The Hybrid Video Registry: Safety and Efficacy of the Hybrid Approach in Coronary Chronic Total Occlusion Percutaneous Coronary Intervention

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The Hybrid Video Registry: Safety and Efficacy of the Hybrid Approach in Coronary Chronic Total Occlusion Percutaneous Coronary Intervention

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Abstract:

Objectives: The aim of the Hybrid Video Registry (HVR) is to assess the acute safety and efficacy of the Hybrid Approach in comparison to other contemporary methods of CTO PCI. Background: Recently, multiple techniques in Percutaneous Coronary Intervention (PCI) for coronary Chronic Total Occlusions (CTO) have been synthesized into a method referred to as the “Hybrid Approach”.

Methods: 194 video taped timed live cases from CTO PCI training workshops were analyzed by independent data abstractors and compared to three contemporary CTO PCI registries stratified by case complexity on the basis of the J-CTO score. Results: Overall procedural success was 95% of all cases attempted with an excellent safety profile. In the most complex lesion subset, which made up 45% of all HVR cases, success was 92.8%, which was significantly higher than either the Royal Bromptom (78.9%), or Japanese-CTO (73.3%) registries, $p = 0.04$ Hybrid vs. Royal Brompton, $p = 0.006$ Hybrid vs. Japanese-CTO). The Hybrid Approach was also associated with shorter procedure times and lower contrast utilization. Conclusions: In a real world angiographic registry of complex CTOs, the Hybrid Approach to CTO PCI is safe, and may be superior to other contemporary approaches to CTO intervention with
respect to procedural success and efficiency among a diverse group of operators and lesion complexity.

Introduction:

Percutaneous Coronary Intervention (PCI) for coronary Chronic Total Occlusions (CTO) is associated with improvements in quality of life, left ventricular function, and perhaps survival (1-3). Despite this evidence, many patients are not offered CTO-PCI as a therapeutic strategy (4). We developed a systematic approach to CTO-PCI called the “Hybrid approach”, which has been described in detail elsewhere (5). To date, there is a paucity of data on the success rate and efficacy of the hybrid approach. In the current study we abstracted angiographic data from video recorded CTO-PCIs performed by hybrid operators to create the Hybrid Video Registry (HVR). Here we present acute success rate and procedural efficiency of the Hybrid approach and compare these outcomes to other published series of CTO-PCI.

Methods:

The hybrid approach refers specifically to an algorithmic analysis of the CTO angiogram and subsequent initial as well as provisional strategies to most efficiently perform CTO PCI. Specifically, lesion length less than 20 mm are
approached with a wires escalation strategy as these lesions have been shown to have a high success rate with this approach (4). Lesions greater than 20 mm are treated with an intention to perform dissection and re entry given the lower likelihood of efficient wire escalation leading to CTO crossing. If the proximal cap is clear and the distal landing zone just beyond the distal cap is an adequate target, an antegrade approach is initially selected. If either an ambiguous proximal cap or a poor distal landing zone exists, a retrograde approach is initially selected provided adequate interventional collaterals exist. Utilizing this Hybrid approach, 194 Video taped, timed live case demonstrations were compiled from 25 two to four day CTO PCI training workshops across the United States and the United Kingdom between January 2011 and June 2013. 28 Hybrid operators performed the cases at 9 centers. 10 operators had > 10 years of PCI experience, 15 had 5-10 years and 3 operators had < 5 years of experience performing PCI. No patients were excluded on the basis of angiographic characteristics. The video footage including fluoroscopy, hemodynamics, and audio commentary were transferred to digital media and randomly distributed to 9 independent data abstractors not involved in the performance of the cases. A database including 61 data elements was constructed and populated from review of the cases. Success was defined as TIMI > 2 flow and < 30% residual stenosis, the same definition used in the European CTO (ERCTO) registry. TIMI 3 flow, which is considered an optimal outcome, was analyzed and additionally reported. Patients gave informed consent, and all recordings were de identified. Data from the Royal Brompton,
Japanese CTO, and ERCTO registries were abstracted from the published works (6-8). The J-CTO score, a previously described index of CTO lesion difficulty, was calculated for each case in the HVR\textsuperscript{8}. Case time was defined as the time from the first guidewire or device to be introduced into the target vessel to the final angiogram. Techniques for CTO PCI included antegrade and retrograde wire escalation, and antegrade and retrograde dissection and re-entry. Wire escalation is defined as the use of increasingly aggressive guidewires as needed to ultimately cross the CTO segment into the true lumen. Dissection and re-entry makes use of the sub intimal space within CTO segment with ultimate re-entry into the true lumen (5). Categorical variables were analyzed using Chi Square or the Fischer’s exact test where appropriate. Scalar variables were analyzed using the student’s t test. All p values were 2 tailed and a p value of < 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 21.

