Short-term Outcomes of Infrapopliteal Angioplasty for Critical Lower Limb Ischemia

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ABSTRACT

This prospective study included 43 patients presented to the vascular surgery department in Kasr Al Aini and New Kasr Al Aini teaching hospitals with critical lower limb ischemia between September 2011 and May 2013. The patients' age ranged between 50 and 94 years with a mean of 64. 84 years. There were fourteen females and twenty-nine males. All males were cigarette smokers and the females were not. All patients were diabetics, thirty four hypertensive (79%), four patients with atrial fibrillation (AF) (9%), four with old cerebrovascular stroke (9%), and eleven patients with coronary heart disease (25%), only one patient has end stage renal disease on regular dialysis (0.02%). All patients presented with critical limb ischemia (CLI); Rutherford (5&6). Technical success was achieved in 40 cases. One patient died post-operative because of extensive myocardial infarction. In the first three months follow up three patients had below knee amputation. Two patients died mostly of cardiac event in the second 3 months follow up. Clinical success was definitive with regaining pulse in 28 patients and clinical improvement (good capillary circulation and relief of pain) in 11 patients. The limb salvage in this study was 79.06 % after 3 months that dropped to 62.6% by the end of the one year follow up. Between 3-6 m follow up there were two more mortalities and one major amputation. By the end of the one-year follow up, the total mortalities were seven and major amputations were nine cases.

Conclusion: *Angioplasty alone with the development of low profile wires, and long low profile alone can be the sole treatment of infrapopliteal disease and limb salvage especially with comorbid patient and short life expectancy. The endovascular therapy has less patient burden with short hospital stay and return to normal life.*

Key words: *Angioplasty-infrapopliteal –critical limb ischemia*

INTRODUCTION

Peripheral arterial disease (PAD) is a worldwide illness. It is estimated to occur in 3% of people aged 40-59 years and in 20% of people over 70 years[1]. Critical limb ischemia (CLI) is a severe form of PAD, which may, or may not be preceded by intermittent claudication. It is more common with increasing age. It is definitely related to smoking, diabetes mellitus, hypertension, dyslipidemia, hyperviscosity, hypercoagulable states, and hyperhomocysteinemia. It is associated with chronic renal insufficiency.[2] CLI is defined as limb pain that occurs at rest, or impending limb loss that is caused by severe compromise of blood flow to the affected extremity.[3] The international consensus on the definition of CLI is the following: any patient with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease. Given that CLI is a severe manifestation of PAD, these patients would be classified in the more severe ends of the Fontaine classification (stage III-IV) or the Rutherford classification (grades 4-6)[3]. Patients with PAD confined to the infrapopliteal arteries may be asymptomatic due to the excellent collateral network between tibial arteries; one patent tibial artery is often sufficient to keep a patient free from ischemic symptoms . When these patients present with CLI they often have severe, extensive three-vessel disease and only 20–30% have a simple, focal lesion with good distal run-off[4].

Aim of the study:

It is to assess feasibility and outcome of limb salvage in patients with CLI after infrapopliteal angioplasty. The primary end-point of the study is the technical and clinical success of the angioplasty. The secondary end-point is the limb salvage and major amputation free survival up to one year post procedure.

PATIENTS & METHODS

This included 43 patients presented to the vascular surgery department in Kasr Al Aini and New Kasr Al Aini teaching hospitals with infrapopliteal disease, critical lower limb ischemia for whom percutaneous transluminal angioplasty (PTA) was done, between September 2011 and May 2013. All enrolled patients were subjected to:

I) Clinical assessment:

History taking and clinical examination were done including Age and gender, major risk factors for atherosclerosis including diabetes Mellitus, smoking, hypertension, cardiac diseases, chest diseases, renal insult and stroke. Clinical categorization of chronic lower limb ischemia followed the categorization of Rutherford - Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia.

II) Pre-procedural investigations:

- Routine laboratory tests: complete blood picture, kidney and liver function tests, coagulation profile, lipids profile and blood glucose level.
- Duplex scanning: patients were scheduled for duplex scanning before intervention, at one, six and twelve months follow up.

The following measures were taken:

- Anatomical site, occlusion or stenosis (single or multiple, concentric or eccentric).
- Runoff status distal to the affected segment.
- New lesions detected at follow up.

