




Surgical technique for placement of the automated low flow ascites pump (Alfapump)

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Abstract

Approximately 10% of patients with ascites associated with cirrhosis fail to respond to dietary rules and diuretic treatment and therefore present with refractory ascites. In order to avoid iterative large-volume paracentesis in patients with contraindication to TIPS, the automated low flow ascites pump system (Alfapump) was developed to pump ascites from the peritoneal cavity into the urinary bladder, where it is eliminated spontaneously by normal micturition. This manuscript reports the surgical technique for placement of the Alfapump.

Keywords Refractory ascite · Automated low flow ascites pump system

Introduction

Approximately 10% of patients with ascites associated with cirrhosis fail to respond to dietary rules and diuretic treatment and therefore present with refractory ascites (RA).

The only definitive treatment for RA is liver Transplantation, with a few exceptions as for instance successful treatment of hepatitis C or alcohol abstinence in case of alcohol related liver decompensation, but for patients on the

liver transplant waiting list or with contraindication to transplantation, RA is commonly managed by iterative large-volume paracentesis (LVP) with albumin supplementation. LVP is associated with potential complications and requires numerous visits at hospital (LVP are performed in an outpatient or an inpatient setting according to local protocols) markedly reducing quality of life in these patients. In selected patients, placement of a transjugular intrahepatic portosystemic shunt (TIPS) may be a valid alternative. However, TIPS

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placement comes at a price (mainly represented by encephalopathy and shunt thrombosis) and harbours several contraindications [1].

The automated low flow ascites pump system (Alfapump) was developed to pump ascites from the peritoneal cavity into the urinary bladder, where it is eliminated spontaneously by normal micturition. The Alfapump is programmable and can thus be adapted to an individual's need, depending on the amount of ascites production. The safety of the device was highlighted in 2013 in a prospective study [2]. Recently, a multicentre randomized controlled trial (RCT) showed the efficacy of the Alfapump in reducing the need for paracentesis and improving the health-related quality of life in cirrhotic patients with RA [3]. In this study, there were significantly more adverse events in the Alfapump group, including acute kidney injury in the immediate postoperative period (≤ 7 days), as well as re-interventions for pump-related issues. In most patients however, these complications were easily resolved. Concerning re-interventions in the RCT, the main reasons were infection of the pump pocket and wound dehiscence. A RCT is currently ongoing in France evaluating the medico-economical impact of the care of RA by implantation of the Alfapump device in cirrhotic patients (NCT 03506893 (Medical-economic Evaluation of the Care of Refractory Ascites by Implantation of Alfapump® Device in Cirrhotic Patients (ARIAPUMP))).

Taking into consideration the medical context of these patients with end-stage liver disease and the implantation costs of the Alfapump, it is essential that the implant procedure is highly standardized and optimized, hereby maximally reducing the need for re-interventions due to technical issues [4, 5, 6]. We present a detailed surgical technique for implantation of the Alfapump, based on the experience of an expert group, in order to avoid common pitfalls during the procedure. All the steps are illustrated by schematic figures and intra-operative photographs.

Preoperative course

Patient selection is performed by the hepatologist and an experienced visceral surgeon, as proposed in the NCT 03506893, preferably a surgeon with experience in liver and transplant surgery. Combining the experience of both specialists provides the optimal setting to select the best suitable patients for surgery.

Local skin infections, particularly thrush, should be treated before surgery in order to avoid wound complications.

There should be a low threshold to send men to a urologist in order to treat urinary tract obstruction before pump implantation. All patients receive detailed information about the pre-operative setting, the actual surgery itself as well as the post-operative course and the management of the pump. The

patient should also be seen timely by the anaesthetist and, if indicated, by a dietician. Nursing staff on the wards need to be instructed about the pump to ensure an optimal postoperative course.

Patients are usually admitted to a hospital the day before the intervention to benefit from a paracentesis. Care is taken to leave a bit of fluid in the abdominal cavity in order to facilitate surgery. It is recommended to start antibiotic prophylaxis the day before the implant or at the time of surgery according to the hospital guidelines. Antibiotic prescription should be continued for the entire time the pump is in situ.

Surgical technique

Location of skin incisions (Fig. 1) (Photo 1)

Correct choice of the pump pocket location is crucial to avoid complications related to a sub-optimal placement. There should be at least 10 cm between the insertion point of the peritoneal catheter and the incision for the pump pocket located in the right mid-upper quadrant. This allows for a reduction of the rate of ascites leaks/ascites accumulation in the pump pocket. The incision should be several centimetres below the costal margin to allow the patient to bend over without being limited by the actual pump (Fig. 1) (Photo 1).

