ACHIEVING LOW RADIATION EXPOSURE AND CONTRAST USAGE WITHOUT COMPROMISING SAFETY AND EFFICACY DURING WATCHMAN LEFT ATRIAL APPENDAGE OCCLUSION DEVICE IMPLANT

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Highlights

• The study demonstrates the safety, feasibility and effectiveness of a comprehensive approach to minimize fluoroscopy and contrast use during Watchman left atrial closure device implantation.

Background

The introduction of Watchman left atrial appendage occlusion device (WM) has provided an effective alternative to anticoagulation for patients with a high risk of cerebrovascular accidents (CVA) and high risk of bleeding and who are unable to take long-term anticoagulation therapy. Since its introduction, WM has been implanted more than 50,000 times worldwide. While the implant procedure is relatively safe, it involves the use of fluoroscopy and contrast and, as such, poses some associated risk to patient safety. The adoption of procedural techniques which reduce fluoroscopy exposure and contrast use have the potential to provide clinical patient benefit without compromising safety or efficacy.

Aim

To demonstrate that WM implant can be performed with minimal exposure to both ionizing radiation and IV contrast without compromising safety or efficacy.

Methods

A retrospective chart review of all 75 consecutive Watchman implantations by a single operator at a single center between December 2015 and December 2017. Every effort to optimize the WM implant procedure and minimize radiation and contrast exposure was incorporated as implant techniques evolved. Contrast and radiation exposure data were collected and analyzed year-over-year.

Results

Charts from 75 consecutive cases were reviewed with all cases at index procedure (100%), and included the majority of patients presenting in paroxysmal AF (63%). Baseline patient characteristics were consistent across years. Procedural characteristics also were consistent over time. The median absorbed radiation dose was low (75 mGy in 2015) and did not change significantly over time. Similarly, the median fluoroscopy time used after the initial case was low (2.8 minutes) and did not vary. 73 of 75 (97%) of procedures resulted in successful implantation. There were no procedural complications; notably, no cases resulted in stroke, death, pericardial effusion, vascular accidents or device embolization.

Conclusion

The current generation of WM can be successfully implanted using low fluoroscopy and contrast without compromising safety or efficacy using the techniques described.

Keywords

Left atrial appendage closure device • Stroke risk reduction • Fluoroscopy • Radiation • X-ray • Contrast

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Abbreviations

AF – atrial fibrillation
CVA – cerebral vascular accident
EP – electrophysiology
FT – fluoroscopy time
IAS – inter-atrial septum
ICE – intracardiac echocardiography
LA – left atrium
LAA – left atrial appendage
LAO – left atrial appendage occlusion device
OAC – oral anticoagulantion
PA – posterior-anterior
TEE – transesopageal echocardiogram
WM – Watchman left atrial occlusion device

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Introduction

For patients with AF who are at elevated risk of thromboembolic CVA, an elevated risk of bleeding and a relative contraindication to the use of anticoagulants, left atrial occlusion device placement is a proven safe and effective alternative to OAC [1, 2]. WM is a novel technology which involves the delivery of a LAA occlusion device via a transeptal approach and is widely in use in the United States and Europe. While standard implant techniques have been refined since the early clinical trials, device delivery continues to require both fluoroscopy and direct injection of IV contrast into the left atrium to ensure appropriate positioning and to verify appendage occlusion.

Methods

Patients:
This is a retrospective observational study and analysis of all 75 consecutive WM implants performed by a single operator at a single center from 12/1/15 to 12/31/17. All patients met local implant criteria and provided informed consent. In addition, the majority (99%) of patients met the more rigorous Medicare implant criteria which included a CHADS2-VASC2 rank of at least 3 and a HASBLED score of at least [1].