The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained.

III) Selection criteria for our study:

Inclusion criteria:

Patients with critical chronic lower limb ischemia with lesions involving the infrapopliteal vessels with or without proximal lesions presenting with:

- Ischemic rest pain (Rutherford category 4).
- Minor tissue loss as nonhealing foot ulcers or focal gangrene (Rutherford category 5 & 6).

Exclusion criteria:

1. Patients with claudication either capacitating or incapacitating.
2. Aneurysmal disease and arteriovenous fistula.
3. Only peroneal artery distal runoff.
4. Previous vascular surgery or endovascular intervention in the same limb.
5. Known intolerance to study medications or contrast agents.

Pre-procedure preparation

All patients were admitted to the hospital at least 24 to 48 hours before the procedure and the following measures were taken:

- Optimizing the patient general condition; for example, proper control of diabetes and hypertension
- Proper hydration was ensured by adequate fluid intake the day before the procedure.
- N-acetylcysteine was given in dose of 600 mg pre and post the procedure, creatinine level is checked before the procedure to decide whether to use ionic or non ionic dye and also after the procedure.
- A loading dose of clopidogrel 300 mg was given the night of the procedure that is to be continued post-procedurally at a maintenance dose of 75 mg daily.
- The patients were instructed to ensure the cleanliness of both groins.
- All patient were kept fasting at least 6 hours before the procedure.

After proper sterilization and draping, access was established under local anesthetic.

For antegrade access a 6 F sheath was used. Contralateral retrograde femoral access whenever required, was employed using 8F crossover sheath. An initial angiogram was done to confirm the pre-procedure duplex and to determine the morphology of the lesion and the plan of treatment. Heparin was administered during the procedure according to standard practice 10000 IU IV. Afterwards the following data were recorded for every patient concerning the infrapopliteal lesions.

They were categorized into:

TASC A: single stenosis <1 cm long

TASC B: Multiple focal stenosis ,1 cm or 1or 2 stenoses ,1 cm involving the trifurcation.

TASC C: Stenosis 1-4 cm long ,occlusion 1-2 cm long, or extensive stenosis involving the trifurcation.

TASC D: Occlusion .2cm long or diffusely diseased.

- Crossing the diseased segment as regarding type of the wire, modality of crossing either intraluminal or subintimal, or combined, and whether the crossing was successful till the level

of the foot or not. Wires used included standard hydrophilic (Terumo) 0.035", stiff hydrophilic 0.035", V-18 0.018" and 0.014" wire.

- Length and diameter of the balloon used for dilatation regardless of the length of the shaft. Usually inflation of the balloon is more than 180 sec to avoid flow limiting dissection.
- Intra-procedure complications such as vessel recoil, perforation, arteriovenous fistula and spasm, dissection whether flow limiting or not and the need of treatment. In cases of flow limiting dissection, a trial to recanalize another crural vessel was done. In cases of vessel spasm Nitroglycerin trinitrate (Tridil) 5 mg/ml (1 ml diluted in 10 ml saline) was given intra-arterially. Also post-procedure complications such as access site and systemic complications were recorded.

The outcome was evaluated for every case immediately post-procedure ,and one, three and six months and a year later. Immediate evaluation was based on completion angiography and clinical assessment (pulse, capillary refill, and warmth). Follow up was done for clinical satisfaction and duplex scanning. The success of the procedure was determined by the following:
Angiographic success was defined as good flow with less than 30% residual stenosis at the narrowest point of the arterial lumen. Presence of non flow limiting dissection was considered as successful vessel recanalization.

- Clinical success which may be:
  - Definitive success in the form of regain of pulse.
  - Clinical improvement (good capillary circulation, warmth, relief of symptoms). Patency rates after one, three and six months and one year follow up based on clinical assessment and duplex.
  - Limb salvage rates after short-term clinical follow up (within 3 months) as regards prevention of major amputation and preservation of the heel.

Post-procedure management:

The arterial sheath was routinely immediately after the procedure. Manual compression was done for 15-20 minutes. Mobilization was delayed for 12-24 hours. Fluids and N-acetylcysteine (600 mg) were given. Enoxaparin (Clexane) 40 mg Bd was given according to the weight starting 6 hours after removal of the sheath to be continued for 3-5 days. Successful cases were discharged on the second day on a for life treatment of clopidogrel 75 mg/day, aspirin 150 mg/day. And Atorvastatin (Ator) 40 mg once.

