

Peer Review File

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This is a single arm study assessing the efficacy of the use of Robot in the setting of PCI. The authors had 42 patients with multiple lesions. While I commend the authors on this important step, there remains significant issues with the work that needs to be addressed:

Reviewer's Comment #1

- Please clarify carefully how much of the work is done by the Robot, or when the robot was used to perform the procedure, at time of stent deployment? at the time of target identification? right from the start of RA or FA incision?

Authors' Reply #1

We thank the reviewer for this bringing this important issue up. The role of the robot during the interventional procedure must be precisely described in the method chapter. The text was modified to accommodate the reviewer's comment accordingly:

From (Methods/Robotic-Assisted Percutaneous Coronary Intervention/Robotic-Assisted PCI section; Page 9, line 157 - 162 in the original version):

“Vascular access and insertion of the guide-catheter to the coronary ostium was performed as usual, entirely left at the discretion of the operator. In our study, both total and hybrid robotic-assisted PCI were allowed. However, the operator had to inform prior to the initiation of the procedure which strategy would be used. Also, for those undergoing planned hybrid robotic-assisted PCI, the interventionalist was asked to annotate, before the beginning of the intervention, which steps were intended for manual or robotic manipulation.”

To (Methods/Robotic-Assisted Percutaneous Coronary Intervention/Robotic-Assisted PCI section; Page 9, line 157 - 167 in the revised version):

“Vascular access, insertion of guide-catheters was performed manually as usual care, entirely left at the discretion of the operator. Only after engagement of the coronary ostium the robotic assistance begins, allowing for manipulation of 0,014” guide-wires, balloons, and stents, which are remotely controlled by operators outside the room through a control panel. Additionally, robotic manipulation of the guide-catheter is also possible, permitting small positioning adjustments. Exchanges of materials (e.g. balloons, stents) during the procedure are performed by the interventional staff. In our study, both total and hybrid robotic-assisted PCI were allowed. However, the operator had to inform prior to the initiation of the procedure which strategy would be used. Also, for those undergoing planned hybrid robotic-assisted PCI, the interventionalist was asked to annotate, before the beginning of the intervention, which steps were intended for manual or robotic manipulation.”

Reviewer's Comment #2

Can you identify the Syntax score for the cohort?

Authors' Reply #2

We fully agree with the reviewer that presenting the SYNTAX score is a good way to represent the degree of disease extension of the enrolled cohort, and was added to the text. However, we must note that the low mean average SYNTAX score in our population, which comprised relatively young patients with acute coronary syndromes, may not entirely reflect the level of anatomical complexity in a per lesion analysis. Accordingly, the text was modified:

From (Table 1; Page 22, line 444 in the original version):

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Lesion type	
A/B1	25 (22.3)
B2	21 (18.8)
C	66 (58.9)
Complexity characteristics	
Moderate or severe calcification	21 (18.8)
Moderate or severe tortuosity	25 (22.3)
Lesion angulation > 45°	27 (24.1)
True bifurcation	22 (19.6)
Aorto-ostial lesion	4 (3.6)
Any of the above	56 (50.0)

To (Table 1; Page 22, line 484 in the revised version):

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SYNTAX score	11.0 ± 7.0
Lesion type	
A/B1	25 (22.3)
B2	21 (18.8)
C	66 (58.9)
Complexity characteristics	
Moderate or severe calcification	21 (18.8)
Moderate or severe tortuosity	25 (22.3)

Lesion angulation > 45°	27 (24.1)
True bifurcation	22 (19.6)
Aorto-ostial lesion	4 (3.6)
Any of the above	56 (50.0)

From (Discussion; Paragraph #2; Page14, line 259-267 in the original version):

“As previously shown by other groups and ours, robotic-assisted PCI undeniably provides distancing between the interventionalist and the tableside, producing a much-improved work environment regarding radiation exposure, procedural ergonomics, orthopedic protection, and interpersonal air sharing.(5-13) Notwithstanding the fact that those are valuable benefits, in order to be fully and largely adopted, the novel technology must be proven functional and reliable, without compromising the already good clinical results achieved with traditional manual intervention. Our findings suggest that robotic PCI is a safe and effective procedure when applied to a relatively complex patient population, maintaining the expected high levels of clinical performance even as shortly as upon its introduction.”

To (Discussion; Paragraph #2; Page 14, line 286-298 in the revised version):

“As previously shown by other groups and ours, robotic-assisted PCI undeniably provides distancing between the interventionalist and the tableside, producing a much-improved work environment regarding radiation exposure, procedural ergonomics, orthopedic protection, and interpersonal air sharing.(5-13) Notwithstanding the fact that those are valuable benefits, in order to be fully and largely adopted, the novel technology must be proven functional and reliable, without compromising the already good clinical results achieved with traditional manual intervention. Our cohort, composed of young patients with acute coronary syndromes, presented a low mean average SYNTAX score, which reflects a modest disease extension but may not entirely describe the level of anatomical complexity of the target lesions. In fact, half of the patients presented at least one feature of angiographic complexity of the treated segment. Our findings suggest that robotic PCI is a safe and effective procedure, maintaining the expected high levels of clinical performance even as shortly as upon its introduction.”