Procedure:
All patients presented for WM implant at our center’s EP or hybrid structural heart laboratory. All patients were diagnosed with well-documented atrial fibration and underwent a screening TEE pre-procedure. All patients received general anesthesia including intubation and underwent TEE probe placement at the beginning of the procedure. Intra-procedural TEE was used to rule-out left atrial appendage thrombus and to guide transeptal puncture and WM delivery. Femoral vein access was obtained only under direct ultrasound visualization to avoid vascular accidents. In all patients a figure-of-eight stitch was placed around femoral vein access wires at the beginning of the procedure and were used to achieve hemostasis post-procedure and to minimize the need for manual pressure during recovery. All patients underwent arterial pressure monitoring via radial artery sheath placement. All transeptal punctures were performed under either TEE guidance or, in a minority of patients, using a combination of both TEE and intracardiac echocardiography (ICE) guidance. ICE was performed using the Zonare ultrasound system (Zonare, Mountainview, CA). A single transeptal puncture was performed using the Baylis radiofrequency needle and ProTrack transeptal spiral wire. In those cases where the standard 14 F Boston Scientific transeptal sheath could not be easily passed through the intra-atrial septum (IAS), a 6 mm x 40 mm angioplasty balloon was inflated across the septum to pre-dilate. All patients presented on chronic warfarin therapy for at least four weeks prior and warfarin was not held prior the procedure. In addition, all patients received heparin bolus and continuous infusion to maintain an activated clotting time (ACT) >300 seconds prior to the transeptal puncture and until all catheters and sheaths were removed from the LA. 73 patients (97%) underwent successful implant with the current generation WM device with sizes ranging from 21 mm to 33 mm diameter.

Techniques to reduce fluoroscopy and contrast use
Low fluoroscopy exposure and contrast use were achieved through several measures:
1. Fluoroscopy system adjustment: fluoroscopy exposure can reduced by complying with general principles of radiation protection including maximizing collimating, optimizing projection angle and reducing frame rates. Our standard frame rate is 3.8 frames/second to start, though this was increased as necessary during contrast injections and device deployment as necessary to optimize imaging. Most implants were performed in a hybrid cardiac catheterization laboratory dedicated to structural heart procedures and equipped with the newest available fluoroscopy software.
2. Saved images: In addition to using a low frame rate, we also used a «single shot» technique where individual one-second exposures were performed and the static image was saved to a separate review screen and used to guide decision-making.
3. Operator preference: perhaps the most critical component to reducing fluoroscopy exposure is operator awareness, motivation and diligence. In our experience, physicians agree to monitor their use and actively «stay off the pedal» when they realize that fluoroscopy is best used in combination with over other forms of imaging (TEE in this case) and not as the sole form of direct visualization.
4. Contrast minimization during appendage cannulation and catheter positioning: we were able to reduce contrast use by administering small (1–2 cc) injections with initial cannulation of the appendage and to confirm distal appendage positioning of the diagnostic pig-tail catheter. We then performed as few longer contrast injections as were necessary to adequately visualize the distal appendage anatomy and os (for sizing and to determine a «landing zone» for the device).
5. Contrast injection during deployment: from the moment deployment is started, small (1–2 cc) injections were performed at short intervals until the device was released.

For this study fluoroscopy and contrast use reduction were seen in the context of an overall «safety first» approach to this procedure. Additional safety steps were taken to reduce the risk of complication including:
• The use of US guidance and micro-puncture kits to access peripheral vessels which minimizes the risk of trauma and effectively eliminates the risk of
Achieving low radiation and contrast exposure during Watchman implants

Results

Baseline characteristics:
Between 2015 and 2017, data from 75 procedures were collected retrospectively and presented in Table 1. 73 of 75 patients underwent successful implant. Both patients with failed implant underwent multiple attempts with multiple devices but, due to challenging anatomy and concern for patient safety, the procedures were terminated without successful implant. Patients were a median age of 76 years old and 54.6% male. Patient characteristics were generally consistent across procedures.