RESULTS

This prospective study included 43 patients presented to the vascular surgery department in Kasr Al Aini and New Kasr Al Aini teaching hospitals with critical lower limb ischemia due to infrapopliteal disease, between September 2011 and May 2013.

The age of patients ranged between 50 and 94 years with a mean of 64. 84 years.

There were fourteen females and twenty nine males. All male patients were cigarette smokers, and females were not. All patients were diabetics, thirty four hypertensive(79%), four patients with atrial fibrillation (AF) (9%), four with cerebrovascular stroke (9%),and eleven patients with coronary heart disease (25%). Only one patient has end stage renal disease on regular dialysis (0.02%). All patients presented with Rutherford's category (5&6). Access was ipsilateral antegrade femoral in thirty eight patients and retrograde contralateral femoral in five. Two patients had retrograde pedal access (both were dorsalis pedis), one was fluoroscopically guided and the other was arterial cut down .access in both was sheathless,(fig 2). Crossing the lesion was intraluminal in eighteen cases, subintimal in sixteen cases, and combined in nine cases. According to the Trans-Atlantic Inter- Society Consensus (TASC) classification of the infrapopliteal lesions, we had no limbs with TASC type A, eleven limbs (25.6%) with TASC B, fifteen limbs (34.8%) with TASC C lesions, and seventeen limbs (39.5%) with TASC D lesions, table (1). The 0.035", 0.018", 0.014" inches wires and low profile long balloons were used in these cases. Balloon angioplasty was done in all cases. The balloon diameter ranged between 2.5-3 mm for infrapopliteal lesions, 4-7 mm for femoropopliteal lesions. Balloon length ranged between 40 mm and 200 mm. Inflation time ranged between 15 and 180 seconds (Wanda® balloon from Boston Scientific or Opta® from Cordis),Fig(3-7). Two stents were carried out in two SFA lesions associated with infrapopliteal disease .Only one stent was deployed in popliteal artery extending to posterior tibial artery due to flow limiting dissection.

Table 1: Morphology of the lesions.

TASC A	0	0%
TASC B	11	25.6%
TASC C	15	34.8%
TASC D	17	39.5%

The number of vessels treated were posterior tibial artery alone in nine cases, anterior tibial alone in five cases, peroneal artery with posterior tibial artery in 5 cases, peroneal artery with anterior tibial in seven cases. Anterior tibial with posterior tibial in fourteen cases. Angioplasty failed in three cases due to inability to cross the lesion in two cases and unresolved thrombosis in one. Limited perforation occurred in three cases and was treated by prolonged balloon dilation. limited arterio-venous fistula developed in two cases and similarly treated by prolonged balloon dilation. Twenty six cases had spasm that resolved upon nitroglycerine injection.

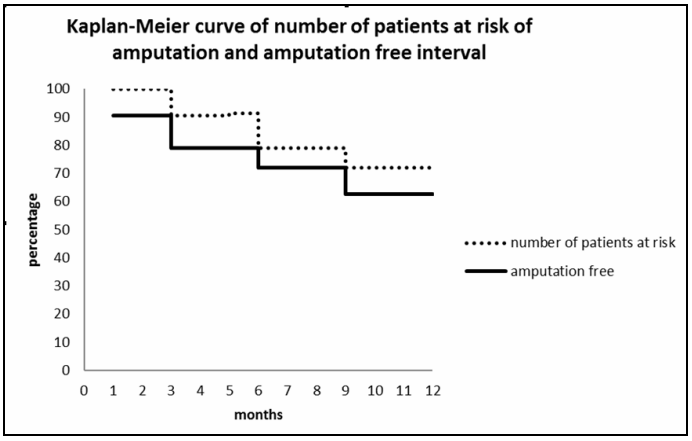

Fig.1: Kaplan –Meier curve for patients at risk of amputation, dotted line and amputation free interval, continuous line.

