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Synthetic Sapheno-peritoneal Shunts in Treatment of Refractory Ascites in Egypt

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ABSTRACT

Complications of ascites such as refractory ascites and hepatorenal failure are usually associated with the worsened quality of lifestyle so carry a very high mortality rate. The aim of the present study was to determine whether a usage of a synthetic graft could resolve the problem and offer potential advantages over Autogenous peritoneo-venous shunt. Synthetic sapheno-peritoneal shunts were done for 13 patients with refractory ascites. Clinical data such as bodyweight, abdominal girth, daily urinary output and Child-Pugh Score (*S. albumin*) were recorded. Patients were followed up for at least 6 months after surgery. The bodyweight and abdominal girth tended to decrease in 92.3% of cases. The dose of diuretic was notably reduced in all patients and totally stopped in (30.8%) after 3 months and Child-Pugh scores had improved after the saphenous-peritoneal shunts. Groin seroma, hematoma and cellulitis were reported in a case (7.7%) for each but Shunt occlusions occurred in 2 cases (15.4%) following this procedure. Liver transplantation was done successfully for 15.4% in this group of patients. In conclusion, the quality of lifestyle of cirrhotic patients with refractory ascites was improved with marked decrease in wound complications and shunt obstructions in short term. However, long-term follow up is difficult because of the bad prognosis in these patients. This technique may be a pre-request for some patients before transplant.

Key words: Synthetic, sapheno-peritoneal, shunts, refractory and ascites

INTRODUCTION

Ascites may be a complication of both hepatic and non-hepatic diseases (Wolf, 2008) and is formed in above of 75% in cirrhotic patients. The splanchnic and systemic haemodynamics in cirrhotic patients have been markedly altered, causing central hypovolaemia in addition to arterial hypotension with consequent activation of the vasoconstrictor systems. Also, activation of sympathetic systems, rennin-angiotensin and increased sodium re-absorption were much more evident. Refractory ascites is the inability to be resolved by standard medical treatment with low sodium diet and diuretics and this is the most serious complication in cirrhotic patients with ascites; (Salerno *et al.*, 2010).

Other causes of ascites such as portal vein thrombosis, malignancy or infection and non-compliance with medications and low sodium diet have been excluded the diagnosis of

refractory ascites can be made based on strict criteria (Senousy and Draganov, 2009). The diagnosis of refractory ascites can be done based on strict criteria by excluding other causes of ascites including portal vein thrombosis, malignancy, infection and non-compliance with medications and low sodium diet (Senousy and Draganov, 2009). Dietary sodium restriction and improving sodium excretion with suitable diuretics are the corner stone in management of ascites caused by cirrhosis (Sandhu and Sanyal, 2005). Borie *et al.* (1999) stated that the treatment of ascites itself induce complications such as water and electrolyte disturbances, functional renal failure, encephalopathy and also development of refractory ascites.

Also about 10% of patients with ascites do not respond to such medical treatment and require something more invasive (Itami *et al.*, 2003). Other procedures can be used in treatment of these patients such as periodic paracentesis or transjugular intra-hepatic porto-systemic shunt (Salerno *et al.*, 2010). The most widely accepted therapy for patients with refractory ascites is outpatient setting of repeated large-volume paracentesis with albumin administration every two to four weeks intervals (Elmaadawy *et al.*, 2010).

Many different definitions were stated for refractory ascites such as it is ascites that cannot be clinically corrected by diuretics or ascites that recurs rapidly with using appropriate diuretic doses or lastly when diuretics complications overcome their continuation. In about 10% of patients with ascites refractoriness develops with type 2 hepato-renal failure association (Zetterman, 2011). Deen *et al.* (2001) stated that complications were usually associated with all peritoneal-venous shunts employed in patients with refractory ascites. These complications included early recurrence of ascites as frequent paracentesis does not affect the mechanisms involving in ascetic fluid accumulation, the result reported also by Gines *et al.* (2004). A simple and cheap operative method has been found in the surgical treatment of refractory ascites to overcome the significant expenses and high complication rates in using traditional shunt pumps like LeVeen, Denver or Agishi shunts.