Results:

**Angiographic and procedural characteristics:**

194 CTO lesions were included in the analysis. Table 1 contains the baseline angiographic characteristics of the hybrid video population and the comparator registries. The target vessel was the right coronary artery (RCA) in 62%, left
anterior descending (LAD) in 23%, and left circumflex (LCX) in 13% of cases of the HVR cases. J-CTO score was higher in the HVR as compared to either the Japanese-CTO or Royal Brompton registries (2.33 ± 1.11 vs. 1.71 ± 0.068 vs. 1.87 ± 1.2 respectively p<0.001 for HVR vs. both Japanese-CTO and Royal Brompton). There was a higher frequency of prior CABG in the HVR as compared to the J-CTO registry. The case complexity in the HVR was high with a J-CTO > 3 in 45%, which was similar to the Royal Brompton registry 37%, p 0.08, and higher than the Japanese-CTO registry 27%, p < 0.001.

Four initial techniques were used in the HVR including antegrade wire escalation (AWE) in 28%, antegrade dissection and re-entry (ADR) in 49%, retrograde wire escalation (RWE) 8%, and retrograde dissection and re-entry (RDR) in 15% of cases. The initial strategy attempted was successful in 67% of cases, or 1/3 of cases required a switch to a different technique. Final successful strategy was AWE in 25%, ADR in 45%, RWE in 7%, and RDR in 13%. 26% of cases that were started with an intention to utilize the retrograde approach ultimately required an antegrade strategy, the majority of which was ADR.

The overall procedural success rate was 95%. Final TIMI 3 flow was present in 95% of successful cases. Overall 87% of successful cases had TIMI 3 flow in all left ventricular side branches ≥ 2 mm in diameter.
Success rate stratified by JCTO score:

In low or intermediate J-CTO score lesions (score 0-2) there was no difference in success rates between the registries. Among cases with a high JCTO score (>3), the success rate was 92.8% in the HVR, which was significantly higher than either the Royal Brompton (78.9%), or Japanese-CTO (73.3%) registries, p = 0.04 Hybrid vs. Royal Brompton, p = 0.006 Hybrid vs. Japanese-CTO). (figure 1).

Efficiency Analysis

Mean procedure time in the HVR was 82 ± 53 minutes and 105 ± 58 in the ERCTO registry (p <0.0001). No comparison with the Royal Brompton or J-CTO registries was possible for this variable because procedure time was not reported. Contrast utilization was also lower in the Hybrid registry when compared to ERCTO, 238 ± 105, vs. 313 ± 184 mls (p <0.0001). The J-CTO registry and Royal Brompton registries reported contrast, however standard deviations were not given so statistical comparisons could not be performed. The absolute values were higher than the hybrid registry, 293 and 350 mls respectively.

Radiation metrics were not uniform and therefore could not be compared among the registries.

Safety Analysis
Safety was similar in all three registries with low rates of major perforation requiring intervention (table 2). Of the 5 perforations in the HVR, 4 required pericardiocentesis, and 4 required a covered stent.

Discussion:
The main finding of our study was that the Hybrid approach to CTO PCI implemented by a broad spectrum of Hybrid operators is associated with a high success rate independent of case complexity as assessed by the J-CTO score. This differs from other contemporary registries in which escalating J-CTO scores predicted lower success rates. It is notable that with low J-CTO score lesions, expert operators can achieve a high success rate using any of the available techniques. However, among those with a J-CTO score greater than 2, success rate in the other contemporary registries was lower, while among the Hybrid operators success rate continued to exceed 90%.

The difference in success rates among high JCTO patients may relate to the higher use of sub intimal techniques. Early prospective use of these techniques may represent the major difference between Hybrid and non-Hybrid strategies.

Antegrade or retrograde dissection and re-entry was utilized in 64% of the cases in the HVR, whereas these techniques were used in <26% of the cases in the Japanese-CTO and <38% of cases in the Royal Brompton registries.
Sub intimal dissections with a blunt catheter, such as the Crossboss (Boston Scientific, Natick, Ma), or a knuckled guidewire may increase efficiency in complex lesions when compared to traditional techniques, which aim to stay within the intimal plaque. While wire escalation techniques both antegrade and retrograde were employed in the HVR in 60% of cases with a J-CTO score ≤ 1, the prospective utilization of subintimal dissection and re-entry was higher in more complex lesions, representing 68% of lesions with a J-CTO score ≥ 2. In addition, as a provisional strategy for antegrade wire escalation failure, antegrade dissection and re-entry with the Stingray device (Boston Scientific, Natick, Ma) has been demonstrated to be safe and effective (9).