The technical success was achieved in 40 cases. One patient died post-operative because of massive myocardial infarction. In the first three months follow up three patients had below knee amputation ,and two patients died of cardiac event. In the second three months follow up, there were two mortalities and three major amputations due to spreading of infection. Between 3-6 months follow up there were two more mortalities and one major amputation. By the end of the one year follow up, the total mortalities reached seven and major amputations were nine cases, table (2).

Table (2): Outcome of angioplasty during the one year follow up.

period(months)	number of patients at risk	no of death	no of amputation	amputation free	km amputation free
after 1 m	43	1	3	39	0.906
1-3m	39	2	3	34	0.789
3-6m	34	2	1	31	0.719
6-12m	31	2	2	27	0.626

Clinical success was definitive with regaining pulse in 28 patients and clinical improvement (good capillary circulation and relief of pain) in 11 patients.

Patency rates after one, three and six months and one year follow up was based on clinical assessment and duplex. The limb salvage in this study was 79.06 % after 3 months that dropped to 62.6% by the end of the one year follow up.

Fig. 1: Transpedal approach (sheath less)

Fig. 2: Perforation of anterior tibial artery during lesion crossing

Fig. 3: Sealing of the perforation by balloon dilatation

Fig. 4: Loop of 0.014" wire passing from posterior tibial artery (PTA) up the dorsalis pedis artery to the anterior tibial artery (ATA) through the foot arch. The (hollow arrow) shows the tip of the wire in the ATA. The solid arrow shows the long low profile balloon in PTA

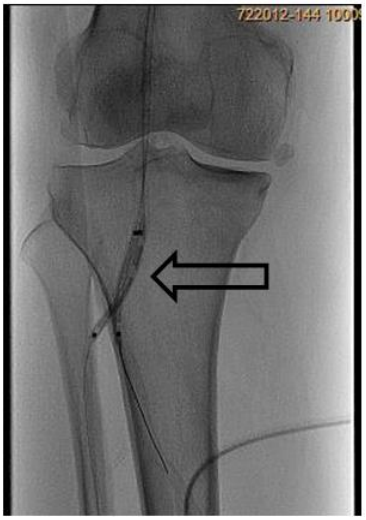

Figure 5: Kissing balloons with passage of one of the balloons in lower popliteal with ATA. The other balloon is passing from lower popliteal to tibial-peroneal trunk. .Both wires were 0.014".

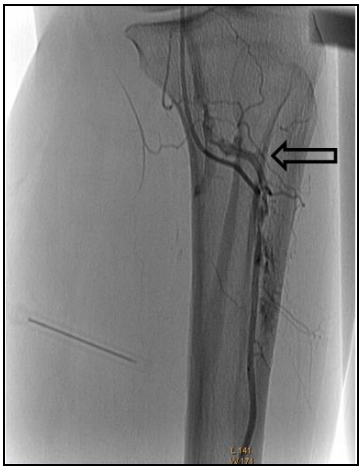

Fig. 6: Arterio venous fistula during angioplasty of anterior tibial artery.(arrow)

Groin hematoma occurs in 9.3% (n=4) , duplex had excluded connection with either the artery or the vein and they were treated by Hirudin gel, hot fomentation and antibiotics and resolved about 3-4 weeks later. The cases complicated with perforation, dissection, or arteriovenous fistula formation were treated by angioplasty for 180 sec, table (3).

Table 3: Complications

Complication	Number (17)	Percentage (3 9.5 %)
Groin hematoma	4	9.3%
Dissection	8	18.6%
perforation	3	6.97%
AV fistula	2	4.65

Table (4): Follow up, primary patency, limb salvage, and major amputation.

		0 months	3 months	6 months	One year
Primary patency (PP)		39 (90.6%)	33 (76.7%)	29 (67.4%)	25 (58%)
limb salvage (LS)		39 (90.6%)	34 (79.06%)	31 (72.09%)	27 (62.7%)
Major amputation	BKA	2	2	1	1
	AKA	1	1	0	1
Death		1	2	2	2

At the end of the follow up period (one year), there were nine (20.9%) cases who had major amputation, six BKA, and three AKA. Indications for major amputation in four cases were spreading infection despite successful revascularization. Whereas, in five cases the amputation was indicated due to failed angioplasty. At three months, follow up the PP rate was (76.7%) (n=33) while LS rate was (79.06%) (n=34) as there is a case in whom vessel occlusion occurred after the wound had healed. At 12 months follow up the PP rate was (58%) (n=25), while LS rate was 62.7% (n=27). The overall mortality rate was 12.7% (n=7) out of them 5 cases died from myocardial infarction (one case died two days after the procedure, two cases at three months, one case at six months and another one at twelve months follow up), the other two cases died from stroke at six, and twelve months, table (4).