The first sapheno-peritoneal shunt was reported by Pang *et al.* (1992) from Singapore, Utikal *et al.* (2004) but saphenoperitoneal shunt, as performed now is a pure biological shunt and has many potential advantages. Fishman (1982) and Winn and Harlan (2005) were reported the significant reduction in the risk of thrombotic occlusion caused by the intrinsic antithrombotic activity of endothelium. Nagy *et al.* (2001) in their valuable series, had performed 267 peritoneo-venous shunt operations, by introducing a new method using an autolog-venous graft with a peritoneo-venous anastomosis that drains the ascetic fluid into the saphenous vein, then into the femoral vein. Their short term results proves successful use of sapheno-peritoneal shunt in management of refractory ascetic with significant improvement in quality of lifestyle with minimal postoperative complications, in addition to avoidance of insertion of foreign materials in these risky patients; the results supported by Vizsy *et al.* (2005).

Elmaadawy *et al.* (2010), in their series of 19 patients; although they used natural saphenous vein graft, reported that synthetic shunts are devices that permit the return of ascites fluid and proteins to the intravascular space and also, these devices are successful at relieving ascites and reversing protein loss in some patients. Patients with refractory ascites have very poor prognosis and therefore referral for consideration for liver transplantation should be initiated (Senousy and Draganov, 2009) as only liver transplantation may improve the survival of such patients (Salerno *et al.*, 2010). Zervos and Rosemurgy (2001) in their series proved the major role of

peritoneo-venous shunt in treatment of refractory ascites in cirrhotic patients. Positive pressure gradient between peritoneal cavity with ascetic and the central venous pressure is the principle factor to achieve permanent peritoneal cavity drainage with return of accumulated ascetic fluid into the circulation. A number of drainage systems have been developed over the course of time. Currently, the systems, which permit active flow management (Denvers shunt) enabling us to retain long-term cumulative function, are optimal (Utikal *et al.*, 2004).

The introduction of natural peritoneo-venous shunt with avoidance of insertion such foreign material has been proved to be very effective and successful in treatment of refractory ascites with minimal postoperative draw-backs and significant improve in the quality of lifestyle of these patients.

MATERIALS AND METHODS

This study was conducted in New Damietta Faculty of Medicine Al Azhar University in the period between September 2007 and December 2010 on 13 patients; 8 males and 5 females complaining of tense ascites not responding to medical treatment. Their ages ranged from 32 to 61 years with mean 36 ± 2 years, as seen in Table 1. All patients were cirrhotic with hypoproteinaemia hypoalbuminaemia. They received frequent albumin administrations. Paracentesis had been done 2 to five times in some patients.

A full clinical history was taken and complete physical examination was performed. Laboratory investigation including complete hematologic examination, coagulation profile and an assessment of renal and liver functions tests were obtained. Serum sodium and potassium were estimated and corrected in some patients before operation.

Pelvi-abdominal ultrasonography to exclude the presence of hepatocellular carcinoma or portal vein thrombosis and bilateral great saphenous veins duplex Doppler U/S to verify the vein valves competence.

Upper gastrointestinal endoscopy was done for all patients to evaluate the esophageal and gastric varices condition. Ascetic fluid was examined physically, bacteriologically and chemically. Patients who have signs of spontaneous bacterial peritonitis (infection, abdominal pain), encephalopathy or gastrointestinal bleeding were excluded.

All patients had liver cirrhosis with hepatic cell failure and portal hypertension with Child-Pugh classification grade C, as seen in Table 1.

