Temporary extracorporeal femoro-femoral crossover bypass to treat critical limb ischemia due to occlusive femoral transaortic microaxial left ventricular assist device – A novel technique and case series

Sabine Richarz
University Hospital of Basel and University of Basel https://orcid.org/0000-0002-0986-656X
Martin Siegemund
University Hospital Basel, Department of Intensive Care Medicine and University of Basel, Department of Clinical Research
Rosalinda d'Amico
University Hospital of Basel and University of Basel
Bernadette Bachofen
University Hospital of Basel and University of Basel
Thomas Döbele
Universitatsspital Basel
Lorenz Gürke
University Hospital of Basel and University of Basel
Edin Mujagic (edin.mujagic@usb.ch)
https://orcid.org/0000-0003-0479-1682

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Abstract

Background The Impella transaortic microaxial left ventricular assist device (MLVAD) is a temporary circulatory support (TCS). It's percutaneous insertion through the common femoral artery (CFA) bears the risk of severe ipsilateral limb ischemia. As long as the MLVAD is required for cardio - circulatory support, treatment options are limited. To approach this problem, we developed a temporary extracorporeal femoral - femoral crossover bypass to restore and maintain perfusion of the affected leg.

The aim of this report is to introduce our novel technique and present results of a case series of accordingly treated patients.

Methods From October 2018, we treated all patients with severe limb ischemia due to the MLAVD with a femoral - femoral crossover bypass and collected their data prospectively. For comparison, all consecutive patients undergoing placement of the MLAVD between January 2011 and July 2019 were identified retrospectively.

The primary outcome of the study is the feasibility and safety of our percutaneously established extracorporeal femoral - femoral crossover bypass. As secondary endpoints, we report overall 30 - day mortality and limb salvage rates.

Results Between January 2011 and July 2019, 25 of 245 (10.3%) patients developed a severe limb ischemia of the ipsilateral leg following the MLVAD placement.

Until October 2018, 20 patients were treated conventionally (C - cohort) and since October 2018, five (consecutive) patients have been treated by an extracorporeal femoral - femoral cross over bypass (BP - Cohort).

Following the BP - procedure, an immediate improvement of the perfusion of the affected limb was seen clinically and on Duplex ultrasound in all patients. 20% of the BP - cohort needed additional surgical salvage procedures compared to 25% of the C - Cohort. Limb salvage was documented in 100% of our patients and 30 days mortality was 60% in both groups.

Conclusion This is the first case series reporting on a novel technique of limb salvage in patients with severe limb ischemia due to an MLVAD. We demonstrated that the percutaneous creation of an extracorporeal crossover bypass is feasible, safe and effective and should therefore be promoted.

Background

The Impella transaortic microaxial left ventricular assist device (MLVAD) is a temporary circulatory support (TCS) device which maintains cardiac output in severely hemodynamically compromised patients. By unloading the left ventricle and reducing the ventricular size and wall tension, the myocardial oxygen demand decreases while cardiac output and systemic and coronary perfusion increase.(1–3)

The device is most commonly applied to provide cardiac support in patients undergoing high risk percutaneous coronary intervention or suffering from cardiogenic shock.(3)

The construction includes an axial pump, which aspirates blood from the left ventricle through an inlet cage and expels it into the ascending aorta. The system is based on a 9 French catheter.(3)

Depending on the size of the patient and the hemodynamic situation, different pumps are available for implantation. Percutaneous peripheral insertion through the common femoral artery (CFA) is a standard procedure for the Impella 2.5 and CP pumps while axillary artery access by surgical cutdown is preferred for the Impella 5.0 pump.

The most common complications associated with insertion through the CFA include access site bleeding and infection. (3) While ongoing bleeding and hematoma formation are reported in up to 17.5% of cases, the risk of limb ischemia due to an occlusion of the iliac or femoral arteries by the device has been reported to occur in less than 4% of patients.(4–7) However, if it occurs, severe ischemia of the leg distal to the pump represents a potentially limb- or even life-threatening condition when left untreated, especially in patients suffering from cardio-circulatory failure. Treatment options for severe limb ischemia in the presence of an MLVAD are limited as long as the cardiac situation does not allow weaning of the pump. Unlike the much thicker ECMO cannulas that by default include a sidebranch that can be connected to a sheath in the superficial femoral artery (SFA) for distal perfusion(8) the Impella system – due to its low profile – does not offer a lumen with a sidebranch. Surgically, the femoral bifurcation is hardly accessible whithout removing the pump.

