

Intra-aortic Balloon Pumping

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Valorization

In this thesis we have studied several aspects of intra-aortic counterpulsation balloon pump (IABP) therapy. Although its initial use dates back to the 1950s, no real changes regarding the design of this mechanical hemodynamic support modality have occurred. Furthermore although IABP is generally considered as one of the least invasive mechanical hemodynamic support modalities, no standardized treatment protocols are used in daily practice. Finally, in the current era of increased demand for mechanical hemodynamic support modalities, current cardio(surgical) guidelines advocate against the routine use of this least invasive modality following the highly debated 'SHOCK-II trial' and advise the use of newer more invasive mechanical support devices. These more invasive mechanical cardiac support devices are less easily inserted and come with new complications. Therefore; the IABP and its use might require optimization, in order to fulfill its full potential.

IABP Design Optimization

As studied in **Chapter 2**, IABP therapy, with a normal size catheter, leads to a reduction in early diastolic flows, which is more profound in the superior mesenteric artery (SMA). In late diastole increases in flow occur in the SMA as well as in the renal flows as observed using arterial wave pattern analysis.

Furthermore, as seen in **Chapter 4 to 7**, shorter IABP-catheters are associated with improved visceral flows, whilst providing similar hemodynamic benefits when compared with conventionally used longer IABP-catheters.

These findings could raise interest from both device manufacturers as well as clinical caregivers, since visceral ischemia leads to irreversible organ damage in a critically ill patient population. Next to the severity of this complication, visceral ischemia forms a diagnostic challenge, requiring a laparotomy, which is yet another intervention for these patients with little to no reserve. Thus, if no surgery is performed, patients could die from visceral ischemia, but when a laparotomy is performed and no visceral ischemia is objectivated, patients can deteriorate even further.

Different catheter designs with multi-chambered IABP-catheters, different or adjustable catheter lengths, require in-vitro testing using a closed circuit of flexible tubes with close-to-human aortic dimensions and compliance properties. An eventual optimal design, subsequently requires in vivo-testing.

IABP therapy; towards a more protocolized approach

Although cardio(surgical) guidelines have given recommendations about the indications for IABP therapy, its practical application is based on institution protocols, since there are no practical guidelines for the use of such devices. Aside from the discussion when to use

IABP therapy, there is no general consensus about the ceasing of IABP therapy: i.e. weaning from IABP.

This thesis showed that a volume-based weaning strategy is favorable over a ratio-based weaning strategy, leading to improvements in visceral flows, while further enhancing cardiovascular beneficiary effects in comparison to a rate-based strategy (**Chapter 3**). These results may provide directions for future research in humans in order to create a practical consensus statement regarding the use of IABP. In order to study such an approach, patients on an Intensive Care Unit, being supported with IABP therapy should be randomly assigned to either a rate-based or a volume-based weaning approach. In this setting visceral flows should be assessed during the different phases of weaning using duplex ultrasonography, while invasive hemodynamic monitoring and echocardiographic evaluation will provide clear insights in the physiological alterations during each weaning strategy. An optimal weaning approach will eventually lead to a shortening of ICU-stay duration and consequently less complications. This optimal weaning protocol will most likely lead to less complications and, better patient outcome and, a reduction in the costs of care, which are favorable for the individual patient, caregiver and society.

Mechanical hemodynamic support; still a role for IABP?

Following the latest European guidelines on myocardial revascularization, advocating against routine use of IABP in patients suffering from cardiogenic shock, the interest of the cardiovascular community has shifted towards more invasive hemodynamic mechanical support modalities like the Impella CP® device or Extracorporeal Membrane Oxygenation (ECMO). However, these complex devices go hand in hand with more severe complications, potentially necessitating extensive surgery. Therefore, in comparison with IABP therapy, these techniques might provide hemodynamic benefits, but come with a price.

When looking more in detail into the evidence supporting the current guidelines, it can be seen that the guideline advocating against the routine use of IABP merely rely on the famous 'SHOCK-II trial', which received wide criticism about its methodology. Critics raised questions about a relative high cross-over rate between control group towards IABP group, a relative liberal use of catecholamines, a wide spread of inclusions in numerous (smaller) potentially less experienced centers and a relative hemodynamically stable patient population.

Given the fact that IABP therapy has not evolved since its initial introduction and following the observations obtained in this thesis, we might have not seen the best of this relatively 'simple balloon on a catheter' yet. Therefore, an optimization of the current relatively easy implantable IABP might still be the golden standard of therapy. In order to determine this, manufacturers should join hands with clinicians and researchers in order to come up with an optimized design. Such design should subsequently be tested in a more practically

controlled protocolized study, thereby eliminating institution's beliefs about the practical use of IABP therapy.