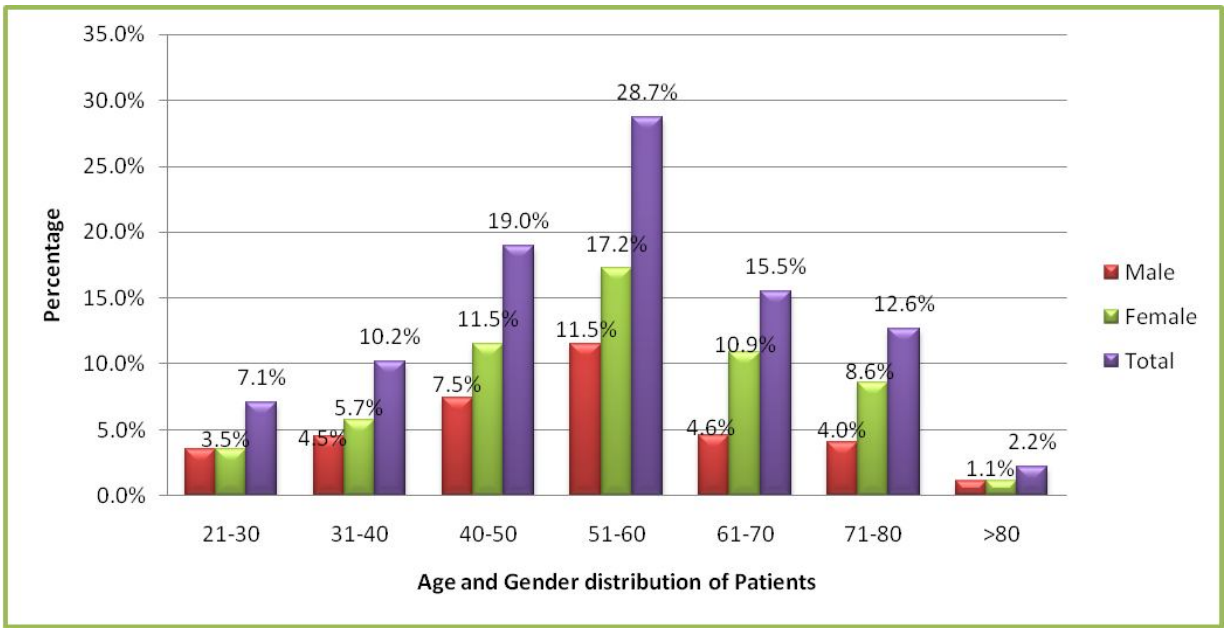

Fig 1. Age and Gender distribution of Patients.