Reviewer’s Comment #3

How can you justify the longer operating time for last 41 patients?

Authors' Reply #3

This is an important observation by the reviewer. We think that due to the small sample size of the cohort, this situation may have occurred as a bias. Thus, we chose not precisely exemplify it but we made a modification on this way as following:

Discussion; Paragraph #4 Page15, line 275-281 in the original version:

“The collection of the present cohort completely encompass the learning curve of our group with the new technology. Curiously, we were not able to demonstrate a clear-cut difference in the profile of patients and results of procedures between the first half and the last half of the population. It is noteworthy that the team comprised a highly experienced group of interventionalists, nurses, and technicians who rapidly embraced robotic-PCI, something that might have damped the learning curve. Robotic-PCI seemed to be easily implemented to the daily practice of a busy catheterization laboratory”.

Discussion; Paragraph 4, Page 15, line 308-316 in the revised version:

“The collection of the present cohort completely encompasses the learning curve of our group with the new technology. Curiously, we were not able to demonstrate a clear-cut difference in the profile of patients and results of procedures between the first half and the last half of the population. It is important to mention that the study was not designed for this purpose and therefore does not have statistical power to differentiate this situation. On the other hand, it is noteworthy that the team comprised a highly experienced group of interventionalists, nurses, and technicians who rapidly embraced robotic-PCI, something that might have damped the learning curve. Robotic-PCI seemed to be easily implemented to the daily practice of a busy catheterization laboratory”.

Reviewer's Comment #4

Can you add more on the operator experience? how many cardiologist / tech people were actually involved in the process.

Authors' Reply #4

As all new technology that embraces medical procedures is an important step to understand the learning curve of the entire team and previous experience with comparable procedures as well. So, we appreciate the reviewer's observation for the authors and we made a modification in the text in an attempt to clarify this issue.

Deleted sentence: (Results; Paragraph #1; Page12, line 227-228 in the original version):

“All procedures were performed by five fully certified interventional cardiologists with

a minimum of 20 years of experience in manual PCI”.

From: (Methods/Robotic-Assisted Percutaneous Coronary Intervention/Training and Education Plan section; Page 9, line 164 - 167 in the original version):

“After the system was installed in the hospital, before the first patient was treated, the whole team of interventionalists, technicians and nurses was extensively exposed to the functioning details of the equipment, in a training and education program provided by the manufacturer, conducted at the hospital”.

To: (Methods/Robotic-Assisted Percutaneous Coronary Intervention/Training and Education Plan section; Page 9-10, line 169-184 in the revised):

“After the system was installed in the hospital, before the first patient was treated, the whole team of interventionalists (five fully certified interventional cardiologists with a minimum of 20 years of experience in manual PCI), together with six registered nurses, and seven cath lab technicians were extensively exposed to the functioning details of the equipment, in a training and education program provided by the manufacturer, conducted at the hospital”.

Reviewer’s Comment #5

Perhaps it will make more useful if you compare those results with a normal PCI cohort in the same period?

Authors’ Reply #5

We thank the reviewer for this important comment. We fully agree that a study such as ours must be a comparative one. Surely, one could think of a randomized study, fully powered to evaluate clinical outcomes, as an ideal trial. The present project, however, was conceived to interrogate the initial experience of a single center. In this context, we opted for a relatively small, one-arm, study that aimed to assess safety and efficacy in comparison against pre-defined optimal goals. We extensively cogitated having a prospective parallel control arm, as suggested by the reviewer, but we considered that this would increase greatly the complexity of the study without adding a proportional gain in quality of the data. In any ways, we trust that the optimal goals of performance, which were pre-defined upfront, contain sufficient information to be utilized as a standard point estimation of efficacy and safety against which our robotic-PCI results were compared.

Reviewer’s Comment #6

6. How about cost efficiency and it is reflect on current practice? why some should use robot instead of conventional practice? how can this be justified please?

Authors’ Reply #6

This a very important issue showed by the reviewer and we are thankful for that. Robotic

angioplasty is a new technology that is still under development. Overcoming the already excellent results of conventional angioplasty is a great challenge for the robotic PCI. On this way we already provided some argumentations into the discussion and added a new sentence as following:

In the original version: (Discussion; Paragraph #6, pages 15-16; lines 291-298 in the original version)

“It is our perception that a full and comprehensive utilization of the technology at its highest interventional capacity might require longer and continued use, most probably coupled with a change in the mindset of operators, who will need to renovate their manual skills into new “joysticking” abilities. As of today, robotic-PCI is totally dependent on the operators’ scrutiny and abilities. Future developments, already in course, that will add automatic and programmed features to the platform, may be able to enhance the procedure workflow by offering to interventionalists new and advanced maneuvering capabilities that may surpass manual operation in subtlety, delicacy, precision and repeatability”.

Added sentence (Discussion, Paragraph 5, Page 15-16, line, 325-329 in the revised):

Finally, as all new technology, robotic-PCI may result in additional costs essentially at early stages of the method. However, we believe that a more widespread use can reduce the current costs of the procedure and if the development of the method beats the safety and efficacy results of conventional coronary angioplasty, especially for more complex cases, it will be cost effective in the most of the procedures.