DISCUSSION

There is no doubt that endovascular management of infrapopliteal disease in critical limb ischemia is best accomplished by percutaneous transluminal angioplasty (PTA). There is more experience with PTA as a stand-alone therapy for infrapopliteal (IP) intervention than any other method. This is aided by low profile long (0.014-inch/0.018-inch) balloons (up to 200mm) .Also the low profiles crossing catheters aided in angioplasty.[5] Long-term clinical outcomes were acceptable after endovascular management for patients with CLI due to pure isolated infrapopliteal lesion. Risk stratification by baseline characteristics is useful in estimating long-term prognosis.[6] Successful endovascular recanalization of Infrapopliteal occlusions can be achieved with guidewire and support catheter techniques in most patients. In patients selected for an endovascular-first approach for IP occlusions in CLI, this strategy can be successfully implemented with favorable rates of limb salvage.[6] Tawfik and his colleagues in 2010 mentioned in their study that infrapopliteal angioplasty is an efficient method to salvage patients' limbs presented by CLI especially diabetic patients with multiple comorbidities.[7] Use of the Peripheral Cutting Balloon (Boston Scientific Corporation, Natick, MA) for infrapopliteal intervention has been described as an effective alternative for

infrapopliteal lesions with significant calcification and/or resistance to standard PTA as described by. Cardon et al.[8]. This was never needed in our study**.** The AngioSculpt Scoring Balloon (Angioscore, Inc., Fremont, CA) is a semicompliant balloon with a flexible nitinol scoring element that scores the target lesion with the intended effect of a more uniform and precise outcome. It is a 0.014-inch/0.018-inch over-the wire system with 5-French/6-French sheath compatibility[9]**.** CryoPlasty involves use of the PolarCathTM Peripheral Dilatation System (Boston Scientific Corporation)[10] None of the previously mentioned balloons (cutting balloon ,angiosculpt, or cryoplasty had shown benefits over regular low profile balloons.[8,9,10].

The high dissection rate in complicated infrapopliteal occlusive lesions and limited data regarding vessel patency (despite positive clinical results, i.e., wound healing, relief of rest pain, etc.) has incited many investigators to work on the benefit of the use of low-profile stents. Both bare-metal (BMS) and, drug-eluting (DES) and more recently, bioabsorbable variations are not yet available.[11]

Athrectomy devices like the Diamondback 360TM Orbital AtherectomySystem (Cardiovascular Systems, Inc., St. Paul, MN)[12], The CLiRPath Turbo Elite laser catheter (Spectranetics, Inc., Colorado Springs, CO) (excited dimer) laser [13].Jetstream TM Atherectomy Catheter (Pathway Medical Technologies, Inc., Kirkland, WA)[14]**.** The Simpson Coronary AtheroCath (Devices for Vascular Intervention, Redwood City, CA) The SilverHawk Plaque Excision System[15] all showed no superiority over angioplasty alone.

Kevin et al did a retrospective study including 418 tibial interventions over 2 years. Their series involved comparison between angioplasty alone, angioplasty with stenting, Excimer laser, SilverHawk directional atherectomy, and Diamoundback 360º orbital atherectomy. There was no significant differences with respect to early outcome (30-day) as regard to patency, complications, or major amputations in two comparative groups (the angioplasty alone group versus the atherectomy assisted group). They stated in their conclusion that the use of atherectomy offered no improvement in primary patency over PTA alone in either early or late outcomes in CLI patients who underwent IP interventions. Considering the additional cost and increased procedural time, these findings put into question the routine use of adjunctive atherectomy[16].