Tools
The primary tools for the statistical analysis were Excel (Microsoft Excel 2016 with the QI Macros 2015 add-in) and RStudio (RStudio v3.4.4 with the ggplot2 package, accessed via RStudio.cloud).

Analysis – Statistical
The data were cleaned and statistically analyzed using Excel. There was only one observation from 2015, so, for the purposes of analysis, that observation was removed from the data set during hypothesis testing.

For the descriptive statistics, the median was selected due to several of the variables exhibiting non-normality. For consistency, median was the preferred method for determining central tendency throughout the analysis. When calculating the interquartile ranges, the Excel function QUARTILE.EXC was employed.

Hypothesis testing used nonparametric approaches. Continuous-variable data were analyzed using the Mann-Whitney U test. For each such variable, the observations were stratified into two groups by year (2016 and 2017). In each case, the null hypothesis was that the two distributions were equal.

Attribute data were analyzed using the 2 Proportions test. For each such variable, the observations were stratified into two groups by year (2016 and 2017). In each case, the null hypothesis was that the difference between the two proportions was zero.

Analysis – Graphical
Several variables were analyzed graphically using box plots, created in RStudio. In one case (Fluoroscopy Time for 2016), one observation (326 minutes, observation ID 12) was removed. The removal of this outlier did not change the median value (2.8 minutes).
challenging anatomy. 32% of cases required at least one partial recapture while 24% of cases required at least one full recapture.

4. Radiation exposure and contrast use: Median fluoroscopy time after the first case in 2015 was low (2.8 minutes) and remained low over time. Median absorbed dose (mGy), a more relevant measure of radiation exposure, was low (median 193 mGy) and, while it increased over time, the change was not statistically significant.

Complications:
There were no procedural complications.

Procedural success:
Procedural success was defined as successful implant of WMN device which met all PASS criteria: appropriate Position, sufficient Anchor, correct Size (compression between 8 and 20%), evidence of adequate Seal (no peri-device leak of >5mm). Implantation was aborted in 2 (2.7%) patients due to inability to confirm all four PASS criteria after multiple attempts and multiple devices.

**Discussion**
As the number and types of invasive cardiac catheterization laboratory procedures continues to grow worldwide each year, so has the concern for the use of procedure-related fluoroscopy. This is due to the understanding that fluoroscopy requires the use of ionizing radiation, that fluoroscopy continues to be the sole or primary imaging mode for such procedures and that patients who are increasingly likely to need multiple radiation-based procedures over their lifetimes.

### Table 1. Clinical characteristics of studied patients

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Statistic</th>
<th>All observations</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>P value</th>
<th>Hypothesis Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>count</td>
<td>75</td>
<td>1</td>
<td>33</td>
<td>41</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>median</td>
<td>76</td>
<td>63</td>
<td>76</td>
<td>77</td>
<td>0.22</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>9</td>
<td>n/a</td>
<td>10</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>% who are male</td>
<td>54.67%</td>
<td>100.00%</td>
<td>57.58%</td>
<td>51.22%</td>
<td>0.58</td>
<td>2 Proportions</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>median</td>
<td>170</td>
<td>185</td>
<td>170</td>
<td>168</td>
<td>0.39</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>14.0</td>
<td>n/a</td>
<td>12.5</td>
<td>14.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>median</td>
<td>85.1</td>
<td>106.1</td>
<td>84.6</td>
<td>81.7</td>
<td>0.18</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>32.4</td>
<td>n/a</td>
<td>40.7</td>
<td>29.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last BSA (m²)</td>
<td>median</td>
<td>1.99</td>
<td>2.32</td>
<td>1.99</td>
<td>1.96</td>
<td>0.23</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>0.37</td>
<td>n/a</td>
<td>0.46</td>
<td>0.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last BMI (kg/m²)</td>
<td>median</td>
<td>30.02</td>
<td>31.39</td>
<td>29.92</td>
<td>30.19</td>
<td>0.37</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>10.26</td>
<td>n/a</td>
<td>12.53</td>
<td>7.87</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHADS-VASc Score</td>
<td>median</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>0.17</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>2</td>
<td>n/a</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>% with CHF</td>
<td>16.00%</td>
<td>0.00%</td>
<td>24.24%</td>
<td>9.76%</td>
<td>0.10</td>
<td>2 Proportions</td>
</tr>
<tr>
<td>LVEF</td>
<td>median</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>0.23</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>11.0</td>
<td>n/a</td>
<td>9.5</td>
<td>10.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
<td>% with OSA</td>
<td>20.00%</td>
<td>0.00%</td>
<td>15.15%</td>
<td>24.39%</td>
<td>0.31</td>
<td>2 Proportions</td>
</tr>
<tr>
<td>Diabetes</td>
<td>% with Diabetes</td>
<td>38.67%</td>
<td>100.00%</td>
<td>45.45%</td>
<td>31.71%</td>
<td>0.22</td>
<td>2 Proportions</td>
</tr>
</tbody>
</table>