Bladder catheter placement (Fig. 2) (Photo 2)

The first step is to fill the bladder with 300–500 mL of sterile saline with methylene blue. Once the bladder is sufficiently filled such that it is palpable above the symphysis, a 1–2-cm skin incision is created midline above the symphysis pubis. In

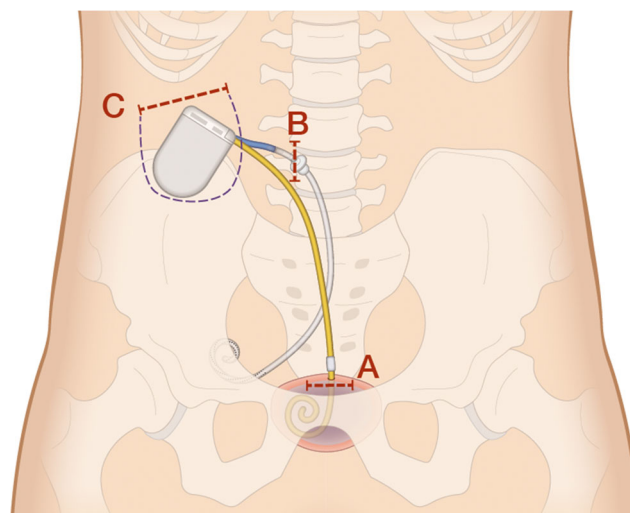
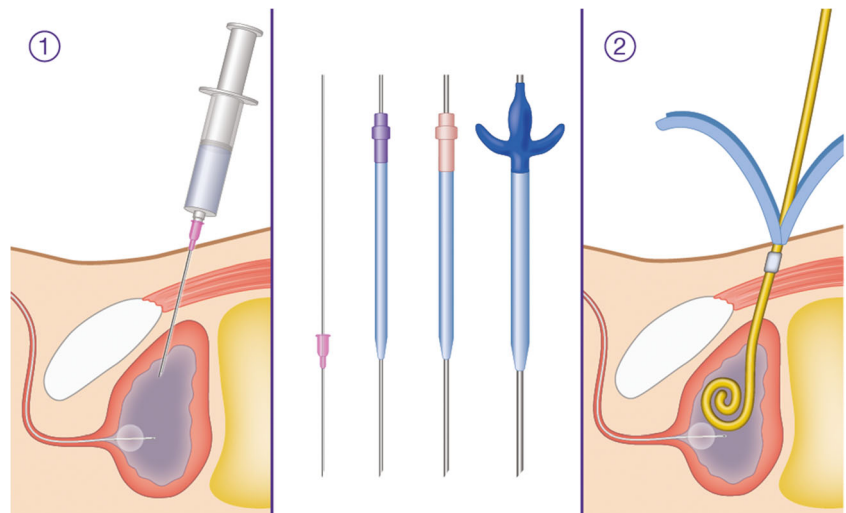


Fig. 1 Placement of skin incisions and planning of the pump position. Red dotted lines: incisions for (A) the bladder catheter, (B) the peritoneal catheter and (C) the pump pocket. Purple dotted line: pump pocket

Fig. 2 Bladder catheter placement. (1) Punction of the bladder. (2) Insertion of the bladder catheter and removal of the peel-away introducer



obese patients where palpation of the bladder may be difficult, it is strongly advised to make use of an intraoperative ultrasound to help with insertion of the bladder catheter of the pump (Photo 2.1). The abdomen should be as flat as possible (no large volumes of ascites) to avoid the chance of peritoneal overlap at the bladder puncture point. The outside of the catheter and the insertion stylet are lubricated. The bladder is stabbed with the introducer needle while aspirating with a syringe in order to check correct positioning of the needle (methylene blue coloured saline in the bladder) (Photo 2.2).

The syringe is removed from the introducer needle and the guidewire inserted into the bladder through the needle. The needle is then removed while leaving the guidewire in place.