Concerning the use of drug eluting balloon , we didn't use in this study as it was not available yet at the time of this study. Listro et al 2013 in a randomized trial in Diabetic patients with CLI comparted drug –eluting balloon to angioplasty alone. They enrolled 132 patients with 158 infrapopliteal disease, there is binary restenosis in 27% in DEB vs & 74% in PTA alone. Target vessel occlusion occurred in 17% of DEB vs 55% in PTA. There was one major amputation in the PTA alone group. They also recommended the use of drug eluting balloons, as there is significant difference in outcome in favor of DEB over angioplasty alone.[17]

In our study, stent deployment was done in one patient in lower popliteal and posterior tibial with technical failure and ends by bellow knee amputation. The use of stents in tibials is not common. *Anew bifurcated stent* Nile Croco bifurcated stent for below-the-knee angioplasty in selected patients with CLI is associated with high rates of technical success, early and midterm patency, and clinical improvement. Limb salvage rates are acceptable for this technically highly challenging anatomy, yet further studies with larger patient populations are necessary to validate these results.[18]

In our study most of patient were offered ipsilateral femoral access as gives more pushability and easily control the wire, some *(lyden 2009)* advocates other access like retrograde contralateral femoral access ,antegrade popliteal access, or retrograde dorsalis pedis or posterior tibial artery access whenever the ipsilateral femoral access is not feasible.[19] The whole procedure is done under fluoroscopy. Some authors (*Ascher and his colleagues in 2005*) do the procedure duplex guided .It need expert duplex operator. In our study crossing of lesion is mostly intraluminal using 0.035 in (Terumo), or 0.018",or, 0.014" to drill through the lesion by a torque[20]. Lyden et al in 2009 prefers crossing using 0.035" as they found it most effective[19] .Gagan and his colleagues 2013 cross the stenosis or lesion using standard hydrophilic-tipped guidewire, such as PT Graphix or PT2 (Boston Scientific, Quincy, Mass), and a low-profile catheter support, such as Quick Cross

(Spectranetics, ColoradoSprings, Colo).If this fails , they use more supportive devices or wires like, Confianza or Miracle Bros 6 (Abbott Vascular,Abbott Park, Ill) or V18 Control (Boston Scientific). If fails they use chronic total occlusion (CTO) devices like Outback (Cordis, Bridgewater, NJ) and Crosser (Bard, Tempe, Ariz). However the use of CTO devices is limited to very few cases.[21] Wang et al. uses the 0.035 hydrophilic wire and shape it to form U with the aid of 4 FG catheter or use a branch of the collateral vessel in the proximal part of the occluded lesion. The guide wire is advanced to cross the occlusion. Then the 4 FG vertebral guiding catheter is advanced over the wire then the wire is withdrawn, angiography is done to ensure distal outflow. They then exchange the 0.035 wire with 0.014 wire to do angioplasty with low profile long balloons. In their study the subintimal angioplasty was done using 0.035" in cases of CTO.[22] Lyden et al. uses preformed J shape with floppy guide wire and limiting the amount of wire involved in forming large J shape (liable to make perforation). If perforation happens, the equipment is removed and a trial to obtain a new passage plane proximal to the occlusion and reattempting to cross the lesion from the top again.[19] Successful crossing aids in sealing the perforation. Transcollateral approach was done in one case where only distal runoff over the distal part of posterior tibial artery. The tibial occlusion couldn't be crossed, only by the transcollateral approach. Fusaro in 2009 described transcollateral recanalization of when standard retrograde recanalization is not possible .Fusaro described a CLI patient with patent anterior tibial artery (AT), tibioperoneal trunk (TPT) occlusion, and long proximal posterior tibial (PT) occlusion with distal reconstitution at the ankle. The approach was described using antegrade guide wire placement through the AT with retrograde recanalization of the occluded TPT via prominent collateral from the AT to the peroneal 3 cm from the TPT origin. After successful PTA, a similar transcollateral approach was used through collateral from the distal peroneal with retrograde recanalization of the long PT occlusion.[23]

In this study one case or retrograde dorsalis pedis approach was tried however failed percutaneously and arterial cut down was done to complete the procedure; SAFARI technique (Subintimal arterial flossing antegrade- retrograde intervention) technique with either retrograde dorsalis pedis or posterior tibial artery access, described by *Spinosa et al*.

CONCLUSION

Angioplasty alone with the development of low profile wires, and long low profile alone can be the sole treatment of infrapopliteal disease and limb salvage especially with comorbid patient and short life expectancy. The endovascular therapy has less patient burden with short hospital stay and return to normal life .

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