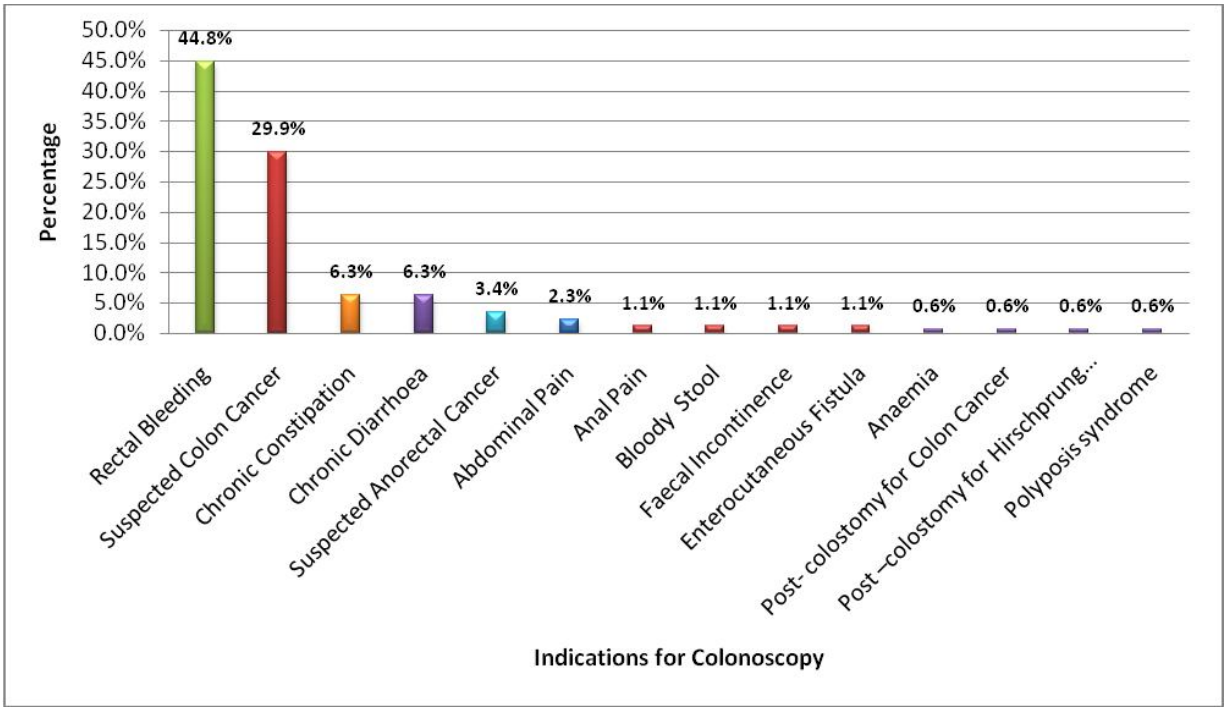

Fig 2. Indications for Colonoscopy.

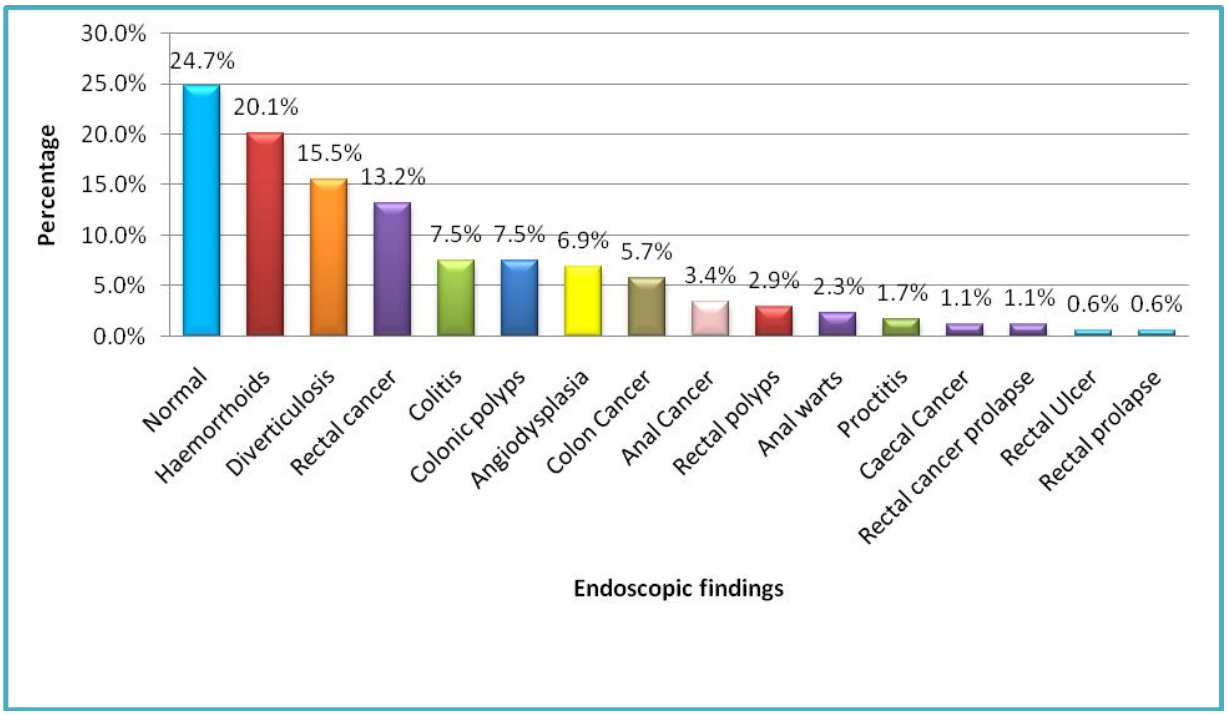

Fig 3. Endoscopic findings.

