HEMODYNAMIC COMPARISON OF THIN VS STANDARD INTRA-AORTIC BALLOON USING A PATIENT-SPECIFIC CFD MODELING

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ABSTRACT

Intra-aortic balloon pump -IABP- is a mechanical cardiocirculatory support used to treat patients with cardiovascular diseases. Balloon volume influences both the standard therapy, since it is correlated to some clinical complications, and the weaning from the assistance, since one approach is the volume-based reduction.

The aim of this study was to investigate the influence of balloon volume on hemodynamics, evaluating the perfusion of the four main districts by comparing two volumes (standard and thin). Computational fluid dynamic - CFD - simulations were performed in a patient-specific aorta model. Balloons were numerically reproduced with their inflation-deflation behaviors.

The results highlighted how size influences the hemodynamics, generating a decrease of perfusion in head and arms and a hyperperfusion in visceral vessels and in legs when adopting a thin volume compared with the standard one. This computational comparison demonstrated that a reduced-volume balloon is healthier, since it produces a better hemodynamic profile.

Keywords: intra-aortic balloon pump, computational fluid dynamics, hemodynamics, simulations

1. INTRODUCTION

Intra-aortic counterpulsation is used to treat patients with different cardiovascular diseases, such as cardiogenic shock, myocardial infarction, etc. (Krishna and Zacharowski 2009), generating different beneficial effects, like the augmentation of diastolic aortic pressure and the increase of coronary perfusion (Papaioannou and Stefanadis 2005).

This mechanical support consists of two major components (Krishna and Zacharowski 2009): a catheter, with a balloon connected to its distal end, and a console, which shuttles helium through the catheter lumen in order to inflate and deflate the balloon with opposite trend respect to the cardiac cycle, thus obtaining a counterpulsating pump (Trost and Hillis 2006). Indeed, it is also known as intra-aortic balloon pump -IABP-.

In daily practice, Maquet/Datascope IABPs (MAQUET Cardiovascular, New York, United States) are widely used devices for the counterpulsation treatment. According to its guidelines, the balloon must be placed in the descending aorta, with its tip 2 or 3 cm distal to the origin the left subclavian artery -LSA- (Krishna and Zacharowski 2009) and before the iliac bifurcation. Moreover, balloon volume must be chosen according to the patient's height (Krishna and Zacharowski 2009).

For a fully cardiocirculatory assistance, an assist ratio of 1:1 is generally adopted (Gelsomino et al. 2012), whereas, for the counterpulsation weaning, two methods are available: frequency-reduction and volume-reduction (Lewis and Courtney 2006). Actually, there are very few studies that compare these two approaches in order to identify the best method. A preliminary investigation was performed by Lewis and Courtney (2006), who reviewed literature. They concluded that the volume-reduction was the most effective weaning approach. Recently, the same result was reached by Gelsomino et al. (2016 a) with an *in-vivo* comparison in a cohort of twelve pigs.

In addition, different clinical complications, such as bleeding, thromboembolism, distal leg ischemia, or hypoperfusion of visceral organs can occur, which are related to malpositioning, to a too long balloon or to a wrong balloon size.

El-Halawany et al. (2015) present a case of patient who suffered from bowel ischemia as a result of a malpositioned IABP. Also Vondran et al. (2016) investigate the impact of a low balloon position on visceral perfusion in an *in-vivo* animal model, reporting that the positioning is critical for obtaining a satisfactory outcome. Similar results were obtained by Siriwardena et al. (2015).

A recent research compares a 35 mL short balloon with a 40 mL standard size balloon (Gelsomino et al. 2016 b). Authors conclude that the short IAB is as effective as the standard one in supporting hemodynamics and coronary circulation. Since the two analyzed balloons have different lengths, the results are related both to volume and to length variations.

The influence of length was investigated by (Gelsomino et al. 2016 c) considering a short and a normal 40 mL balloon, highlighting that the short balloon is advantageous to prevent visceral occlusions and it is beneficial cardiac and coronary-related effects.

Finally, the same authors evaluate the influence of balloon size and volume on mesenteric and renal flows considering a short 35-mL IABP, a short 40-mL IABP, a long 35-mL IABP and a long 40-mL IABP (Gelsomino et al. 2017).
For these reasons and since there are no numerical investigations that analyze the effects of balloon volume/size on aortic hemodynamics, the purpose of this study was to assess the influence of IAB size on flow in aorta, evaluating the perfusion ratio on vascular districts (head, arms, abdomen and legs) comparing two balloon volumes (standard and thin) with the same length. Computational fluid dynamics -CFD- was chosen to perform this analysis, since this method presents different advantages, as illustrated in our previous work (Caruso et al. 2017).