**Note:** Baseline characteristics. An «n/a» entry means not applicable, since there was only one observation. Where performed, hypothesis testing compares the observations from 2016 with the observations from 2017.

### Table 2. Atrial fibrillation type distribution

<table>
<thead>
<tr>
<th></th>
<th>All observations</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxysmal atrial fibrillation</td>
<td>% of cases</td>
<td>62.67%</td>
<td>100.00%</td>
<td>45.45%</td>
<td>75.61%</td>
</tr>
<tr>
<td>Persistent atrial fibrillation</td>
<td>% of cases</td>
<td>21.33%</td>
<td>0.00%</td>
<td>36.36%</td>
<td>9.76%</td>
</tr>
<tr>
<td>Permanent atrial fibrillation</td>
<td>% of cases</td>
<td>16.00%</td>
<td>0.00%</td>
<td>18.18%</td>
<td>14.63%</td>
</tr>
</tbody>
</table>

**Note:** Case mix by year.
Achieving low radiation and contrast exposure during Watchman implants

In addition, it is well understood that there is no safe level of radiation exposure [3]. The hypothesis regarding the harmful effects of low-dose exposure is extrapolated from the known effects of radiation at high doses, referred to as the «linear non-threshold model» which accepts that risk is related to the cumulative exposure over time. Fortunately, multiple published studies have demonstrated the feasibility, efficacy and safety of minimizing or eliminating fluoroscopy during electrophysiology studies and the techniques which reduce fluoroscopy use appear to be transferable to other interventional procedures, including WM [4‒8].

It is well documented that WM is a safe and effective alternative to OAC in patients with AF and high risk of CVA and bleeding who also have a contraindication to long-term use of OAC [1, 2]. While implant is relatively safe, it requires the use of a combination of fluoroscopy and intra-atrial contrast injections under TEE guidance [9, 10] with the in associated risks. In spite of attempts to find alternatives to fluoroscopy and contrast use (including reported cases of successful device delivery under ICE guidance), implant techniques have not changed significantly since the device received FDA approval for widespread use in the United States in 2015. Until now there are no published studies that have evaluated a systematic approach to reducing fluoroscopy and contrast use during implant.

Over the course of the first 75 implants at our center by a single operator from December, 2015 to December, 2017 a conscientious effort was made to minimize fluoroscopy and contrast use by employing a variety of techniques and safe practices originally developed for other invasive EP procedures. These data demonstrate that taking such an approach does not increase procedure time beyond what would be expected or result increased complications and does not require additional equipment or operator training beyond what is currently recommended. While this study did not demonstrate a significant reduction in radiation exposure and contrast use over time, median levels started and remained low across time. While median radiation exposure dose did appear to increase over time, this was not statistically significant. Of note, while no direct cause of increased radiation exposure time is obvious from the data, it appears to be at least in part to the complexity of the cases which appeared to increase in 2017 as we attempted more challenging anatomy. These data reflect a conscientious effort by the operator to ensure patient safety.