Table 1: Demographic data for the patient's group

Items	No.	%	p-value
Total number	13 Pts.	100	
Sex			
Male	8 Pts*	61.5	0.3*
Female	5 Pts*	38.5	
Age			
Range between 32 and 50	8	61.5	0.3*
Range between 51- 61 years	5	38.5	
Mean 36 ± 2 years			
Etiology			
Hepatic cell failure and Portal hypertension	13 pts*	100	

*All patients had liver cirrhosis and portal hypertension (Child-Pugh grade C). s: Significant

Local anaesthesia (lidocaine 5% solution) has used in all patients in this study because of the bad general health condition of this group of patients.

Through the classical incision the saphenous vein is dissected downwards from the saphenofemoral junction and the proximal 2 cm cut end is anastomosed to one end of the synthetic PTFE graft. Another incision is made above the inguinal crease through which the peritoneum is reached. A tunnel from the upper thigh to the lower abdomen is made deep to the inguinal ligament through which the synthetic graft is passed. An opening is made in the peritoneum through which the tube is entered as a nipple about 2 cm inside it. Stitches are taken between peritoneum edges which are invaginated into a tunnel and around the tube to be water tight. Non-absorbable suture materials are used. Wounds are closed drains.

Postoperatively during the follow-up period, weekly Duplex ultra-sound examination for the shunt patency, measurement of the abdominal circumference and body weight and daily urine output was done.

Statistical analysis: We used in our study two system of statistical analysis:

- Standard deviation is a widely used measurement of variability or diversity used in statistics and probability theory. It shows how much variation or "dispersion" there is from the average (mean, or expected value). A low standard deviation indicates that the data points tend to be very close to the mean, whereas high standard deviation indicates that the data are spread out over a large range of values
- p-value in statistical significance testing, the p-value is the probability of obtaining a test statistic at least as extreme as the one that was actually observed, assuming that the null hypothesis is true. One often "rejects the null hypothesis" when the p-value is less than the significance level α (Greek alpha), which is often 0.05 or 0.01. When the null hypothesis is rejected, the result is said to be statistically significant

RESULTS

Postoperatively, clinical follow up revealed, gradual decrease in body weight and abdominal girth. Also, an increase in diuresis with the unchanged diuretics doses in 12 patients representing (92.3%). There was reduction of dyspnea, an increased appetite and improved ambulation due to gradual decrease in ascites. These were evaluated weekly, as seen in Table 2.

Successful shunt formations were been found in 11 patients representing (84.6%) and were been evaluated every week by duplex ultra-sound examination.

There was a need for paracentesis in 3 patients representing (23%) and the dose of diuretic was significantly reduced in all patients and totally stopped in 4 cases representing (30.8%) after 3 months. It was noticed that frequency of patient's admission to the medical department was lowered postoperatively from once/month to once/three months.

Median hospital stay was of 7 days (range 4 to 14) all these results in comparison to our previous series with autologus SP shunts are seen in Table 3.

Complications: All were minor complications that were resolved in one week except a failure in 2 cases due to massive ascetic leakage. Shunt occlusions occurred in 2 cases and occurred at the

Table 2: Postoperative data

Parameters	One week	2 weeks	One month	2 months	3 months	6 months
Average abdominal girth reduction	8- 10%	10-12 %	12-15 %	15-20 %	20- 24%	~30%
Average body weight reduction	2-3%	3-5%	5-7%	8-10%	10- 15%	~20%
(<i>S. albumin</i>) child-pugh score	2.5	2.6	2.7	2.8	3 mg dL ⁻¹	3.2 mg dL ⁻¹
Daily urinary output						
Average	600-650cc	650-720cc	720-820	820-940	940 ~1100	~1.4 L
% of increase	8.3%	10.8%	13.9%	14.6%	17%	27.3%

(~: up to)

Table 3: Comparison between the synthetic SP shunt series results with autologous SP shunt series results of the same group of researchers

Synthetic saphenoperitoneal shunts			Autologous SP shunts (Elmaadawy <i>et al.</i> , 2010)	
Items	Number/13	(%)	Number/17	(%)
Decrease discomfort	12	92.3	13	76.5
Successful shunt formations	11	84.6	11	64.7
No need for P.O. paracentesis	8	61.5	9	52.9
Need for paracentesis	3	23	2	11.8
Patients totally stopped diuretics after 3 M	4	30.8	5	29.4
Median hospital stay	7 days (range 4 to 14)		11 days (range 7 to 21)	



Fig. 1: Different presentations of preoperative tense ascites with different types of its complications

middle of the 5th month and 8th month due to blocking with intestinal loops or omentum, as seen in Table 4. Different presentations of preoperative tense ascites with different types of its complications are shown in Fig. 1.

