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Review of Surgical Outcomes associated with Robotic Assisted Mitral Valve Repair (RMVR)

Abstract

Objective: The purpose is to examine how robotic assisted mitral valve repair affects surgical outcomes for patients with degenerative mitral valve disease. Methods: A comprehensive literature review was conducted by examining literature from the MEDLINE database. Research articles, literature reviews, and statistical reports were accessed using PubMed through the UMD Database Finder. Literature which examined the surgical outcomes of RMVR and its comparison with conventional mitral valve repair (CMVR) were analyzed. Results: The literature shows consistent surgical outcomes for mortality, morbidity, and mitral valve durability for patients who underwent RMVR. However, cardiopulmonary bypass (CB) and cross clamp (XC) times are significantly longer, hospital stay times are significantly shorter, and the quality of life for patients is significantly higher. Conclusions: RMVR is a safe and effective operation which provides consistent and even superior surgical outcomes for patients with degenerative mitral valve disease. Further research into long term mitral valve durability (>5 years) for patients who underwent RMVR is recommended.

Introduction

The heart is an essential organ which powers the cardiovascular system of the human body. Cardiac function is responsible for adequately pumping blood throughout the body, which is essential for nutrient transport, oxygen delivery, and carbon dioxide expulsion. Unfortunately, cardiovascular disease is the leading cause of death in the United States, with cardiovascular issues being responsible for 1 in 4 deaths (Benjamin et al., 2017). Therefore, the clinical

advancement of cardiovascular medicine is crucial for mitigating deaths due to cardiovascular pathologies.

The primary aim of cardiovascular medicine, including cardiothoracic surgery and cardiology, is to correct, reduce, or prevent cardiac pathology. The heart acts as a double pump, pumping oxygen deficient blood to the lungs for oxygenation, and then pumping the returning oxygenated blood to the rest of the body. To ensure proper blood flow, the heart contains four valves which prevent blood from regurgitating backwards. The valves continuously open and close, making the valves prone to degenerative disease over the course of a lifetime. The mitral valve, which regulates blood flow between the left atrium and the left ventricle, is most susceptible to degenerative damage. Since the left ventricle pumps blood throughout the entire body, the mitral valve is under higher pressure when regulating blood flow.

Mitral valve disease is typically a degenerative process which results in mitral valve prolapse, or an improper movement of the leaflet. Mitral valve degenerative disease may result in stenosis or regurgitation of the valve, interfering with blood flow and causing the heart to work harder. Impaired cardiac function leads to poor cardiovascular function, making it more difficult for patients to perform day to day activities. As the mitral valve degenerates more and more, its impaired function can lead to heart failure, which can eventually lead to death. To prevent further mitral valve degeneration and to prevent regurgitation, cardiothoracic surgeons can perform mitral valve repair, a commonly practiced open heart surgery (Cohn et al., 2015).

Mitral valve repair is a surgical procedure aimed at repairing mitral valve leaflet prolapse, so that proper function of the mitral valve is restored as much as possible. The practice of mitral valve repair has drastically changed clinical outcomes for patients with mitral valve disease, making it possible for patients to achieve full function of the mitral valve post-surgery. This procedure can be performed through three main approaches: conventional, mini, and robotic. In the conventional approach, a full sternotomy is performed and the surgeon uses his/her hands

to repair the mitral valve. The mini approach utilizes a smaller incision for the sternotomy, reducing the trauma done to the sternum. The third approach, and more recently developed, is the robotic approach which utilizes robotic machinery (Da Vinci System) to repair the mitral valve.

RMVR is currently the least invasive option for anatomically repairing the mitral valve, utilizing a right thoracotomy rather than a conventional sternotomy. The implementation of RMVR into surgical practice poses huge questions on how it is affecting patient outcomes. Currently, it is still being debated within literature about which surgical approach provides the most optimal surgical outcomes for patients (Gillinov et al., 2016). This literature review looks at the implications of robotic assisted mitral valve repair on the surgical outcomes of patients with degenerative mitral valve disease. The work starts by discussing the development of mitral valve surgeries into present day. Then, the paper discusses the surgical outcomes of robotic mitral valve repair, including mitral valve durability, hospital stay time, cardiopulmonary bypass and cross clamp time, stroke risk, mortality risk, and quality of life. Lastly, the paper discusses the efficacy and safety of practicing robotic repair by assessing the quality of surgical outcomes.

History

Although cardiac procedures are routinely performed today, the world of medicine was resistant to cardiac procedures in the 19th and 20th centuries. The inability to operate on a beating heart made cardiac surgery a notion outside the capabilities of medicine. There were, however, few innovative surgeons who attempted novel cardiac procedures, leading the way to the development of open-heart surgery. In the late 19th century, Dr. Henry Dalton became the first surgeon to successfully repair a pericardial wound, and thus cardiac surgery was born (Weisse, 2011).