2. MATERIALS AND METHODS

2.1. Aorta model

The physiological model of aorta was reconstructed from Dicom images of computerized tomography -CT- scan of a 56-year-old woman (158 cm tall), performed for clinical reasons. The sequence of images included 512, 416 and 90 slices in axial plane, sagittal plane, and coronal plane, respectively, with an in-plane resolution of 0.9375 × 0.9375 mm and a slice thickness of 1.2 mm. The written informed consent of the patient was obtained to use these images in the study.
The 3D virtual model of aorta and of its vessels was obtained by applying the segmentation approach using the open source software Invesalius (de Moraes et al. 2011). Since it provides a STL file, in order to obtain a 3D solid model exploitable for CFD simulations, different reverse engineering techniques (Pham and Hieu 2008) were applied.
The final model included the ascending and the descending trunks and ended with the iliac bifurcation. Also the supra-aortic and the visceral/abdominal vessels were reported (Table 1 and Figure 1).

Table 1: Aorta vessels

Acronym	Name	District
RSA	right subclavian artery	arms
RCA	right carotid artery	head
LCA	left carotid artery	head
LSA	left subclavian artery	arms
SMA	superior mesenteric artery	abdomen
CT	celiac trunk	abdomen
IMA	inferior mesenteric artery	abdomen
RRA	right renal artery	abdomen
LRA	left renal artery	abdomen
RIA	right iliac artery	legs
LIA	left iliac artery	legs

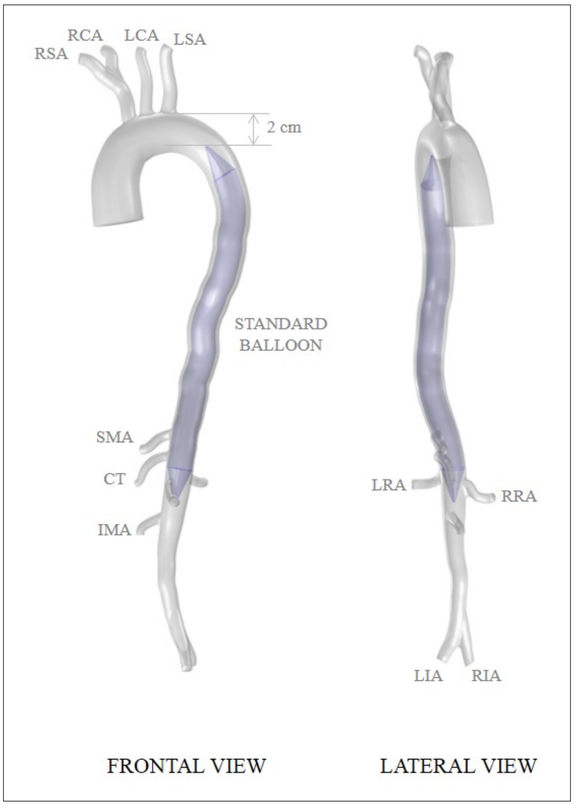

Figure 1: Aorta and standard IAB (34 cm^3) models in frontal and lateral views

2.2. Balloon selection and modeling

Even if technical guidelines indicate that the balloon must be selected considering the patient's height (Trost and Hillis 2006), different studies reported that the distance between left subclavian artery -LSA- and the celiac trunk -CT- is the best selection criterion (Rastan et al. 2010, Tapia et al. 2015, Parissis et al. 2011, Sukhodolya et al. 2013), as it reduces clinical complications. For this reason, the Linear 7.5 Fr with 34 cm^3 (fully inflated caliber of 15 mm) was chosen for full assistance and considered as standard balloon. A balloon of 30 cm^3 was supposed with the aim of considering a lower volume and, therefore, a smaller size. Assuming the same length of 221 mm, this thin-balloon had a fully inflated caliber of 14 mm.
The two 3D balloons were placed in the descending aorta with a distance of 2 cm from LSA emergence (Figure 1), as suggested by Caruso et al. (2017). The 1:1 assist ratio was considered for both assistance cases. The inflation/deflation behaviors were numerically reproduced with parametric studies, in which balloon radius changes according to the cardiac cycle with 8 degree Fourier functions (Figure 2). A cardiac cycle of 1s was set.

