1. Introduction

Morbidity related to intra-aortic balloon pump (IABP) treatment mainly occurs during insertion [1, 2]. Moreover, vascular complications during prolonged use of IABP have been quoted to occur in up to 8–10% of cases [3].

This study looks at the dynamic action of the IABP within the intact porcine aorta in an artificial circulation, in an attempt to delineate the movement of the balloon shaft within the aortic environment. This model also identifies modes of weaning of the IABP that could possibly lead to endothelial injury of the aorta.

2. Materials and methods

Twenty-nine intact porcine aortae (animals 6–12 month old, weight 45–65 kg) were utilized, from animals at the slaughterhouse. The intrathoracic organs were excised ‘en block’. The supportive role of the tissues along the entire aorta and minimal tissue dissections, render an optimal anatomical model.

Each aorta was rinsed with saline to remove blood clots from its lumen. All side branches were ligated (using minimal dissections) with the exception of the left subclavian and the common iliac vessels.

An artificial circulation was constructed. The circuit consisted of a standard 3/8 inch PVC perfusion tubing loop and a pulsatile dual chamber pump.

The pulsatile flow pump (Fig. 1a) consisted of a cylinder with a one-way valve on each side to direct flow. A pneumatic cylinder with a piston at its end drove the pump. The action of this fixture would work very much like the push–pull of a large syringe. The pneumatic cylinder was driven via a solenoid valve, which was controlled by a simple oscillator circuit. The system was triggered into action by pressurized air (60 psi), a heated reservoir and a 120/220 vacuum converter. The stroke volume of the pulsatile dual chamber pump was 50 ml (Data Scope Laboratories).

The PVC loop was divided and an intact porcine aorta was incorporated into the circuit with the inflow at the aortic valve and the outflow at the right common iliac artery. We utilized the intrathoracic and intra-abdominal organs ‘en block’. The supportive role of the tissues along the entire aorta and minimal tissue dissections, render an optimal anatomical model.

As a blood analogue Dextran 70 was used for perfusion. Pulsatile flow at rates of 50, 60 and 80 beats per min (bpm) were employed. Flow at an irregular rate (simulating atrial fibrillation) of 120 bpm was also tested.

Direct angioscopic images of the interior of the aorta were obtained using a rigid video endoscope (Olympus Keymed, camera OTV 54, light source CLV U20, Sony mon-
itor) inserted via the left subclavian artery and snagged securely. An intra-aortic balloon (Datascope 9.5Fr) was then advanced under angioscopic control into the aorta via the left common iliac artery until its tip was just distal to the left subclavian artery (Fig. 1b). All the IABP used were appropriately sized and matched to the corresponding aorta.

Triggering of the balloon pump was achieved with a datascope ECG signal generator. Blood pressure and flow stability was maintained throughout the experiments by continuous transfusion of the pump. The traditional way of weaning has been to reduce the assist rate from 1:1 to 1:2 to 1:3 while maintaining diastolic augmentation at 100%.

Alternatively, weaning could be achieved by gradually decreasing the extent of diastolic augmentation while the rate is kept at 1:1. That can be achieved by calculating the augmentation pressure (Fig. 1c) from the presystolic point (C) to the peak of balloon augmentation (B).

This value is then decreased by 25% each time during two weaning phases. In order to decrease the diastolic augmentation by 25% the balloon volume should be decreased by 50%.

2.1. Protocol

With full augmentation and a pump rate of 80 bpm the first three sets of experiments were performed while the IABP was weaned by mode (in order to minimize bias, each experiment was repeated three times). During the next set of experiments the rate simulated atrial fibrillation of 120 bpm and the IABP was weaned by mode 1:1, 1:2. During the last set of experiments the mode was kept 1:1 and the pump rate at 80 bpm. However, the augmentation was weaned to 75%, 50% and 25%, respectively.

Endoscopic monitoring and video recording was obtained throughout the experiments. Biopsies at the proximal of the descending thoracic aorta were taken at 30 min, 6 h and 12 h following counterpulsion.

2.2. Endoscopic observation of the movement of the shaft of balloon

1. Direct contact of the shaft of the deflated balloon on the aortic wall was scored subjectively as mild (score 1) moderate (score 2) or severe (score 3).
2. Direct stroke of the shaft of the IABP on the aortic wall was scored as mild (score 1), moderate (score 2) or severe (score 3).
3. Antegrade/retrograde movement of the shaft of the IABP was scored as mild (score 1), moderate (score 2) or severe (score 3).
2.3. Pathologic examination

Biopsies were taken throughout the experiment. Following mummification the specimen was examined under light microscopy (Zeiss Axiolab) with hematoxyline–eosine for tears at the inner layer.