Therefore, we developed a novel approach in order to temporarily treat critical limb ischemia during the time that an occlusive MLVAD has to remain in place.

The aim of this report is to describe the technique and to present a case series of patients treated with it. Furthermore, patients that had critical limb ischemia due to an occlusive Impella pump but were not treated using the novel technique are described in comparison. To note that during the preparation of this manuscript, Geyer et al published a case report describing a similar technique.(9)

Methods

Data collection and study population

Approval from the local ethics committee (Ethikkomission Nordwestschweiz, EKNZ) was obtained for this study (identifier number 2019 – 01438). Informed consent was not obtained for this study because patients reported here are tipically not in a state where informed consent can be obtained and furthermore, a relevant proportion of the patients reported here did not survive to consent retrospectively. For these reasons, the requirement to obtain informed consent was waived for this study by the above ethics committee. A prospective database of all patients treated using the novel technique was maintained starting in October 2018 when the first patient was treated accordingly. Furthermore, all

consecutive patients undergoing placement of an Impella pump at Basel University Hospital between January 2011 and July 2019 were identified retrospectively using the intensive care unit electronic chart.

For those patients who experienced limb ischemia after Impella placement, data on age, gender, BMI and diabetes, underlying cardiac condition, duration of Impella pump in place, limb complications, limb salvage procedure, need for additional surgical procedure on the affected limb (e.g. fasciotomy) and overall 30 day mortality were recorded from our electronic patient documentation program (ISMed).

Follow up was performed using all electronic hospital charts. Follow up for this report was completed on December 31st 2019.

Due to the typically unstable condition of the patients reported here, critical limb ischemia was defined combining clinical symptoms (cold, pale and mottled legs, no palpable pulse) and doppler and/or Duplex ultrasound findings (no doppler signals, reduced or abscent flow distal to the CFA).

Technique *(Image 1)*

Our technique essentially represents the percutaneous creation of a temporary external femoro-femoral crossover-bypass. It is tipically installed bedside in the intensive care unit.

For inflow, an ultrasound guided retrograde puncture of the contralateral common femoral artery is performed and a 7 Fr sheath (free life CruraSave→ Femoral Perfusion Set 07Fr) is inserted after the iliofemoral axis is deemed suitable clinically and sonographically. A second identical 7 Fr sheath is inserted, again under ultrasonic vision, antegradely into the SFA or popliteal artery of the ischemic leg distal to the Impella pump. These sheaths have originally been designed for peripheral perfusion via an ECMO sidebranch. In order to prevent dislocation of the sheaths, both are fixed with single stitches through the skin. Both sheaths are connected using a specific adapter (Braun Combifix Adapter).

The patency of the bypass is assessed on an hourly basis by both clinical assessment of the leg distal to the sheath on the one hand and by doppler ultrasound of the bypass and the distal leg on the other hand. In case of thrombotic occlusion of the system, the two sheaths are disconnected, flushed, rinsed with heparinized saline and then reconnected. To prevent a thrombotic occlusion, a heparine infusion (prophylactic dosage) is connected via an additional three-way stopcock.

We keep the system in place as long as the cardio-circulatory support by the Impella device is needed. Once the Impella support is not needed anymore, patients are transferred to the operating room. The Impella device is removed through a cutdown to the common femoral artery. The puncture site is either closed with a transverse arterial suture or the femoral bifurcation is reconstructed as needed. The contralateral donor sheath is removed and the puncture site closed using a vascular closure device (Angio - Seal ® VIP Vascular Closure Device, Terumo). The ipsilateral puncture site in the SFA or popliteal artery is closed either by simple compression, by a closure device, by prolonged internal occlusion using a PTA balloon (under fluoroscopy) or through cutdown and suture, depending on the quality of the receiving artery, the coagulation status and the need of concomitant endovascular interventions.

Outcome

The primary outcome of this study is the feasibily and safety of a percutaneously established extracorporeal femoro–femoral crossover bypass. As secondary endpoints, we report overall 30 day mortality and limb salvage rates.