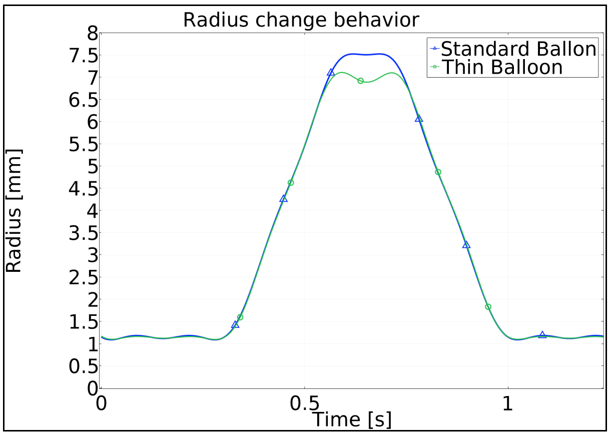

Figure 2: Radius change behavior for the standard and the thin balloons

2.3. CFD modeling

Since the aorta is a large vessel, blood can be approximated as a Newtonian and incompressible fluid, with a density of 1,060 kg/m^3 and a viscosity of 0.0035 Pa·s (Caruso et al. 2016). Moreover, the flow can be numerically described by means of 3D Navier-Stokes equations (Gramigna et al. 2015). As boundary condition, the same mean inlet flow of about 5 L/min was applied in the two cases, whereas zero-pressure conditions were set as outlets in all vessels, as in similar comparative studies (Caruso et al. 2017, Karmonik et al. 2012).

Since information regarding the effects of counterpulsation on aorta wall elasticity is unavailable (Lawford et al., 2008), all aorta walls were modelled as rigid surfaces and the no-slip boundary condition was imposed in both assistance cases. The same approximation is generally chosen in comparative analyses (Caruso et al. 2016, Gramigna et al. 2015, Karmonik et al. 2012).

The CFD simulations were carried out using COMSOL 5.2 (COMSOL Inc, Stockholm, Sweden). Since parametric studies are very expensive, in order to ensure a good compromise between accuracy and computational costs (Caruso et al. 2017), the meshes had four boundary layers and tetrahedral elements, with a changeable total number of elements according to the cardiac cycle, as illustrated in Table 2.

The Pardiso solver was employed to solve the Navier-Stokes equations, choosing the P1-P1 discretization and a step of 0.001.

Table 2: Mesh details: total number of elements

Balloon	Fully inflation	Fully deflation
Standard	466,806	1,382,321
Thin	499,615	1,358,654

3. RESULTS

Flow distribution waveform in each district of human body during counterpulsation with standard balloon and with thin balloon is reported in Figure 3. In both cases, the flow followed the balloon inflation/deflation behavior, with the same trend in the head and arms and with an opposite trend in the abdomen and in the legs. Moreover, comparing the standard counterpulsation with those obtained with a thin balloon, a reduction of perfusion occurred in the supra-aortic vessels, whereas the visceral and the iliac flows increased. These changes in the hemodynamics produced a decrease in the mean perfusion of head and arms and an increment of flow in the abdominal vessels and so in the abdominal organs and in the legs, as illustrated in Figure 4.

In detail, the use of thin balloon created a reduction of about 1.36% and 1.51 % in the cerebral and in the arms flow rates, respectively, and an increase of about 1.59% and 3.40 % in the visceral and legs perfusion, as reported in Table 3. Thus, the volume reduction of about 13% generates changes in the hemodynamics in aorta for a mean flow value of about 2%.

Moreover, to better understand the influence of thin balloon on hemodynamics, the wall shear stress -WSS-, which is the friction force created by blood motion on vessel walls, was evaluated according to equation reported in Caruso et al. (2015). Since this mechanical indicator is time-dependent, it was estimated when the balloon was fully-inflated (t=0.65 s) in order to compare the effects of the two volumes on aorta walls, as reported in Figure 5.

The physiological level of WSS is about 1.5-2.0 Pa, as reported by Malek et al. (1999), whereas values less than 0.481 Pa are considered as low and correlated to atherosclerotic place formation (Lee et al. 2008). For this reason, a color scale with a maximum value of 0.5 Pa was set in Figure 5, in order to identify the areas characterized by very low WSS.