The injury was scored:
Score 0 for no injury.
Mild (score 1) – when there were two or less endothelial disruptions per visual field (at magnification of 40).
Moderate (score 2) – when there were 4–6 inner layer disruptions.
Severe (score 3) – when there were 8–10 inner layer disruptions and dangerous (score 4) – when there were more than 10 inner layer disruptions per visual field.

The formula for ‘Aortic impact score’ (AIS) was derived as the Sum of scores:
1. Direct contact of the shaft of IABP on the aortic wall
2. Direct stroke of IABP on the aorta
3. Back and forth shift of IABP
4. Biopsy score at 30 min, 6 h and 12 h.

3. Results

Perfusion could not be maintained in five out of the 29 aortae. The mean arterial pressure (MAP) recorded prior to intra-aortic balloon action was 45.4 ± 8.32 mmHg. The MAP during intra-aortic balloon action on 1:1 was 88.6 ± 9.18 mmHg and the peak augmentation pressure was 116.8 ± 22.42 mmHg.

3.1. Angioscopic description

The entire length of the descending aorta was easily seen endoscopically. The balloon catheter did not occlude side branches of the aorta during augmentation.

Throughout the experiment a number of fine intimal flaps (Fig. 1d) were raised and visualized as 1–2 mm tears. The movement of the balloon within the aortic lumen appeared to be repetitive. The central axis of the balloon occupied a series of different positions during pumping (Video 1).

During deflation the balloon was swept to one side of the aorta, by the circulation. This movement appeared to be enhanced during the prolonged phase of deflation associated with a 1:2 and especially with 1:3 mode (Fig. 2). The axis of the balloon re-obtained its central position at the end of inflation.

Video 1. Endoscopic view of the IABP, during 1:1 and 1:2 modes. The position of the central axis of the balloon relative to the aortic wall during deflation is constantly ‘around two o’clock’. This motion is prominent during 1:2 mode.

Video 2. Antegrade and retrograde movement of the IABP during 1:3 mode. This movement is less prominent during 1:1 mode.

Fig. 2. The central axis of the balloon occupied a series of different positions during pumping. During deflation the balloon was swept to the same side of the aorta (whipping effect) by the circulation. This observation was mostly prominent during 1:3 mode.

The catheter also moved relative to the long axis of the aorta (Video 2). During inflation it advanced proximally towards the aortic valve. This position was held until deflation when it dropped back towards the aortic bifurcation as it was moving laterally towards the wall of the aorta (Fig. 3).

Video 3. The catheter also moved relative to the long axis of the aorta (2–3 mm). During inflation it advanced proximally towards the aortic valve (antegrade movement). This position was held until deflation when it dropped back towards the aortic bifurcation (retrograde movement).
Table 1
Aortic impact score (AIS) calculated at different time intervals and modes of weaning. A higher score was observed with time, while weaning by 1:3 mode. (AIS 1:3 > AIS 1:2 and AIS 1:3 > AIS augmentation) (P < 0.05)

<table>
<thead>
<tr>
<th>Experiment</th>
<th>Aortic impact score time interval</th>
<th>0.5 h</th>
<th>6 h</th>
<th>12 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weaning by mode</td>
<td>Mode</td>
<td>AIS 1:1</td>
<td>AIS 1:2</td>
<td>AIS 1:3</td>
</tr>
<tr>
<td>1:1</td>
<td>3.3 ± 0.6</td>
<td>4.0 ± 1.0</td>
<td>4.3 ± 0.6</td>
<td></td>
</tr>
<tr>
<td>1:2</td>
<td>4.7 ± 0.6</td>
<td>6.7 ± 0.6</td>
<td>7.0 ± 0.0</td>
<td></td>
</tr>
<tr>
<td>1:3</td>
<td>8.7 ± 0.6</td>
<td>11 ± 1.0</td>
<td>11.7 ± 0.6</td>
<td></td>
</tr>
<tr>
<td>Weaning by augmentation</td>
<td>Augmentation</td>
<td>AIS augmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75%</td>
<td>2.3 ± 0.6</td>
<td>2.7 ± 0.6</td>
<td>3.0 ± 0.0</td>
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</tr>
<tr>
<td>50%</td>
<td>1.3 ± 0.6</td>
<td>1.3 ± 0.6</td>
<td>1.7 ± 0.6</td>
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</tr>
<tr>
<td>25%</td>
<td>0.7 ± 0.6</td>
<td>0.7 ± 0.6</td>
<td>0.7 ± 0.6</td>
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</tr>
</tbody>
</table>

3.2. Weaning by mode vs. augmentation

Increasing AIS was observed with time, while weaning by mode (AIS 1:3 > AIS 1:2 > AIS 1:1). The mean score was higher (see Table 1) at the group where the balloon was weaned by 1:3 mode (P < 0.05).