10F and 14F dilators are used to increase the opening, taking care to always immobilize the guidewire. In a final step, the 18F peel-away dilator is introduced, the dilator and the guidewire removed. The yellow bladder catheter is inserted into the peel-away introducer. Start to split the introducer when the cuff is at its top and slide the catheter down over the stylet to position the cuff at the fascia level. First, the peel-away introducer is removed and then the rod while holding in place the bladder catheter (Photo 2.3). After the insertion stylet is removed, blue fluid should flow spontaneously from the catheter in order to confirm again correct positioning within the bladder. Once correct placement is confirmed, the Foley catheter can be opened and the bladder drained. The Dacron cuff is fixed in place with a non-resorbable suture (Fig 2).

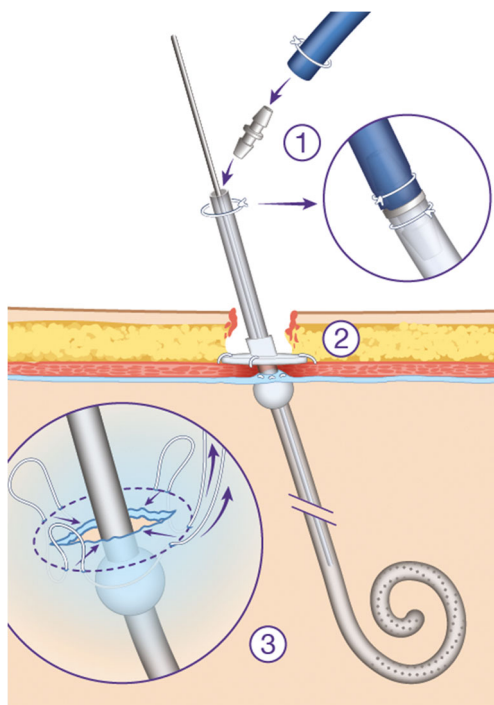


Fig. 3 Peritoneal catheter placement. (1) Adaptation of the blue catheter to the peritoneal catheter. (2) Placement of the Dacron disc subcutaneously and the silicon ball in the abdominal cavity. (3) Closure of the purse string between the Dacron disc and the silicon ball

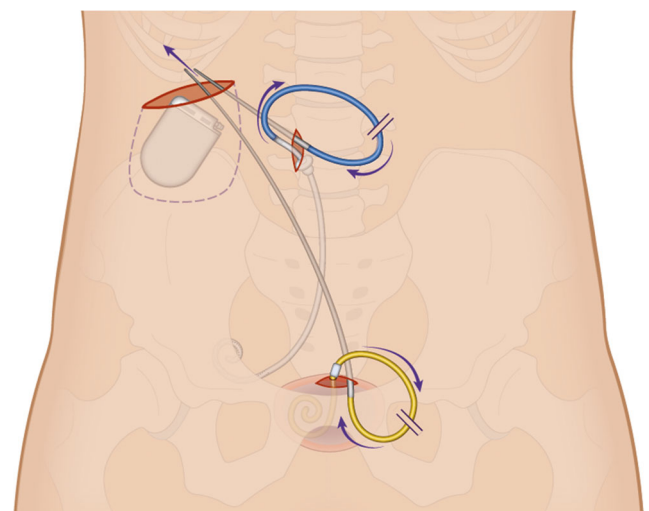
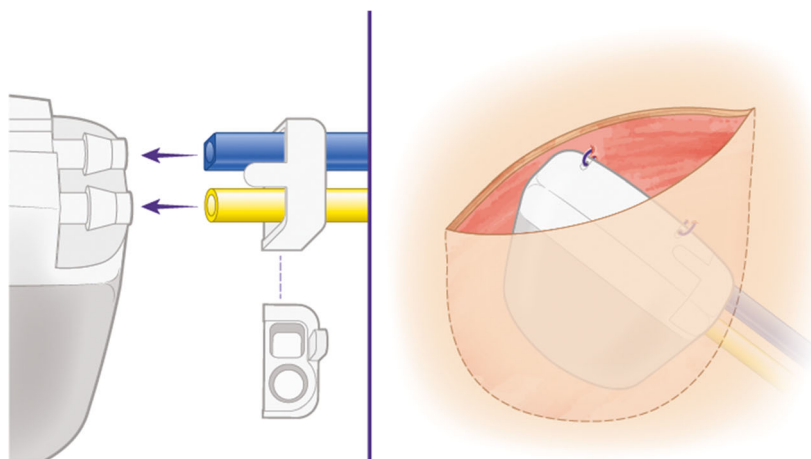


Fig. 4 Pump pocket creation and catheter tunnelling

Fig. 5 Catheter attachment to the pump



Peritoneal catheter placement (Fig. 3) (Photo 3)

The first step is to adapt the blue catheter to the peritoneal catheter using the white plastic fitting. This step may be carried out by the scrub nurse (Fig. 3 (1)). A 2–3-cm skin incision is created lateral to the midline and above the umbilicus, dissecting the rectus muscle, identifying both anterior and posterior sheaths. Alternatively, a midline incision may also be carried out, again above the umbilicus. A purse string suture using non-resorbable material is used to securely close the abdominal incision once the tip of the blue peritoneal catheter has been placed in the direction of the right iliac fossa.

