Julia Schubert*, Tamara Wilfling, Kerstin Schümann, Gerrit Paasche, Niels Grabow, Klaus-Peter Schmitz, Thomas Lenarz, and Wolfram Schmidt

Investigation of balloon dilation devices for treatment of Eustachian tube dysfunction

Abstract: The presented three different balloon dilation devices for treating Eustachian tube dysfunction were compared regarding their geometries and designs. The balloon dilation behaviour was investigated by an in vitro test setup consisting of a test chamber with 37 °C water, a 2-axis laser scanner and a pressure controller.

All balloons could be properly dilated up to the given nominal pressure (NP) or to rated burst pressure (RBP). The balloons reached their expected balloon diameter and length. The compliance data were 1.07 %/atm (TubaVent short), 1.16 %/atm (Acclarent Aera) and 1.28 %/atm (XprESS LoProfile). The measured profile and compliance data can be used for development of new devices for balloon dilation Eustachian tuboplasty.

Keywords: Eustachian tube dysfunction, tube balloon dilation, balloon dilation Eustachian tuboplasty (BET)

https://doi.org/10.1515/cdbme-2018-0127

1 Introduction

An impaired function of the Eustachian tube (ET) is the main underlying pathophysiology of chronic otitis media. Typically, ET dysfunction is located in the cartilaginous part of the ET. Amongst current treatment options for chronic otitis media are Valsalva manoeuvre, grommets, and as more recent treatment concept the balloon dilation Eustachian tuboplasty (BET). The underlying mechanism of BET has not yet been identified and described to its fullest. The idea is to dilate the cartilaginous part to loosen existing obstructions. For this procedure there are different dilating systems available. They differ in their length and variability of the angle of the tip. A common consensus on how to quantify the post-operative outcome is still missing. Short term improvements can be documented, although studies showing long term benefits are rare [1].

There is no literature on a systematic overview on BET systems. As research is done to get general knowledge on dimensions and positions of the ET in humans [2] this study focuses on the different device parameters of three commercially available BET systems.

2 Material and Methods

2.1 Test samples

We investigated three commercially available balloon dilation systems to treat Eustachian tube dysfunction (Johnson & Johnson Acclarent Aera Eustachian Tube Balloon Dilation System, Entellus Medical XprESS LoProfile, Spiggle & Theis TubaInsert & TubaVent short).

All samples are BET systems representing current state of the art. Balloon diameter (D), length (L), nominal pressure (NP) and rated burst pressure (RBP) are specified by the manufacturers (Table 1) [3-5]. There were no specifications according to rated burst pressure (RBP) for the balloon dilation systems Acclarent Aera and XprESS LoProfile.

Table 1: Investigated balloon dilation systems.

<table>
<thead>
<tr>
<th>BET system</th>
<th>D [mm]</th>
<th>L [mm]</th>
<th>NP [atm]</th>
<th>RBP [atm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson Acclarent Aera Eustachian Tube Balloon Dilation System</td>
<td>6</td>
<td>16</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>Entellus Medical XprESS LoProfile</td>
<td>6</td>
<td>18</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>Spiggle &amp; Theis TubaInsert &amp; TubaVent short</td>
<td>3</td>
<td>20</td>
<td>10</td>
<td>16</td>
</tr>
</tbody>
</table>

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The following Figure 1 shows the BET systems. Acclarent Aera Eustachian Tube Balloon Dilation System (A) and TubalInsert & TubaVent short (C) consists of a separate guiding catheter and balloon catheter which have to be used together. XprESS LoProfile (B) consists of only one part but unlike the other systems the balloon catheter is advanced over the guiding catheter. The additional PathAssist LED Light Fiber emits red light (625 nm) from the distal tip for over 60 minutes to get optimal illumination during the procedure (Figure 2).

The catheter geometries were measured by microscopic images to characterize the systems. These include the outer (OD\(_G\)) and inner diameter of the guiding catheters (ID\(_G\)), the outer diameter of the balloon catheters (OD\(_B\)) and the guiding catheter angle near the tip (A\(_G\)). This value refers to the angle between the extended line of the catheter shaft and the bending tip. The XprESS LoProfile tip can also be reshaped to treat multiple spaces, like frontal and sphenoid sinuses or Eustachian tubes and to meet the unique anatomical characteristics of each patient. The appropriate angles range from 45° to 135°. TubalInsert is available in three angles (45°, 60° and 70°) to match different anatomies, too.

Macro photographs of different tip designs of the investigated balloon dilation systems are shown in Figure 3. They all have rounded, atraumatic tips without any sharp edges, which allows a smooth movement even through tight passages.

2.2 Experimental setup

Balloon dilation was performed using a proprietary test device consisting of a water filled test chamber, a 2-axis laser scanner, pressure controller and test software. The technical specifications are listed in Table 2.

During the procedure the balloon is inflated for approximately 2 minutes at the given nominal pressure.
Table 2: Technical specifications of balloon expansion and diameter measurement.

<table>
<thead>
<tr>
<th>Device / Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Scanner</td>
<td>ODAC 64XY-RSN (ZUMBACH)</td>
</tr>
<tr>
<td>Measurement range</td>
<td>0.1 to 30 mm</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 0.01 mm</td>
</tr>
<tr>
<td>Resolution</td>
<td>0.001 mm</td>
</tr>
<tr>
<td>Pressure controller</td>
<td>neMESYS (cetoni)</td>
</tr>
<tr>
<td>Pressure range</td>
<td>0.5 to 40 atm</td>
</tr>
<tr>
<td>Accuracy</td>
<td>&lt; 5 % of actual value</td>
</tr>
<tr>
<td>Environment</td>
<td>pure water at 37 ± 2 °C</td>
</tr>
</tbody>
</table>

2.3 Procedure and analysis

Balloon dilation is conducted in several pressure steps starting at 0 atm and increasing the pressure by 2 atm steps to nominal pressure (NP) and rated burst pressure (RBP) (only for TubaVent short).