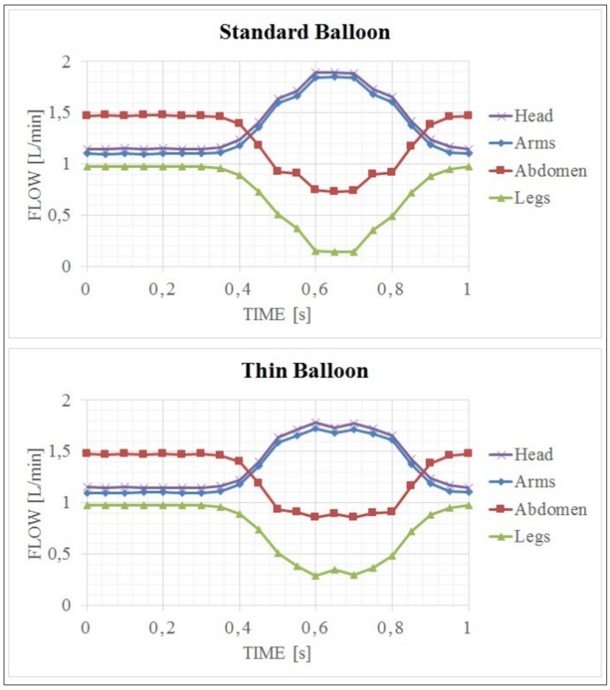

Figure 3: Flow distribution waveform in each district in case of standard counterpulsation and in case of support with thin balloon

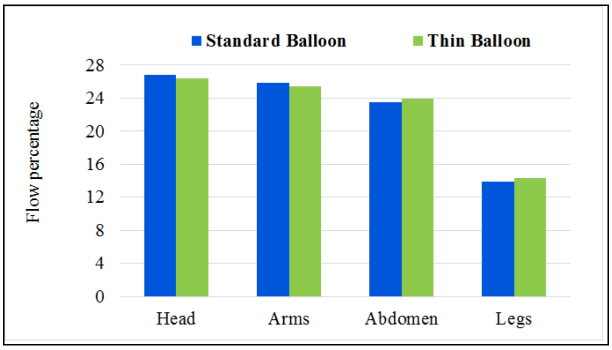

Figure 4: Mean flow percentage distribution in each district in case of standard counterpulsation and in case of thin balloon, evaluated respect to the inlet flow

Table 3: Comparison between standard and thin balloon in terms of volume and flow rates. Note: the perfusion of standard balloon is expressed respect to the inlet flow, whereas the flow rate of thin balloon is evaluated respect to the standard balloon perfusions

Balloon	Standard	Thin
Volume [cm^3]	34	30
Head perfusion	26.77 %	- 1.36 %
Arms perfusion	25.83 %	- 1.51 %
Abdomen perfusion	23.54 %	+ 1.59 %
Legs perfusion	13.86 %	+ 3.40 %

The aorta surface before and around the fully-inflated balloon had the same WSS distribution in case of both standard and thin balloons. In detail, the supra-aortic vessels were subjected to high WSS (>0.5 Pa), whereas the surface around the balloon presented a very low value (≈ 0 Pa). The significant difference between the two balloons occurred below them. Indeed, the WSS in the final part of abdominal aorta was about 0 Pa in case of standard balloon and of about 0.3 Pa in case of thin balloon. Also the renal arteries, the IMA and the iliac bifurcation presented higher WSS values in case of thin balloon.