Mortality: Two patients (15.4%) died; one at the 3rd and the other at the 6th month due to causes unrelated to the procedure. They died from hepatic failure which is considered as the etiological cause for ascites. Operative technique in details are shown in Fig. 2.



Fig. 2: Operative technique in details

DISCUSSION

Ascites is a common complication in patients with chronic liver disease. Some patients are resistant to diuretics and need therapeutic paracentesis on a regular basis. This is inconvenient in the long term and also has resource implications (Elmaadawy *et al.*, 2010). Alternatively, these patients may be treated by peritoneovenous shunts, which require insertion of a foreign body into a central vein and are prone to occlusion (Vadeyar *et al.*, 1999) as they reported a success rate of (87.5%); the remaining patient had to have the shunt removed because of ascitic leakage. In those who underwent successful shunt formation, the need for paracentesis and the dose of diuretic was significantly reduced over a median follow-up of 8 months. Hospital stay in the month after discharge was significantly less than that in the month before operation.

Also, Elmaadawy *et al.* (2010) were reported successful shunt formations (64.7%). The median follow-up was 11 months.

While in our study successful shunt formations were found in 84.6% nearly as reported by Vadeyar *et al.* (1999) and better than that of Elmaadawy *et al.* (2010). There was in this study a failure in 2 cases due to massive ascetic leakage over a median follow-up of 6 months.

Vizsy *et al.* (2005) mentioned that the traditional pumps (LeVeen, Denver, Agishi) used in the surgical treatment of refractory ascites have significant expenses and complication rates and in saphenoperitoneal shunts the one-way flow is maintained by biologically given double saphenous valves.

In this study, the used synthetic graft is not considered expensive as it is short segment of the PTFE that maintain patency and did not require much dissection, so with less complications. Also

it seems that one way direction may be maintained by the increased ascitic pressure over the venous pressure.

Regarding the etiology, Vizsy *et al.* (2005) ascites in their patient's group have been associated with cirrhosis of the liver (secondary to aethyilism in 8, to HBV infection in 1). This correlate to this study where all patients had hepatic cirrhosis while in study of Elmaadawy *et al.* (2010), hepatic cell failure and Portal Hypertension in 14 patients (82.4%), chylous ascites in 2 patients (11.8%) and cardiac cause (Heart failure) in one patients (5.9%)

Regarding the results, Chen *et al.* (2005), autologous procedure study, the urinary output, nutritional status and Child-Pugh scores and their quality of life had improved, but total bilirubin output had not changed significantly. The body weight and abdominal girth tended to decrease, but not significantly. No groin infections were noted following this procedure.

In study of Elmaadawy *et al.* (2010), after operation significant reduction in abdominal girth, body weight and increase in diuresis with diuretics in unchanged doses were observed in 76.5% of patients decreasing their discomfort (relief of ascites symptoms, with reduction of dyspnea, an increased appetite and improved ambulation). There was no need for paracentesis in 52.9%, need for paracentesis in 11.8% and the dose of diuretic was significantly reduced in all patients and totally stopped in 29.4%. Hospital stay (median) was 11 days (range 7 to 21). Hospital re-admission after discharge was significantly less than that in before operation.

Vizsy *et al.* (2004, 2005) reported in their studies, 66.6% improvement in quality of life and reduction in body weight and abdominal girth and increase in diuresis with standard diuretics caused by Autologous Sapheno Peritoneal Shunts (ASPS) with minimal negative operative effects in successful cases.