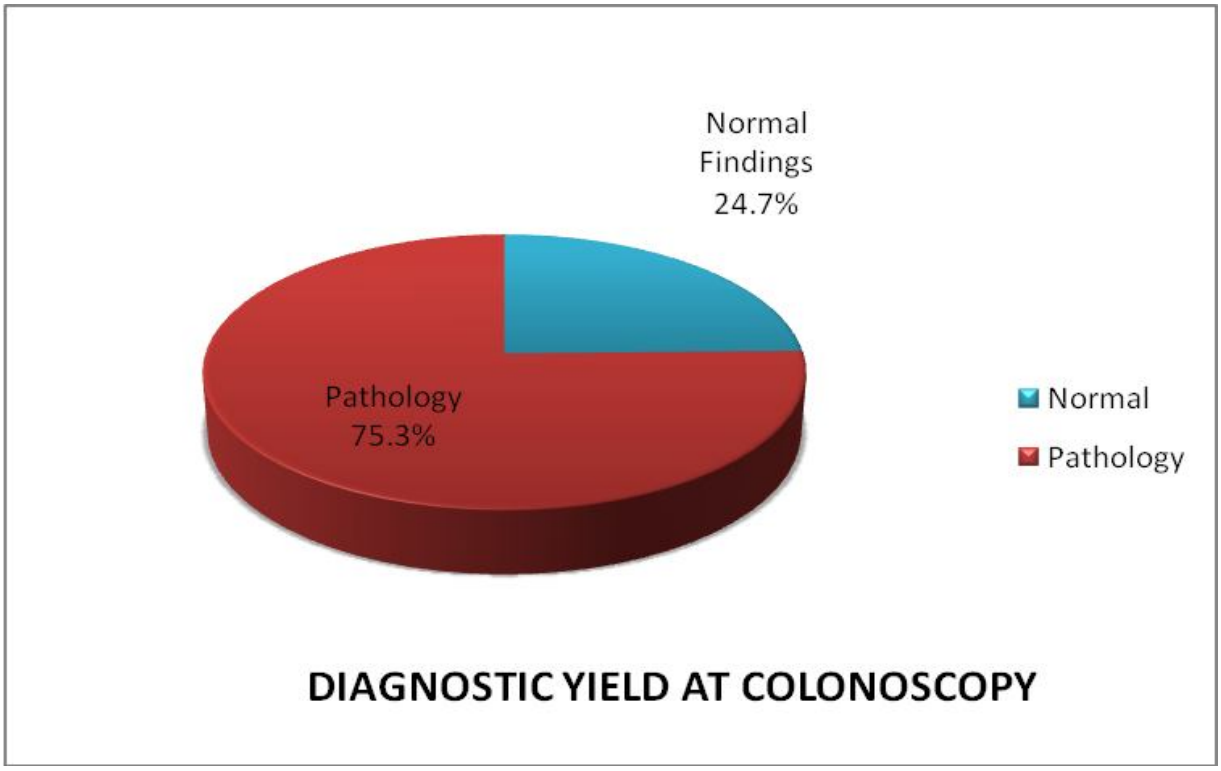

Fig 4. Diagnostic yield.

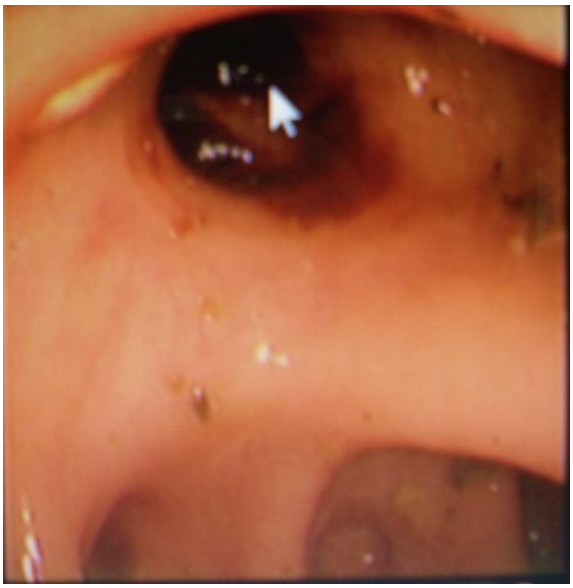

Fig 5. Showing the site of a bleeding diverticulum at the descending colon(arrowed).