4. DISCUSSION

Intra-aortic counterpulsation is the gold standard treatment for different cardiovascular diseases (Trost and Hillis 2006, Krishna and Zacharowski 2009). Balloon size has a key role in this cardiocirculatory assistance. Indeed, it influences both clinical benefits (Trost and Hillis 2006) and complications (Rastan et al. 2010, Tapia et al. 2015, Parissis et al. 2011, Sukhodolya et al. 2013). In addition, the volume-based reduction is a methodology available for the counterpulsation weaning (Lewis and Courtney 2006). For these reasons, the standard counterpulsation and the treatment performed with a thin balloon were compared, using computational simulations carried out in a patient-specific aorta model in order to investigate the influence of IAB size on hemodynamics.
As expected, flow waveforms follow the balloon inflation-deflation behavior, with the same trend for head and arms and an opposite trend for abdominal organs and legs. This was due to the presence of balloon in the descending aorta that obstructed it, creating a hyperperfusion in the vessels above it (same trend) and a hypoperfusion in the trunks below it (opposite trend) (Figure 3). Indeed, different studies demonstrated how IABP improved cerebral blood flow (CBF), such as the research of Pfluecke et al. (2014).
Moreover, flow results highlighted how the thin balloon reduced the head and arms perfusions and intensified the flow in abdominal organs and legs. This founding is in agreement with a recent study whose authors indirectly compared two IAB sizes (Caruso et al. 2017) and with the research of Byon et al. (2011). Similar results were also obtained in an *in-vitro* investigation (Biglino et al. 2008). Thus, this assessment was validated.
The analysis of flow rates demonstrated how the thin balloon is better to prevent the occlusion of visceral vessels and the hypoperfusion of legs, since the hemodynamics had a better performance of about 2% as a volume reduction of about 13% was performed (Table 3).
A recent study evaluated the influence of balloon size and volume on mesenteric and renal flows considering a short 35-mL IABP, a short 40-mL IABP, a long 35-mL IABP and a long 40-mL IABP (Gelsomino et al. 2017). Since our analysis considered two balloons with different volume and size (34 cm3 and 15 mm and 30 cm3 and 14 mm respectively) and the same length of 221 mm, there is an analogy between it and the comparison of two long balloons performed by (Gelsomino et al. 2017). Our increase of about 1.6 % of abdominal perfusion in case of thin balloon (Table 3) is in agreement with their data. Indeed, they indicated that the smaller IAB generates a better visceral flow rate, even if they consider this difference not significant.
Since distal leg ischemia and hypoperfusion-obstruction of abdominal organs are the most frequent complications of IABP treatment (Tapia et al. 2015), we believe that even a little improvement can be important to achieve a better hemodynamic profile.
The WSS investigation revealed that the standard balloon generated stagnant areas (WSS≈ 0 Pa) in the descending aorta below the balloon, creating stasis in this trunk segment and in the iliac arteries (Figure 5), whereas, in case of thin balloon, WSS was about 0.3 Pa. WSS is highly correlated to the atherosclerosis (Malek et al. 1999). Thus, the worst situation occurred in case of standard balloon. As a result, thromboembolic events could happen, which are another diffused disease after counterpulsation treatment (Tapia et al. 2015).

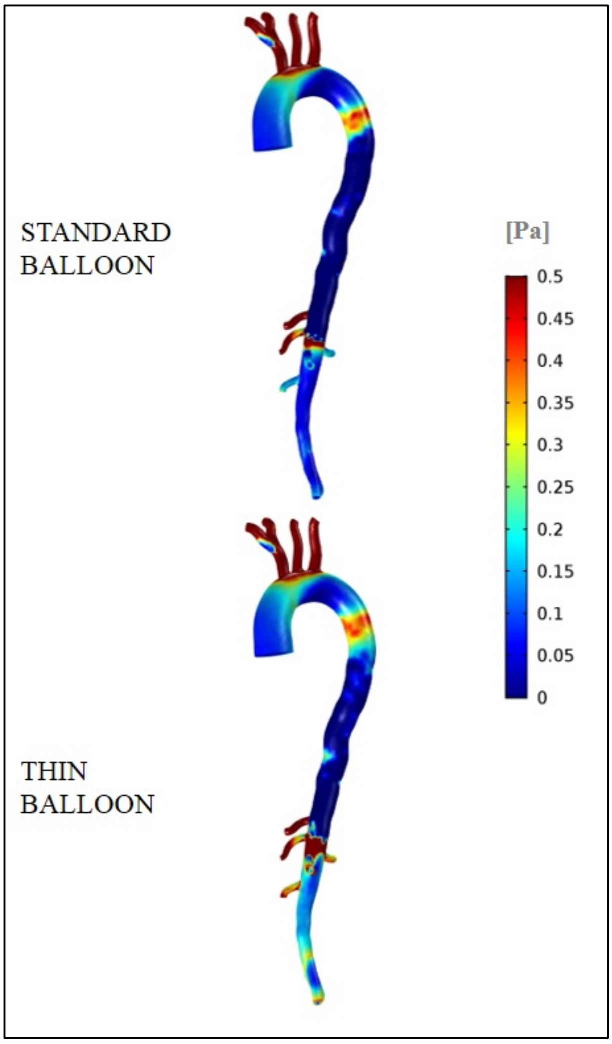

Figure 5: WSS evaluated during the fully inflation (t=0,65 s) in case of standard counterpulsation and in case of support with thin balloon. Note: the color scale was set with a maximum of 0.5 Pa in order to visualize the areas with very low values

5. CONCLUSION

This computational investigation compared the standard balloon used for the counterpulsation treatment and a thin balloon in a patient-specific model in order to investigate the influence of IAB size on hemodynamics. Significant changes were reported, both in terms of flow and WSS, indicating that a thin balloon is a better choice for reducing clinical complications when compared to those suggested by actual guidelines. As a result, a smaller volume could be adopted both during treatment and for the weaning, thus improving the patient's outcome.

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