Statistical analysis

Continuous variables are presented as median +/- interquartile range (IQR) and categorical variables are shown as counts with percentages. Data collection was performed in Excel (2016 MSO). Due to the low numbers of patients, all analyses are purely descriptive. Patients with critical limb ischemia due to an Impella pump are reported stratified by treatment (conventional treatment modalities before October 2018, cohort C (n = 20) and novel treatment using the external crossover bypass from October 2018 onwards, cohort BP (n = 5)).

Results

Between January 2011 and July 2019, 245 patients had an Impella pump placed, 2 through a subclavian and 242 through a femoral approach. In one patient the IP was placed via the ascending aorta, whilst undergoing cardiac surgery. Of all patients with femoral Impella pumps, 25 (10.3%) had an ischemic complication on the ipsilateral extremity.

Until October 2018, 20 patients were treated by conventional salvage procedures (e.g. thrombectomy or switch of the Impella pump to the contralateral leg). Since October 2018, five (consecutive) patients have been treated with a femoral – femoral crossover bypass (BP - cohort) for their severe lower limb ischemia. All procedures were performed bedside in the intensive care unit. There were no periprocedural complications such as bleeding, dissection or occlusion.

Demographic data *(*Table 1*)*

Table 1
Demographics of patients with ischemic limb complications due to the MLVAD between January 2011 and December 2019 (n = 25)

	C Cohort (n = 20)	BP Cohort (n = 5)
Age in years, median (IQR)	59 (56 - 67)	62 (57–80)
Gender male, n (%)	18 (75)	3 (60)
BMI kg/m^2, median (IQR)	26 (21.3–29.5)	25 (24–28)
Diabetes mellitus, n (%)	7 (35)	4 (80)
Underlying Cardiac Disease, n (%)	7 (35)	2 (40)
STEMI	5 (25)	0
NSTEMI	1 (5)	0
Elective Intervention	7 (35)	3 (60)
Cardiac Decompensation		
Overall days of MLVAD in place, median (IQR)	2.5 (1–4)	5 (4–9)
Days betweenMLVAD placement and revascularization procedure	-	0 (0–4.5)
> Cross Over Bypass, median (IQR)	1 (0–3)	-
> Salvage Procedure, median (IQR)		
Overall days of Cross Over Bypass, median (IQR)	-	5 (2.5–6)
Length of stay, median (IQR)	8 (3.3–19.8)	14 (6.5–44.5)

The median age was 59 years in the C - cohort and 62 years in the BP - cohort. 84% of the entire cohort were male and 44% suffered from diabetes mellitus.

The median duration between the placement of the Impella device and the salvage procedure was 1 (0–3) days in the C - cohort compared to 0 (0–4.5) days in the BP – cohort.

Procedural Characteristics *(*Table 2*)*

Table 2
Procedural Characteristics and Outcomes (n = 25)

	C Cohort (n = 20)	BP Cohort (n = 5)
Salvage Procedure, n (%)	-	5 (100)
Femoral – Femoral Cross Over Bypass	5 (25)	-
Surgical (Removal of device/ Thrombectomy/ TEA/ Stenting)	3 (15)	-
Switch of Impella to contralateral leg/ arm	3 (15)	-
Weaning/ Removal	1 (5)	-
Distal perfusion through add. ECMO	2 (10)	-
Impella pump already removed	4 (20)	-
Palliative	2 (10)	-
Spontaneous regression		
Additional Procedure, n (%)	5 (25)	1 (20)
Fasciotomy	1 (5)	1 (20)
additional Mash graft / Flap	0	0
Major amputation	14 (70)	4 (80)
None		
Limb salvage, n (%)	20 (100)	5 (100)
Death during hospitalization, n (%)	12 (60)	3 (60)
30 days mortality, n (%)	12 (60)	3 (60)

In the conventionally treated cohort, 25% of patients underwent surgical revision, including thrombectomy, endarterectomy and endovascular procedures. The device was removed and reinserted in the contralateral CFA or the subclavian artery in 15%. 15% of the patients were successfully weaned and in a further 20%, treatment was changed to palliative care. In one patient distal limb perfusion was provided through the sidebranch of an additional contralateral ECMO.