**Study limitations and future perspective**

This study represents a retrospective observational study by a single operator at a single center; interpretations are limited due to the nature of the data. Additionally, the operator is a relatively high-volume WM implanter who also performs over 100 additional transeptal EP procedures annually and has performed over 500 transeptal procedures in the last 7 years. However, as demonstrated here, achieving these results involved no particular skill set which could not be easily developed by any experienced operator.

This study is also limited by the fact that a comparison table:

**Table 3. Procedural characteristics**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Statistic</th>
<th>All observations</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>P value</th>
<th>Hypothesis Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful implant</td>
<td>% successful</td>
<td>97.33%</td>
<td>100.00%</td>
<td>100.00%</td>
<td>95.12%</td>
<td>0.15</td>
<td>2 Proportions</td>
</tr>
<tr>
<td>Device size (mm)</td>
<td>median</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>0.99</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preimplant Os size (mm)</td>
<td>median</td>
<td>20</td>
<td>17</td>
<td>20</td>
<td>21</td>
<td>0.49</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy exposure dose (mGy)</td>
<td>median</td>
<td>193</td>
<td>75</td>
<td>165</td>
<td>225</td>
<td>0.15</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>280</td>
<td>n/a</td>
<td>243</td>
<td>285</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>median</td>
<td>2.8</td>
<td>7.5</td>
<td>2.8</td>
<td>2.8</td>
<td>0.87</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>2.0</td>
<td>n/a</td>
<td>2.3</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contrast volume (cc)</td>
<td>median</td>
<td>70</td>
<td>65</td>
<td>70</td>
<td>70</td>
<td>0.40</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>50.0</td>
<td>n/a</td>
<td>58.0</td>
<td>50.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure time (mins)</td>
<td>median</td>
<td>55</td>
<td>59</td>
<td>55</td>
<td>52</td>
<td>0.07</td>
<td>Mann-Whitney</td>
</tr>
<tr>
<td></td>
<td>interquartile range</td>
<td>19.0</td>
<td>n/a</td>
<td>24.5</td>
<td>18.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial recaptures</td>
<td>% of cases</td>
<td>32.00%</td>
<td>100.00%</td>
<td>30.30%</td>
<td>31.71%</td>
<td>0.90</td>
<td>2 Proportions</td>
</tr>
<tr>
<td>Full recaptures</td>
<td>% of cases</td>
<td>24.00%</td>
<td>0.00%</td>
<td>18.18%</td>
<td>29.27%</td>
<td>0.26</td>
<td>2 Proportions</td>
</tr>
</tbody>
</table>

*Note: Procedural data. An «n/a» entry means not applicable, since there was only one observation. Where performed, hypothesis testing compares the observations from 2016 with the observations from 2017.*
cannot be made with prior WM data on fluoroscopy and contrast use, as this was not reported in any of the published papers.

Possible future directions include the use of ICE to effectively visualize the LAA, obviating the need for simultaneous TEE. To date, two studies have demonstrated its safety and efficacy in comparison to current implant methods but wide-spread adoption appears to be limited by several factors, including cost [8, 9]. Finally, the latest generation device, Watchman FLX, holds promise for easier implants due to the limited LAA depth required to deploy the device and greater flexibility in capturing and repositioning.

**Conclusion**

This retrospective, observational study demonstrates the safety, feasibility and effectiveness of a comprehensive approach to minimize fluoroscopy and contrast use during WM implants without compromising safety. While neither contrast nor fluoroscopy use decreased over time, both started and remained low. There were no complications associated with this study.

**Conflict of interest**

J.A. Reiss declares that there are no conflicts of interest related to this article. D.A. Evans declares that there are no conflicts of interest related to this article.

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**Author Contribution Statement**

JAR – conceptualization, methodology, administration, validation;

DAE – investigation, formal analysis, writing, review.

**REFERENCES**