Additionally, the retrograde approach to CTO intervention is not possible in nearly 20% of cases preselected due to uncrossable collaterals either with the guidewire or support catheter. In these cases, the antegrade success rates are only 60% in a recently reported registry from Japan (10). This limitation of retrograde CTO-PCI can be overcome in many instances with antegrade dissection and re-entry. In the Hybrid registry, of the 35 cases that began with a primary retrograde approach, 26% had failure to cross the collateral or failure to cross the CTO retrograde. In these cases, ADR was successful 78% of the time, which exceeds the success rate with traditional techniques cited above. This highlights the utility of ADR as a bailout when collateral crossing is not possible in a procedure initially selected for a retrograde approach.
Limitations of our study include the lack of available patient level data from the comparator registries. These data would have allowed for propensity matching to more robustly compare contemporary approaches to CTO PCI. In that case, we might expect the Hybrid approach to compare even more favorably than our study suggests given the significantly higher J-CTO score in our patient cohort.

Cases were performed in the context of courses focused on teaching antegrade dissection and re entry along with retrograde techniques so those approaches may be over represented in these data, but nonetheless success rates are quite high with a good safety profile. Due to the design of the HVR, rates of ischemic complications post PCI could not be ascertained so complete safety information is lacking. Finally, we did not collect follow up data and cannot assess long-term patency or safety of sub intimal stenting. A report from the J-Proctor angiographic follow-up study suggests that MACE and TVR rates among IVUS adjudicated intimal vs. sub intimal stenting are similar (11).

**Conclusion:**

Using a real world angiographic registry of complex CTOs, the Hybrid Approach to CTO PCI may be superior to other contemporary approaches to CTO intervention with respect to procedural success and efficiency among a diverse group of operators and lesion complexity. With increasing lesion complexity, the prospective use of both antegrade and retrograde dissection and re-entry is safe and associated with excellent success rates.

**References**


Figure Legend

Figure 1: Final success in the Hybrid Video Registry in comparison to the Royal Brompton and Japanese CTO registries stratified by J-CTO score.

Figure 2: Distribution of J-CTO score as a measure of lesion complexity among the three registries.
Table 1

<table>
<thead>
<tr>
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<th>Hybrid Registry</th>
<th>J-CTO Registry</th>
<th>Royal Brompton Registry</th>
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<tr>
<td></td>
<td>(N=194 lesions)</td>
<td>(N=498 pts, 528 lesions)</td>
<td>(N=195 pts, 269 lesions)</td>
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<tr>
<td>Lesion Length</td>
<td>29.9 ± 24.4</td>
<td>13.5 ± 13.0</td>
<td>22 (IQR 15-32)</td>
<td>&lt;0.001</td>
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<td>Length &gt; 20mm</td>
<td>63%</td>
<td>21%</td>
<td>63.1%</td>
<td>&lt;0.001</td>
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<td>Calcified</td>
<td>61%</td>
<td>58%</td>
<td>50.8%</td>
<td>0.036</td>
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<tr>
<td>Tortuosity</td>
<td>31%</td>
<td>45%</td>
<td>22.1%</td>
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<tr>
<td>Blunt Stump</td>
<td>61%</td>
<td>38%</td>
<td>47.2%</td>
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<td>Prior Failure</td>
<td>16%</td>
<td>10%</td>
<td>37.9%</td>
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<td>Prior CABG</td>
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<td>J-CTO Score</td>
<td>2.33±1.11</td>
<td>1.71±0.068</td>
<td>1.87±1.2</td>
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*Hybrid Registry vs. J-CTO Registry,  † Hybrid Registry vs Royal Brompton Registry
Table 2

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<thead>
<tr>
<th></th>
<th>Hybrid Registry (N=194 pts)</th>
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<th>Royal Brompton Registry (N = 195 pts)</th>
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<tr>
<td>Death</td>
<td>0%</td>
<td>0.4%</td>
<td>0%</td>
<td>NS</td>
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<td>Any Perforation</td>
<td>6%</td>
<td>10%</td>
<td>4.6%</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td>^0.625</td>
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<tr>
<td>Perforation requiring</td>
<td>2%</td>
<td>0.2%</td>
<td>1%</td>
<td>*0.0371</td>
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<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
<td>^0.654</td>
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*Hybrid Registry vs J-CTO Registry,  †Hybrid Registry vs Royal Brompton Registry
Figure 1: Final success in the Hybrid Video Registry in comparison to the Royal Brompton and Japanese CTO registries stratified by J-CTO score.

77x38mm (300 x 300 DPI)
Distribution of J-CTO score as a measure of lesion complexity among the three registries.

2.30±0.091 1.87±1.2 1.71±0.068

p < 0.0004

Distribution of J-CTO score as a measure of lesion complexity among the three registries.

139x119mm (300 x 300 DPI)