All 5 patients of the BP – cohort had severe limb ischemia and were treated by an external femoral – femoral crossover bypass as described above. The extracorporeal crossover bypasses remained in place during a median of 5 days. An immediate improvement of the perfusion of the affected limb was seen clinically and on Duplex ultrasound in all 5 patients.

In the C – Cohort 25% of patients needed additional surgical interventions for limb salvage. In the BP cohort, 1 patient (20%) needed an extensive necrosectomy of the anterior and posterior compartments of

his lower leg followed by reconstructive surgery.

Outcomes *(*Table 2*)*

Limb salvage was documented in 100% of our patients.

In both cohorts, 60% of patients died within the first 30 days after admission. In our BP- cohort all three patients died from cardiogenic shock following periniterventional myocardial infarction, posterior STEMI and decompensated coronary artery disease.

The two surviving patients were discharged from our hospital 2 and 59 days after removal of the MLVAD and the CB and were still alive at the end of FU.

Discussion

To our knowledge, this is the first case series reporting on a novel technique of limb salvage in patients with severe limb ischemia due the Impella transaortic valve pump. As mentioned above, one case report was recently published describing a similar technique, however, there was no follow-up due to the death of the patient on day 1 and furthermore, there are certain technical differences between the technique described in the case report and ours. In detail, we believe that it is essential to use the 7F sheaths described above that were designed specifically as perfusion sheaths for ECMO side branches. First, the sheath itself is reinforced in order to prevent kinking which would in turn negatively impact the perfusion of the recipient leg and potentially cause an occlusion of the bypass. Second, the lumen of the tube is bigger than that of a standard 6F sheath which helps to appropriately perfuse the affected limb and to keep the bypass patent during several days when needed. Furthermore, connecting an infusion with heparinized saline directly to the bypass might help keeping the bypass patent.

This study demonstrates that the percutaneous creation of an extracorporeal crossover bypass is feasible, safe and effective. Most importantly, it can be installed bedside which benefits patients who are hemodynamically unstable and whose transfer to the operating room poses potential risks. The equipment used to install the bypass is broadly available and the procedure can usually be performed in 15 to 30 minutes. We have not experienced any periprocedural complications and an immediate recovery of the affected limbs was observed in all our patients. Therefore, we feel that the technique, if needed, represents an easy, quick, cheap and effective way of bridging the time until an MLVAD can be weaned and removed. This is even more important as patients undergoing elective percutaneous coronary interventions or suffering from severe cardiogenic shock are becoming older and frailer and subsequently the need for temporary ciruculatory support increases. Stretch et al reported on an increase by 1,511% of percutaneous mechanical circulatory support between 2007 and 2011.(10) Furthermore, Mahek et al showed an incremental overall trend for use of the Impella device and the Tandem Heart in patients between 81–99 years suffering from cardiogenic shock.(11) Considering these data, the procedure described in this paper might become more widely used in the future. This is also supported by the fact that in our cohort, over 10% of all patients with a femorally inserted Impella pump had ischemia of the

ipsilateral leg. This is significantly more than the less than 4% of MLVAD-induced limb ischemia rate published so far.

However, it is essential that a severe limb ischemia due to an Impella pump is realized by the intensive care staff in order to prevent delays in treatment. Even with a 10% limb ischemia rate, it is still not a very common complication and hence, people might not be aware of it. In our series, one of the crossover bypasses was installed too late and ischemia had already progressed to necrosis. Although the limb was saved, a relevant part of the calf muscles had to be resected. This could have been prevented by an increased awareness. With this very simple technique at our disposal, we believe that signs for peripheral ischemia should be actively looked for and a bypass installed rather too often than too late. Although we do currently not have the data to support this assumption, it is possible that – by preventing the emergence of a critical limb ischemia in the first place – the prophylactic installation of a crossover bypass in patients deemed at risk of experiencing ischemia in the presence of an Impella pump could improve the overall course of these patients.