For all pairwise comparisons between the two types of weaning (AIS 1:3 > AIS augmentation), the differences were statistically significant (P < 0.05).

(ANOVA followed by Bonferroni post hoc test).

When the datascope ECG signal generator simulates atrial fibrillation, the AIS during various modes of weaning were low (4 ± 2).

4. Discussion

The relationship between the IABP and the intra-aortic environment has not been extensively investigated.

Wolvek [4] draws the attention on the hostile environment of the aging human aorta due to atherosclerotic plaques, or aneurysms. Under those conditions weaning the IABP by mode could be deleterious. Our group has shown in the past [5] that 1:3 mode leads to production of excess embolic material in human atherosclerotic aortas.

This study reveals that regardless of the mode of weaning, the balloon describes a repetitive motion. At maximal inflation the balloon lay centrally within the vessel. During deflation, however, the balloon was swept to one side by the passing circulation rather like ‘a sail in the wind’. Moreover, the deflationary position of the balloon was always observed to be at the same area of the aorta. This movement appears to be forceful (whipping effect) during 1:3 mode.

The movement of the central axis of the balloon catheter could, therefore, be described as circular. During inflation the balloon finds a central position within the lumen and advances by 2–3 mm toward the aortic valve. During deflation the balloon falls back towards the aortic bifurcation by a similar distance and is swept sideways striking the posterolateral wall of the vessel. This position is held longer during 1:2 mode due to the prolong period of deflation.

We can assume that this may be a mechanism of balloon perforation, if the catheter is constantly striking and then rubbing alongside an irregular atheromatous area.

Direct contact between the catheter and arterial wall may also be a mechanism of intimal insult and fissuring of plaque resulting on embolization. The intra-aortic balloon catheter typically cycles at 144,000 beats every 24 h [6]. The increments of repetitive pulse pressure applied on the aortic wall during each cycle may be significant enough to produce excess insult, especially in a calcified inelastic atheromatous aorta.

During this study we have constantly observed high AIS in 1:3 mode. This supports our hypothesis that 1:3 mode has a potential deleterious impact on the aortic wall.

In contrary, atrial fibrillation was not associated with high AIS. There were no differences between 1:1 and 1:2 mode of weaning. This reflects our endoscopic observation that during periods of atrial fibrillation, the balloon shaft movement appears to be weak with the ‘whipping effect’ being absent.

The prolong duration of IABP therapy was associated with higher AIS, in all modes of weaning.

The impact of prolong IABP treatment on the development of complications, is controversial. Duration of use was the only balloon-related variable that approached significance (P = 0.051) in the published studies of Funk et al. [7]. Contrary, Alderman et al. [8] and Gottlieb et al. [9] identified incremental risk factors for the development of vascular complications as being: female sex, peripheral vascular disease and diabetes.

Freed and associates [10] analyzed 733 cases with specific interest upon the complications during prolonged circulatory support with IABP. Vascular problems were frequent in prolonged assisted patients.

Similar conclusions are reported by Iverson et al. [11]. They concluded that patients who required balloon support for more than 60 h had 1.5 times the complication rate compared with those requiring support for less (32% vs. 21%).

In our study the highest score was observed during prolong IABP weaning with 1:3 mode.

There are weaknesses in this study due to:

1. The potential bias from the observational nature of the study.
2. There were difficulties throughout the experiments in maintaining a constant blood pressure and flow.
3. There was a subjective factor in some of the variables used in order to calculate the AIS.

Limb ischemia during treatment with IABP is multi-factorial and mainly reflects the atherosclerotic status of the descending aorta and the difficulty of dealing with a severely atherosclerotic femoral artery. Our study suggests that ‘weaning by mode’ could be a risk factor for adverse vascular outcome.

In conclusion, direct stroke effect and sliding motions of the balloon shaft against the aortic wall (mainly during 1:2 and 1:3 modes) may be involved in balloon-associated morbidity. The clinical implication of that would be avoidance of those modes during weaning. A clinical trial remains to confirm the latter observation.

Acknowledgments

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References