Out of the 27 patients with colonic diverticulosis, 10(37.0%) patients were in the 71-80 age group. 23(85.2%) patients were males while 4(14.8%) were females. (Table 1). Colonic diverticulosis is positively correlated with increasing age (p=0.0002), and male gender (p=0.0059).

Table 1. Age and gender distribution of patients with colonic diverticulosis.

Age groups (Years)	Male(n)	Female(n)	Total(n)(%)
<20	0	0	0
21-30	0	0	0
31-40	0	0	0
41-50	1	0	1 (3.7)
51-60	5	3	8 (29.6)
61-70	7	0	7 (25.9)
71-80	9	1	10 (37.0)
81-90	1	0	1 (25.0)
Total	23(85.2)	4(14.8)	27 (100.0)

Out of the 27 patients with colonic diverticulosis, 20(74.1%) patients presented with rectal bleeding; 3(11.1%) patients each presented with constipation, and abdominal mass; while 1(3.7%) patient presented with abdominal pain. (Table 2).

Table 2. Clinical presentation of patients with colonic diverticulosis.

Presentation	Frequency (n) (%)
Rectal bleeding	20 (74.1)
Constipation	3 (11.1)
Abdominal mass	3 (11.1)
Abdominal pain	1 (3.7)
Total	27 (100.0)

DISCUSSION

The main aim of our study was to determine the occurrence of diverticulosis at colonoscopy in Nigerians. Our study has shown an overall diagnostic yield of 75.3% at colonoscopy. This figure is similar to the 79.0% diagnostic yield found by Ismaila and Misauno in Jos, Nigeria.[16] Studies in the West African sub-region carried out by Mbengue et al[17] and Dakubo et al[18] in Senegal, and Ghana respectively revealed a similarly high diagnostic yield. However, the high diagnostic yield in our study contrasts with the 48.0% obtained by Sahu et al[19] amongst their Indian patients, and the 27.2% found by Siddique et al.[20] Furthermore, it is much higher than the 21.0% diagnostic yield obtained by Al-shamali et al[21] amongst the Saudis. The differences in the diagnostic yield may be due to varying sample sizes in the studies, the differences in the spectrum of colonic diseases seen in the different regions of the world, and the different selection criteria and indications for colonoscopy.

The availability, and the cost of colonoscopy may also be a factor. The more expensive the cost of the procedure, the more stringent the selection criteria.

From our study, a total of 27 cases of colonic diverticulosis were seen out of 174 patients who underwent colonoscopy over a period of about 3 years, giving an incidence rate of 15.5% or 9 cases per year. This is similar to the 40 cases (or 8 cases per year) seen over a 5-year period by Alatise et al[11] in Ile-ife, Nigeria. Our figure is however higher than the 31 cases (6 cases per year), and the 26 cases (5 cases per year) seen over a period of 5 years by Kiguli-Malwaddi and Kasozi,[5] and Madiba and Mokoena[4] among Ugandans and South

Africans respectively. Conversely, our figure is lower than the 42 cases (13 cases per year) seen over a 3-year period, and the 20 cases seen in a year by Segal and Walker,[22] and Calder et al[23] among urban black South Africans, and Kenyans respectively. Studies have shown that colonic diverticulosis is common among the Caucasian populations of Europe, USA, and Australia.[2,24,25]

Earlier studies by Ogunibiyi,[13] and Ihekwaba[14] in Ibadan, Nigeria suggested that colonic diverticulosis may be rare in Nigerians. Similarly, earlier African studies also suggested that even though the disease is rare in Africans, it may be on the increase.[4,5]

More recent studies in black Africans have demonstrated a rise in the incidence of colonic diverticulosis.[11,22,23] Different researchers on colonic diverticulosis in black Africans used various diagnostic methods such as Barium enema, colonoscopy, computerized tomographic scans etc which may have influenced the diagnostic yield of colonic diverticulosis and hence the prevalence of the disease seen in their studies, however what is incontrovertible from their findings is the rise in the incidence of the disease. Various reasons have been adduced for the increasing incidence of colonic diverticulosis in black Africans. Eastwood[26] postulated that the traditional African diet that is high in fibre makes the colon of Africans stronger, wider, and thinner than that of Caucasians, and that this is protective from diverticulosis. Other authors however, suggest that increasing age, and Westernization of the traditional African diet may account for the rise.[11,22,23] Segal and Leibowitz[27] however postulated that because of the varying anatomic locations of colonic diverticulosis in Caucasians, Orientals and blacks, diet (fibre-deficient) may not be the only factor at play. They suggested that diverticular diseases may comprise several entities with different causes. Furthermore, Omojola and Mangete[15] raised the possibility of a hereditary factor unrelated to diet in the occurrence of diverticulosis. Alatise et al[11] suggested that environmental factors, and some yet unidentified factors may play a role in the recently observed rise in the incidence of colonic diverticulosis.