In our series, in-hospital mortality was sixty percent of patients who received a crossover bypass. While this is high, those patients treated with more conventional measures had a 60% mortality as well. In our opinion, these high mortality rates indicate the severity of the general situation of these patients and we do not have any reason to believe that installing an external crossover bypass contributes to mortality.We are aware that this study has weaknesses. Most importantly, it is essentially a series of only 5 patients who were treated with the technique described here. Also, due to the low numbers, the comparison to the “control” group is purely descriptive and hence, outcomes cannot be quantitatively compared between the two groups. This precludes any general conclusion in terms of limb-associated outcomes, even more so because some patients died shortly after creation of the bypasses with the Impella pump still in place. However, we believe that in terms of a proof of principle, this study is valid.

Conclusion

In conclusion, percutaneous installation of an extracorporeal crossover bypass in patients with severe limb ischemia due to occlusion of the common femoral and external iliac arteries by the Impella device is the only safe, straightforward and effective bedside procedure and should therefore be promoted.

Declarations

Ethics approval and consent to participate

Approval from the local ethics committee (Ethikkomission Nordwestschweiz, EKNZ) was obtained for this study (identifier number 2019 – 01438). Informed consent to participate was not obtained for this study because patients reported here are tipically not in a state where informed consent can be obtained and furthermore, a relevant proportion of the patients reported here did not survive to consent retrospectively.

Consent for publication

Consent for publication was also not obtained for this study because patients reported here were not in a state to give informed consent for publication. However, the image used in Fig. 1 does not include any personal information that can be related to a patient and was only taken to demonstrate the installation and the required devices of the external crossover bypass.

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Competing interests

The authors declare that they have no competing interests.

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Figures

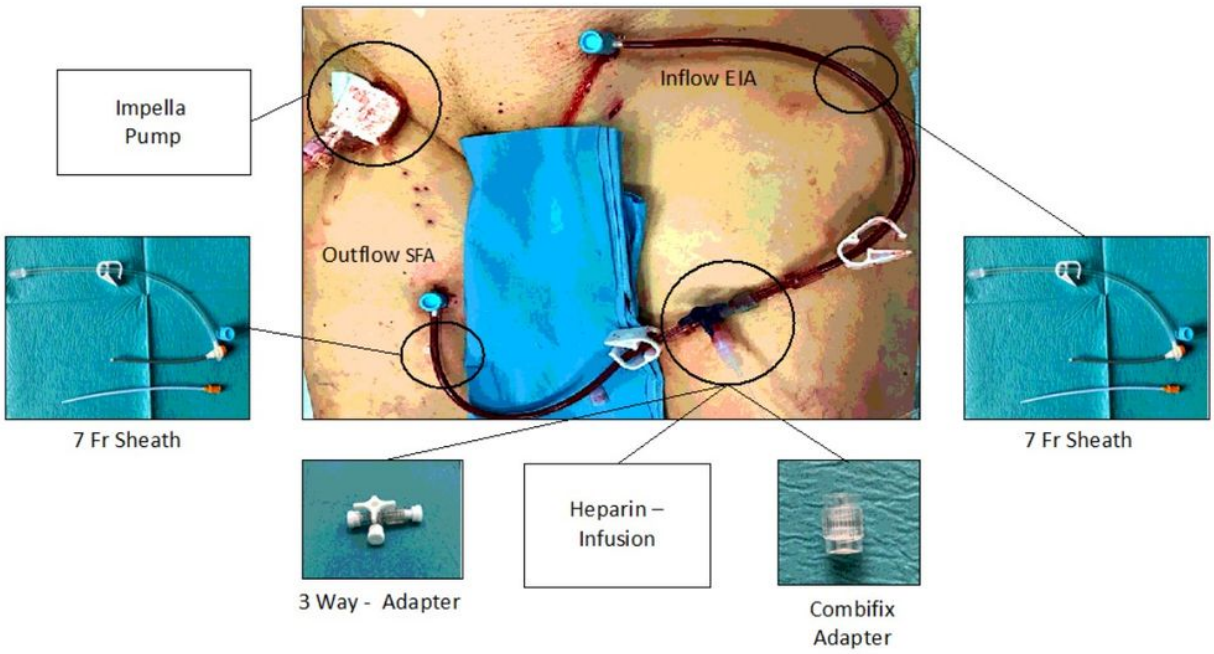

Figure 1

Impella Pump placed in the right CFA and installed external femoral - femoral Crossover Bypass (left - right)

Supplementary Files

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- Graphicalabstractimage.png