When the catheter is inserted as deep as possible, remove the stylet until the Dacron cuff is lying subcutaneously and the

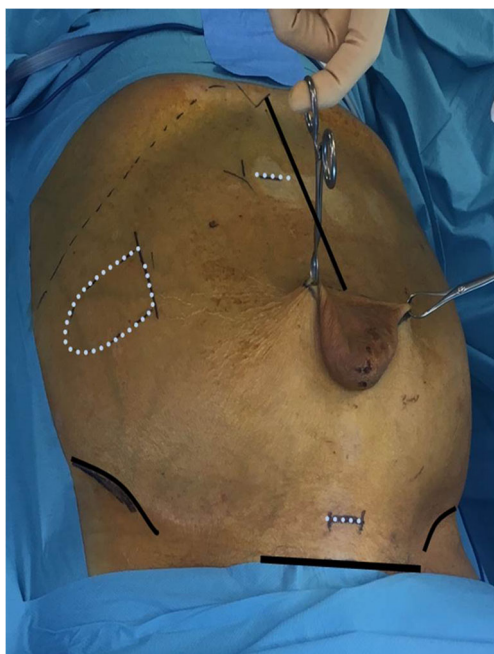
purse string sutures sit between the silicone ball and the Dacron disc (Fig. 3 (2)). The pigtail portion of the peritoneal catheter should be in the Douglas area (in the rectouterine pouch in females and the rectovesical pouch in males). Aspirate some ascites via the peritoneal catheter in order to check the unobstructed flow. At this point, excessive ascites can still be drained via the peritoneal catheter in order to minimize the risk of postoperative ascitic fluid leakage through the surgical incisions. Albumin substitution should be carried out according to international guidelines (such as proposed by EASL guidelines), according to the volume of ascites removed. Care should be taken to not completely drain the ascites as some is needed for testing the alfapump during placement. Check correct placement of 45° cuff. Tie off the purse string sutures between the Dacron disc and silicone ball (Fig. 3 (3)) (Photo 3).

Pump pocket creation and catheter tunnelling (Fig. 4) (Photo 4)

A 4–5-cm skin incision is made for the pump pocket, as previously planned, using the actual Alfapump as a template. The pump should ideally lie directly on the fascia, with the skin incision being sufficiently far away from the corners of the device. The yellow bladder and blue peritoneal catheters are tunnelled subcutaneously into the pump pocket using the tunnelling rod (Fig 4) (Photo 4.1, 4.2).

Catheter attachment to the pump (Fig. 5) (Photo 5)

The two catheters should be shortened so that they are neither too short (tension on the catheters) nor too loose (potential “kinking”) (Fig. 5). Each catheter can be lengthened with the provided catheter extension connector if necessary. The catheter locking cap has two holes: the yellow bladder catheter is inserted through round hole and the blue peritoneal catheter through square hole. The catheters should be attached to the



Photograph 1 Placement of the skin incisions



Photograph 2.1 Punction of the bladder under ultrasound control

Alfapump nipples very carefully, avoiding the use of any sharp instruments to help (risk of catheter damage) (Photo 5). Testing of the Alfapump by an engineer of the Alfapump team is mandatory before securely locking the cap into place on the Alfapump. Once the testing has been successful, the pump may be fixed in



Photograph 2.2 Syngene blue test



Photograph 2.3 Insertion of the bladder catheter and removal of the peel-away introducer.

place using one or two sutures from the pump (designated fixation holes) to the fascia.

Closing the surgical incisions (Photo 6)

Perform a multi-layer closure of each skin incision: peritoneal catheter implantation site, bladder catheter implantation



Photograph 3 Peritoneal catheter placement. Subcutaneous placement of the Dacron disc And the silicon ball

site, pump pocket site. The skin should be closed with continuous suture in order to avoid skin tension and leak of ascites. We recommend not to use absorbable suture for this step (Photo 6).