From our study, the commonest presentation of colonic diverticulosis was rectal bleeding. This is similar to the findings of other workers. Alatise et al,[11] Kiguli-malwadde and Kasozi,[5] Madiba and Mokoena,[4] and Longsteth[28] found rectal bleeding to be the commonest presentation in their Nigerian, Ugandan, South African, and American patients respectively.

From our study, colonic diverticulosis was associated with increasing age, and male gender. This is similar to the findings of Eastwood [26] who found an association between colonic diverticulosis and ageing. Other workers have also demonstrated an association between colonic diverticulosis and ageing.[11,29,30] Similar to our findings, Alatise et al,[11] and Les[29] found a male preponderance among their Nigerian and Singapore patients respectively whereas Madiba and Mokoena[4] found that females were more affected by diverticulosis. However, Kiguli-malwadde and kasozi,[5] and Ooi and Wong[7] found no gender predilection. These differences may be due to the varying sample sizes, and selection bias. So far, no definite gender predilection has been attributed to colonic diverticulosis.

A major limitation in this study, is the low rate of colonoscopy which is mainly due to the high cost of the procedure, and the fact that patients have to pay out-of-pocket for colonoscopy. Larger and more multi-centred studies are advocated to study colonic diverticulosis in Nigerians.

In conclusion, Colonic diverticulosis is common in Nigerians, and is positively correlated with increasing age, and male gender. Rectal bleeding is the commonest presentation.

Conflict of interest: None

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CASE REPORT

RETAINED SURGICAL SPONGE AS A CAUSE OF INTESTINAL OBSTRUCTION; A CASE REPORT

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Abstract

A retained surgical foreign body is an unfortunate although avoidable event. Intraluminal migration is rare. The author reports a case of a retained surgical sponge that had migrated totally into the small bowel and presented with repeated attacks of sub-acute intestinal obstruction. An exploratory laparotomy was done with removal of the retained surgical sponge, which was followed by complete recovery.

Keywords: Gossypiboma, migration, intraluminal.

INTRODUCTION

Gossypiboma, from the Latin "Gossypium" for cotton and Swahili "boma" for place of concealment, is a cotton foreign body retained in a body cavity. The true incidence is probably unknown, it has been reported as 1 in 100 to 3000 for all surgical procedures and 1 in 1000 to 1500 for intra-abdominal operations.[1-2] The condition is rarely reported due to medico-legal implications and consequences. Patients may present with an inflammatory reaction with abscess formation or with a picture of intestinal obstruction. The occult character of this type of intestinal obstruction as well as the absence of an obvious cause usually leads to the delay in institution of therapy. Non-specific clinical symptoms and inconclusive imaging findings may preclude an accurate diagnosis.[3]

CASE REPORT

A 30 year old lady presented with severe colicky abdominal pain, recurrent vomiting, and abdominal distension for the previous 4 days. She was passing small amounts of stool and flatus. She gave a history of previous similar episodes over the past four months, for which she was repeatedly hospitalized with a provisional diagnosis of sub-acute intestinal obstruction that was managed conservatively.

She is married and mother of five children, all delivered by cesarean section, the last one 4months before the start of the current complaint. She has no relevant medical history. She gave a history of a colonic injury during the last cesarean section that was identified and managed at the time of surgery.

On examination she was found to be pale, anxious and tachycardic. Her BP was 120/70, Pulse was 100/min, RR within normal. Abdominal examination showed moderate distension of the abdomen, more in the epigastric and right para-umbilical regions. She was markedly tender in the epigastric and left para-umbilical region, but no palpable masses were felt. PR showed an empty rectum, and her intestinal sounds were audible.