In the present study, the postoperative weekly clinical follow up revealed: gradual decrease in ascites with increase in diuresis with even the reduced diuretic doses and decrease in body weight and abdominal girth, in 92.3%, with reduction of dyspnea, an increased appetite and improved ambulation. There was a need for paracentesis in 23% and the dose of diuretic was totally stopped in 30.8% after 3 months (Table 3). It was noticed that frequency of patient's admission to the medical department was lowered postoperatively from once/month to once/three months. Median hospital stay was 7 days (range 4 to 14). These results agree with Elmaadawy *et al.* (2010), Vizsy *et al.* (2004,2005) and also with Chen *et al.* (2005).

Regarding the complications; in study of Vizsy *et al.* (2005), there were the minor complications (33.3% for either seromas or hematomas) and 22.2% for cellulitis] that have been self-limiting in general. In the presence of major complications as: 11% for either peritoneal reflux or severe hypoproteinaemia and 33.3% for shunt occlusion interventions were needed several times. In one of the occlusions contralateral fistula was created with PTFE prosthesis implantation, in another case desobliteration happened with a silicone drain left in the shunt.

In the study of Elmaadawy *et al.* (2010), the minor complications reported 23.5%, seromas in 11.7%, cellulitis in 5.9% and hematoma in 5.9%; all have been self-limiting in general with the aid of antibiotics and mild anti-inflammatory drugs. Also the major complications reported 23.5%, shunt occlusions in 11.7%, peritoneal reflux in 5.9% needed shunt ligation and severe hypoproteinaemia in 5.9% interventions were needed in the cases of the occlusion and peritoneal reflux where contra-lateral shunts have been created.

The peritoneovenous shunts which require insertion of a foreign body into a central vein are prone to occlusion (Vadeyar *et al.*, 1999). We encountered with major complications occurred in only 2 shunts 15.4% that were occluded at the middle of the 5th month and 8th month respectively due

to blocking with intestinal loops or omentum. The minor complications reported (23%): One seromas, one cellulitis and a hematoma representing 7.7% for each. This result is near to that in Elmaadawy *et al.* (2010) but less than half that occurred in Vizsy *et al.* (2005) study. This can be explained where less dissection was needed compared with the autologous procedure.

Although, Gines *et al.* (1991), Suzuki and Stanley (2001) and Wolf (2008) mentioned that however, serious complications are observed in 10% of the recipients of these synthetic devices; it is noted that similar or even higher percentage of complications are observed in the autologous procedure.

Concerning the mortality, in the study of Elmaadawy *et al.* (2010), 17.7% of patients died during follow-up from causes unrelated to the operation; one patient (5.9%) died from hepatic failure 11 days after the operation, two patients (11.8%) died during follow-up, one at 7 months (5.9%) from liver failure and the other at 11 months (5.9%) from un-controllable variceal hemorrhage.

In research of Vadeyar *et al.* (1999), three patients (37.5%) died during follow-up from causes unrelated to the operation.

We have had two mortality cases (15.4%) one at the 3rd and the other at the 6th month also from causes unrelated to the procedure. They died from hepatic failure which is considered as the etiological cause for ascites. These can be considered as high percent in short periods of follow up but reflects the bad prognosis in these patients.

As regard the post-procedure Liver transplant, in the study of Vadeyar *et al.* (1999) one patient underwent successful liver transplantation. We have successful liver transplants for 2 patients (15.4%). Long-term follow up is required to verify weather this procedure can be considered as a pre request for liver transplant in patients with refractory ascites.

CONCLUSION

Regarding its longer duration of patency and hemodynamic effects the synthetic saphenous-peritoneal anastomosis appears a simple, safe and can be considered as cost-effective method of achieving control of refractory ascites. They improve quality of life to some extent in successful instances.

Wound complications and obstructions decreased in the short term. But, long-term follow up is required to determine if improved patients could be candidates for liver transplant.

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