As extracardiac surgeries became more prominent, surgeons were faced with the ultimate challenge: performing open heart surgery. To be able to perform open heart surgery,

the circulatory system must be redirected so that the heart stops beating. In the late 20th century, the cardiopulmonary bypass machine was developed, allowing surgeons to medically induce cardiac arrest without the presence of blood flow, thus granting access to the heart (Weisse, 2011). The cardiopulmonary bypass machine acts as an outside heart by oxygenating the blood outside of the body and redirecting blood flow so that the heart can be bypassed. Since surgeons now had direct vision into the heart, a variety of cardiac pathologies were now capable of surgical correction.

With the development of the cardiopulmonary bypass machine, many surgeons looked to repair valvular pathologies. In 1983, Dr. Alain Carpentier published a paper called “The French Correction”, which outlined the “pathophysiological complications of mitral valve lesions” and provided a process for performing consistent and effective mitral valve repair (Cohn et al., 2015). The paper inspired surgeons to perform more mitral valve repairs, and subsequently the rate of mitral valve repairs increased dramatically.

Early mitral valve repairs were performed by doing a complete sternotomy. To avoid complications with sternal trauma, many surgeons began practicing minimally invasive mitral valve repair which utilizes a smaller incision in the sternum. Minimally invasive mitral valve repair has been found to “decrease trauma, blood transfusion requirements, and costs” (Cohn et al., 2015). However, the success of this procedure relative to the conventional approach is dependent on the quality of mitral repair performed.

In the early 21st century, many tertiary hospitals began to use robotic assisted mitral valve repair (RMVR) for treating mitral valve regurgitation. Currently, the adoption of RMVR remains questioned by many surgeons due to concerns over “patient safety, mitral valve repair rates, and procedural complexity” (Gillinov et al., 2016). Although RMVR has become a standard at many hospital centers, the quality of its surgical outcomes and its relation to a traditional sternotomy still needs to be assessed. To address the efficacy and safety for RMVR,

the surgical outcomes for patients with degenerative mitral valve disease will be assessed for quality and compared with the conventional approach.

Current Research

To understand the implications RMVR has on patients with degenerative mitral valve disease, the surgical outcomes of patients will be assessed by discussing primary literature of RMVR. The primary literature focuses on echocardiographic data (mitral valve durability), hospital stay time, cardiopulmonary bypass (CB), cross-clamp times (XC), morbidity risk, mortality risk, and the quality of life.

Mitral Valve Durability

The primary purpose of mitral valve repair is to anatomically repair the prolapsed mitral leaflet to reduce mitral regurgitation (MR). Consequently, the overall success of this procedure is determined by how durable the mitral valve is post-operation. A durable mitral valve post-surgery ensures minimal regurgitation of blood, and thus a reduction of symptoms for the patient. If the mitral valve continues to prolapse significantly post repair, then the operation has failed to correct the valvular pathology. The durability of the mitral valve is a crucial surgical outcome which must be considered when assessing the efficacy of a mitral valve repair.

In a study at a Korean Institution, the long-term mitral valve durability of patients whom underwent RMVR was assessed by analyzing echocardiographic reports for 310 patients. The pre-discharge echocardiogram displayed minimal mitral valve regurgitation (MR), indicating that RMVR is successful in the short term. To assess the long-term mitral valve durability, late echocardiographic reports (> 6 months) showed that 86.5% of patients were free from significant mitral valve regurgitation. Although 10.8 % of patients developed significant mitral valve regurgitation, the long-term success in the majority of patients showed that RMVR is a safe procedure with acceptable long-term mitral valve durability (Kim et al., 2017).

Another study at a European Center examined echocardiographic data for mitral valve durability in the short term and long term for patients who underwent RMVR (Navarra et al., 2017). The study found that all patients had none to minimal MR when assessing the pre-discharge echocardiograms. In the long term, 92.5 % of patients were found to have freedom from MR at 12 months and 80.6 % of patients had freedom from MR at 36 months (Navarra et al., 2017). This study also indicated that the use of RMVR yields excellent short term and long-term mitral valve durability for patients.

To better understand the long-term durability of the mitral valve post robotic repair, a third study examines echocardiographic follow ups with 81 patients who underwent RMVR. The analysis found that only 4.9% of patients experienced significant mitral valve regurgitation post-operation, with an average echocardiographic follow up of 36 months post-surgery (Wang et al., 2016). These results support previous studies indicating that RMVR has excellent outcomes for mitral valve durability.

The literature suggests that the use of RMVR has excellent outcomes for mitral valve durability in the short term and long term for patients. This indicates that the repair done through the Da Vinci system is a viable alternative to a repair done through the conventional approach.

Hospital Stay Time

The amount of time a patient must spend recovering in the hospital after surgery is important when considering how effective the surgery is. Surgeries which allow for fewer incisions and less trauma are typically preferred over more invasive surgeries to allow for quicker recovery times for patients. In this section, the hospital stay length will be assessed for patients whom underwent RMVR and compared with patients whom underwent CMVR.