Labs done at the time showed a HB of 10.5, with microcytic hypochromic anemia, white count was 7.3, and platelet count was 590,000. Liver function tests, urea and BUN were all within normal range.

A plain abdominal x-ray showed very few dilated bowel loops with air-fluid level in the right side of the abdomen. An abdominal ultrasound showed a well-defined heterogeneous mass measuring 52x58x55 mm in the umbilical region very close to the abdominal wall with strong echogenic wall and hypo-echoic halo. There was no free fluid. An MRI of the abdomen was performed a week later and showed an ill-defined mass of heterogeneous consistency in the epigastric region in relation to the transverse colon, otherwise normal results. Based on the clinical picture and the presence of this mass it was decided to do an exploratory laparotomy.

Examination under anesthesia revealed a 12 cm rounded mass in the epigastric region that was not mobile, and another longitudinal mass in the left para-umbilical region about 15 by 4cm that was freely mobile. At laparotomy, the round mass in the epigastric region was found to be a mass of amalgamated small bowel loops adherent to the base of the mesentry under the transverse colon. The longitudinal mass in the left side of the abdomen was delivered into the wound and was found to be a jejunal loop that contained a firm indentable structure. The bowel loops beyond that point were collapsed.

The adhesions binding the small bowel loops were found to be very dense and fibrous. During lysis of the adhesions the small bowel was inadvertently opened at the anti-mesenteric border, and the edges of the opening were found to be devitalized and unhealthy, with not much active bleeding. After lysis of the adhesions, the longitudinal mass mentioned earlier was found to be about 30cms distal to the opening in the small bowel. The mass was milked easily and was found to be a rolled-up surgical towel. The towel was removed, and a resection-anastomosis of the devitalized segment was performed.

After confirming the integrity of the anastomosis and free-flow of intestinal contents the abdomen was irrigated with normal saline and closed in layers with tube drains in both para-colic gutters and at the site of the anastomosis.

The patient had a smooth post-operative course. She was put on Ceftriaxone 1gm bid, and Metronidazole 500mg tds. Intestinal sounds were audible on the 3rd post op day, and she started oral fluids on the 4th post op day. She developed a single spike of fever on the 2nd post-op day that was diagnosed as milk engorgement, and subsided after expression of the milk. The drains were removed on the 5th and 6th post op days and the sutures were removed on the 7th post op day. She remains symptom-free to date.

CONCLUSION

Small bowel obstruction due to a retained foreign body does not rank high on the list of differential diagnosis of post-operative mechanical intestinal obstruction. It is rarely seen in daily surgical practice. Contributing factors to this unfortunate event are emergency operations, unplanned surgical procedure- in this case the colonic injury that was sustained during the previous surgery-and a high body mass index.(1)

A retained sponge may result in abdominal pain, abdominal mass, peritonitis, adhesions, fistulas and intra-abdominal abscess. It may present acutely or delayed depending on its size, type, location and the nature of the body's reaction. One of two foreign body reactions may occur. The first is an aseptic fibrinous response that creates adhesions and encapsulation with a resulting foreign body granuloma. The second is an exudative reaction that leads to abscess formation with or without secondary bacterial infection.(4) A rare event is the erosion of the sponge into the lumen where it may lie partially or wholly in the lumen.

Intra-peritoneal surgical sponges evoke an inflammatory reaction that is surrounded by omentum and nearby viscera. The foreign body exerts pressure which forces an opening in the bowel, allowing a fold of the sponge to enter the lumen. Peristaltic activity of the bowel helps to propel the sponge further into the lumen of the lumen, and the point of entry is sealed by the resulting adhesions. The obstruction at this point is partial because liquid intestinal contents can still diffuse through the sponge and serves to decompress the bowel.(5)

Prevention of gossypiboma can be done by simple precautions as manual counting once before and twice after the procedure. The use of sponges tagged with radio-opaque markers can avoid over-investigating patients. An electronic article surveillance system which uses a tagged surgical sponge that can be identified electronically has been examined.(6) Bar codes can be applied to all sponges which can be scanned by a bar code scanner at the end of the procedure. The rarity of the condition and latency in the manifestation of the symptoms as well as the low index of suspicion leads to misdiagnosis and delay in proper management. If discovered early, laparoscopic retrieval may be feasible.(7)

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