The balloon pressure is held 15 s at each pressure step before measuring the outer diameter from the distal to the proximal tip of the balloon at stepwise positions (Δz = 0.5 mm). Each value is summarized by the root mean square (RMS) of the perpendicular x and y projections.

The comparison and characterization of the balloons is based on the measured outer balloon diameter and balloon compliance. The mean balloon diameter at each pressure step is the average of all measured values in the range of the given balloon length. To calculate compliance C, the average diameters at NP (dNP) and RBP (dRBP) are measured at the corresponding NP and RBP. In the cases where no RBP is known, the compliance was calculated as the slope of the pressure-diameter curve around NP.

\[ C = \frac{d_{RBP} - d_{NP}}{(RBP - NP) d_{NP}} \times 100 \% \]  

3 Results

All balloons could be properly expanded up to maximum pressure given by the manufacturers (NP – Acclarent Aera and XprESS LoProfile, RBP – TubaVent short). The balloon profiles as measured by the laser scanner are demonstrated in Figure 4, Figure 5 and Figure 6 showing a constant outer diameter for each balloon in the middle section.

![Figure 4: Diameter of Acclarent Aera 6/16 up to NP=12 atm.](image)

![Figure 5: Diameter of XprESS LoProfile 6/18 up to NP=12 atm.](image)

![Figure 6: Diameter of TubaVent short 3/20 up to RBP=16 atm.](image)

Figure 7 shows measured compliance curves of all tested devices. TubaVent short has a compliance of 1.07 %/atm (cf. formula 1). As there were no further data about RBP of the other balloon dilation systems the following calculated compliance was based on the 2 atm pressure step and NP. Therefore the compliance of Acclarent Aera and XprESS LoProfile is about 1.16 %/atm and 1.28 %/atm.

Table 3: Measured catheter diameters and angles.

<table>
<thead>
<tr>
<th>BET system</th>
<th>OD0 [mm]</th>
<th>ID0 [mm]</th>
<th>Ao [°]</th>
<th>OD6 [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acclarent Aera</td>
<td>3.3</td>
<td>2.4</td>
<td>56</td>
<td>2.12</td>
</tr>
<tr>
<td>(3.9 distal)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>XprESS LoProfile</td>
<td>1.2</td>
<td>-</td>
<td>84</td>
<td>3.15</td>
</tr>
<tr>
<td>Tubalinsert &amp;</td>
<td>3.0</td>
<td>2.0</td>
<td>46</td>
<td>0.85</td>
</tr>
<tr>
<td>TubaVent short</td>
<td></td>
<td></td>
<td></td>
<td>(1.0 distal)</td>
</tr>
</tbody>
</table>
4 Discussion

All tested balloon dilation systems reached their expected balloon diameter at nominal pressure based on manufacturer data. Manufacturer data of the TubaVent short system include a rated burst pressure which is higher than the pressure at which the balloon reaches nominal profile.

In case of the TubaVent short catheter the measurement and calculation of diameter compliance were exactly comparable to those standardized for vascular balloon catheters. Since this procedure requires a known nominal and rated burst pressure, it could not be applied for the XprESS LoProfile and Acclarent Aera devices. For the latter systems an estimation of diameter compliance was derived from the diameter slope in the region of the recommended application pressure of 12 atm.

Considering this, the balloon compliance is comparable for all dilation devices. Compared to coronary balloon systems the measured pressure-diameter relationship would be classified as semi-compliant. This feature allows for fine adjustment of target diameter for dilation of the Eustachian tube in the range of some tenths of mm, which can potentially be useful due to anatomical variations within the ET. The measured balloon lengths also correspond to the given lengths. In general all of the tested dilating systems are utilizelbe for BET.

Typically the tip design of the dilation catheters is of particular importance for safe use. Long tips reaching far beyond the cylindrical part of the balloon might reach through the bony isthmus and implicate the risk of middle ear trauma and should thus be avoided. Furthermore, as the smaller diameter of the isthmus is in the range of 1 mm [6], a long tip with a large diameter would prevent the balloon from dilating the entire cartilaginous part of the ET. Thus short and slim tips without sharp edges will be preferred for atraumatic application.

In general small profiles of the folded balloons appear as an advantage for use with low profile insertion devices. This holds in particular for single balloon catheters such as TubaVent short and Acclarent Aera. The design of the XprESS LoProfile system follows another functional principle with the balloon catheter mounted outside the insertion device. In this case the inner lumen is used for illumination of the dilation site and can therefore be used as a position control parameter. This kind of position control is new. Other devices use a pre-defined length of the catheter to ensure the correct position.

As for clinical importance the widening of the ET depends on the length and configuration of the tip of the used device. This is of importance due to anatomical varieties in patients speaking of the angle of insertion into the tubal ostium in the nasopharynx.

Clinical studies comparing different dilating systems are missing yet.

Acknowledgment: We gratefully thank bess medizintechnik gmbh for providing a test sample and the staff of the independent Test Laboratory for Cardio-Vascular Devices at the Institute for Implant Technology and Biomaterials – IIB e.V. for their technical support.

Author Statement

Research funding: Financial support by the Federal Ministry of Education and Research (BMBF) within RESPONSE "Partnership for Innovation in Implant Technology" is gratefully acknowledged. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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