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Editorial

The way forward in research on robotic cardiac surgery: the need for transatlantic robotic cardiac surgery registry

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Robotic cardiac surgery is gaining momentum owing to the less invasive approach that may facilitate patient recovery. Although there is no randomized controlled trial (RCT) comparing robotic-assisted approach with conventional approach, the observational data from the National Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS ACSD) suggest an advantage of the robotic approach over sternotomy or thoracotomy in mitral valve repair (MVr) (1). However, there exists a fundamental challenge in studying comparative effectiveness or safety in robotic operations because the robotic approach is most commonly adopted by a more experienced surgeon and team. Expertise-based trials, including the UK Mini-Mitral trial, showed no significant difference between mini-thoracotomy MVr versus open MVr, demonstrating that less invasive approach may be as safe and effective as open MVr (2). Whether such findings apply to robotic MVr compared with sternotomy or thoracotomy approaches remains unknown. In this Editorial, we outline the challenges and gaps in the research on robotic cardiac surgery that may be addressed through international collaborations.

Current landscape

A robotic approach to cardiac surgery was initially adopted in minimally-invasive coronary artery bypass graft (CABG), either by minimally-invasive direct coronary artery bypass (MIDCAB) or totally endoscopic coronary artery bypass (TECAB) approach (3). MIDCAB uses a robotic approach during internal mammary artery harvest only, while TECAB is totally endoscopic, with vessel anastomosis also being performed robotically (4). The adoption has fluctuated over time, increasing recently in Europe (5). Robotic-assisted CABG comprises about 1% of the CABG performed in the USA but may be rising (6). USA has seen a steady increase in the proportion of MVr's done robotically for degenerative mitral disease, approaching 15% of all MVr's (1). High-volume centers report excellent survival and durability at mid-term after MVr (7). Atrial septal defect or patent foramen ovale closures can also be performed robotically in adults and older children (8).

Research challenges in evaluating comparative effectiveness and safety

Despite its increasing interest, the best evidence on robotic cardiac surgery is limited to observational studies. In procedures that require sub-specialization and unique infrastructure, it may not be possible to conduct a broadly generalizable RCT. In the USA, surgeons with predominantly robotic practice are usually marketed as such, and randomizing patients with a strong preference for one approach over another is challenging. At the surgeon-level, randomization would require each participating surgeon to be proficient in both approaches. A more conventional approach likely has higher cumulative experience among surgeons, and the trial design would have to ensure that the surgeon has surpassed the learning curve of the more novel approach. Inferring from the UK Mini-Mitral trial, RCT's comparing robotic to sternotomy approaches could be successfully performed in Europe, but broad adoption of robotics in cardiac surgery may be limited due to the cost and regulatory landscape in the European Union (EU).

Another potential source of bias in comparing the robotic approach to mini-thoracotomy or sternotomy is patient characteristics that could exclude them as a robotic candidate. These characteristics may be related to outcomes, necessitating documentation and adjustment. Examples include femoral vessel size, tortuosity, atherosclerosis, low ejection fraction, mitral annular calcification, and aortic insufficiency. A conservative screening criteria may exclude almost half the potential candidates for robotic mitral valve (MV) operations (9) Therefore, retrospectively comparing the outcomes requires a database designed with these potential sources of bias in mind.

Data management requires additional caution with rigorous deidentification protocol to comply with multiple federal and regional laws, such as USA's Health Insurance Portability and Accountability Act (HIPAA) and EU's General Data Protection Regulation.

Research needs

There are three major topics needing further research in robotic cardiac surgery: (I) efficacy/safety; (II) cost and utilization; and (III) learning curve.

The challenges in conducting a conventional RCT may necessitate a novel pseudo-trial study design. For example, a prospective international registry could require participants to undergo a virtual committee evaluation to document whether the patient is a good candidate for either approach, with thorough documentation of the reason for disqualification. This would allow investigators to minimize the key bias source in treatment assignment between conventional versus robotic approaches. Conventional clinical variables, along with the committee consensus, could be adjusted for in multivariable models with a more robust causal inference approach, such as target trial emulation, to yield less biased estimates. The key is recognition of the retrospectively insurmountable selection bias that is inherent in existing registries. Important endpoints include survival, complication rates, long-term recurrence of significant mitral regurgitation after mitral repair, and major cerebral and cardiovascular events after CABG.

Cost and utilization depend on the temporal and economic landscape of the country, which is important to consider in international studies. Recognizing the dynamic nature of the cost, robotic mitral operation at an experienced center in the USA may be cost-neutral to conventional approaches (10). Cost estimation in robotic operations requires particular attention to unique disposable instrument costs as well as different financing options (per use base, lease) for the robotic infrastructures. Observational studies have consistently shown that robotic approaches decrease hospital resource utilization such as blood transfusion and length of stay (1,10), which may neutralize the cost of the robot and instruments.

The learning curve for a less invasive approach in mitral operations has not been investigated rigorously beyond a single center setting. Although the national STS ACSD analysis suggested a threshold of forty cumulative robotic mitral cases at a center level, how this translates to the surgeon-level learning curve and whether non-mitral robotic experience or non-robotic mitral experience contributes to this volume remain unknown. This topic can be further researched using existing national-level registries to provide a more granular understanding of characteristics associated with the successful trajectory of newly instituted robotic programs.

Taken together, developing a transatlantic registry encompassing broad care settings and regulatory landscapes that captures long-term follow-up would be a critical tool to provide more evidence of the benefits of robotic cardiac surgery.

Conclusions

Robotic cardiac surgery has gained momentum over time, and we currently live in the exciting era of further evidence generation. We proposed three areas needing future research that could be facilitated by a close international collaboration.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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