Postoperative course

Patients are usually monitored in hospital for several days postoperative. Postoperative management includes early oral feeding and drinking and early removal of the bladder catheter as well as standard thrombosis prophylaxis. The patient is treated by antibiotherapy (according to each team's habits: neither an intravenous broad spectrum antibiotic cover 48 h post operatively (amoxicillin-clavulanic acid 1 g three times a day), then switched by Norfloxacin (400 mg a day) neither Norfloxacin (400 mg a day)). The Foley catheter should be left in situ for the next 12–24 h but should be removed once the patient is mobilized.

Special attention is taken to weight and urine output. Sutures should not be removed too early to avoid secondary wound dehiscence, generally about 3 weeks after surgery.

Expert tips and tricks

- During the whole procedure, the catheters should be handled cautiously without pinching them with surgical instruments in order to avoid damaging them.
- Previous abdominal surgery does not represent an absolute contraindication, but patients with severe abdominal



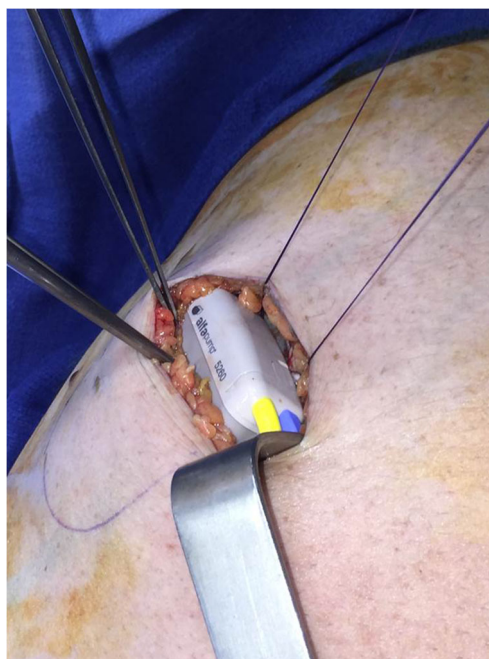
Photographs 4.1 Urinary catheter tunnelling



Photographs 4.2 Peritoneal catheter tunnelling

adhesions may develop loculated ascites, requiring a diagnostic laparoscopy prior to the Alfacapump implantation.

- Combining the repair of a small umbilical hernia with the pump placement is possible [7, 8], whereas an inguinal hernia repair should be delayed after the decrease of ascites as there is a good chance that it becomes smaller and asymptomatic once the tense ascites is no longer an issue.



Photograph 5 Catheter attachment at the level of the pump pocket incision



Photograph 6 Final aspect at the end of the procedure (patient with concomitant umbilical hernia repair)

- The pump position should be chosen wisely. Positioning of the pump on the left side is possible and may be preferred by certain surgeons. In case of an umbilical hernia, the pump should be placed far enough away in order to allow the aponevrotic closure at the end of the procedure.
- In the setting of very little subcutaneous fat, the pump may be placed in the submuscular space to avoid pump erosion through the skin
- In case of an emaciated patient, the distance between the position where the catheter enters the peritoneal cavity and the pump may be too short. In order to avoid the plication of the catheter, the peritoneal catheter can be placed through the contralateral rectus muscle.
- In case of an obese patient, we recommend to draw the localisation of the skin incisions in a standing upright patient in order to prevent the shifting of the skin incisions due to the mobility of the excess abdominal wall fat. This excess of fat should be folded upwards during the urinary catheter insertion, to allow a direct path to the bladder, and the bladder must necessarily be punctured under ultra sound control. The catheter tunelisation should be as deep as possible in the abdominal wall to avoid excess tension due to the abdominal wall fat movements on the Alfapump components. Concerning the peritoneal catheter, it should be inserted dissecting the anterior and posterior aponeurosis of the right muscle one by one, and using suture strings on each aponeurosis in order to clearly identify and easily close them around the catheter [9].
- MRI should be avoided for patients with Alfapump in place as the pump is not MRI compatible.

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Compliance with ethical standards

Conflict of interest Pr Sauter and Dr. Banz received speaker honorarium from Sequana Medical AG.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Abbreviations RA, refractory ascites; LVP, large volume paracentesis; TIPS, transjugular intrahepatic portosystemic shunt; RCT, randomized controlled trial

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