In a study by Dr. Hawkins, data of 2300 patients from the Society of Thoracic Surgeons were extracted and stratified by approach, including the robotic, mini, and conventional

approach (Hawkins et al., 2018). The study found that patients who underwent RMVR had lower lengths of stay in the hospital when compared with patients who underwent the conventional approach. The results of this study show that perhaps the less invasive thoracotomy performed in the robotic approach yields faster recovery times than a sternotomy. Other literature also supports RMVR yielding shorter hospital times for patients. In another study aimed at assessing perioperative outcomes of RMVR and non-robotic approaches, it was found that there was a significant decrease in hospital stay times for patients who underwent RMVR (Paul et al., 2015). In a third study examining success of RMVR vs nonrobotic surgery in older patients, patients who underwent robotic surgery had faster recovery times (Wang et al., 2018).

However, some literature reports finding no difference in post-operative stay between the robotic and conventional approach. In a metaanalysis aimed at assessing the surgical outcomes of RMVR, data analysis found no significant difference in hospital stay between both approaches (Cao et al., 2015). However, the authors emphasize interpreting the results with caution, as the patients used for the metaanalysis have differing characteristics.

Most literature on clinical outcomes of RMVR indicate that the procedure yields shorter recovery time in the hospital; however, a single metaanalysis provides evidence to the contrary. The difference in hospital stay time is most likely caused by the respective incisions made in each approach, with the robotic approach on the more minimally invasive end. The shorter hospital stay times indicate that RMVR may provide superior recovery times when compared with CMVR.

Cardiopulmonary Bypass and Cross-Clamp Time; Morbidity (stroke risk)

The cardiopulmonary bypass machine redirects blood from the heart and allows surgeons to operate on the heart during cardiac arrest. To use bypass, the aorta must be clamped to prevent blood flow into the heart while surgery is being performed (cross clamp time). Unfortunately, cardiopulmonary bypass comes with its own complications, including

inflammation of the blood and an increased risk of embolisms. The rotor machinery used to pump blood can damage red blood cells and facilitate the formation of embolisms, which can lead to stroke and renal failure. To assess the efficacy of an open-heart surgery, the length of cardiopulmonary bypass (CB), length of cross-clamp (XC) time, and risk for stroke must be examined.

In a systematic review examining the clinical outcomes and cost effectiveness of RMVR, data from 27 papers were extrapolated, with 16 of the papers having data from greater than 50 patients. From the metaanalysis, the CB and XC times were found to be longer in the robotic approach when compared to times in the conventional approach (Seco et al., 2013). Other individual studies also yielded similar results regarding CB and XC times. In the beginning stages of RMVR, the FDA approved a phase II trial of several patients undergoing RMVR. For this clinical study, researchers examine the safety of using RMVR by examining clinical outcomes for 112 patients with mitral valve disease. The results provide especially long CB and XC times, and researchers recommended advances in robotic technology to help decrease the procedural time for RMVR (Nifong et al., 2005).

Although literature shows that CB and XC are longer in the robotic approach, the risk for stroke is found to be at an acceptable level, and even similar to stroke risk from the conventional approach. In a study examining the first 1000 cases of RMVR at a tertiary center, the stroke risk was found to be 1.4%, a relatively low risk for patients (Gillinov et al., 2018). In another study examining surgical complications between the two approaches, the risk for stroke was found to be similar for both approaches (Paul et al., 2015).

The literature shows that although CB and XC times are longer for the robotic approach, the risk for stroke is acceptable and corresponds with stroke risk from the conventional approach.

Mortality

The mortality risk represents how many patients survive an operation, providing insight into how risky or effective a given surgery is. The mortality rate is indicative of how successful a given operation is, therefore the mortality rate for RMVR will be assessed in terms of risk and comparison to the conventional approach.

Two studies show that the mortality risk for RMVR is acceptable and low. In the first study, the first 1000 cases of RMVR at a tertiary center are examined for the safety and efficacy of the procedure. The mortality risk was found to be 0.1% for patients, an acceptable and “low operative mortality” (Gillinov et al. 2018). In another study examining perioperative outcomes between the robotic and non-robotic approach, 3147 cases of RMVR were examined for rates of mortality and morbidity. The rates of mortality are found to be acceptable and similar between both approaches (Paul et al., 2015).

The literature primarily shows that mortality risk is acceptable and relatively low for RMVR, and similar to mortality rates found through the conventional approach. The rates of mortality indicate that RMVR is a safe procedure for patients with degenerative mitral valve disease.

Quality of Life

The quality of life indicates how satisfied the patient is with their lives post-surgery. Most literature does not address this clinical outcome, as it is difficult to operationalize. Nonetheless, it is an important surgical outcome to examine when assessing the implications of a certain operation. From all the literature examined, one study uses a quality of life (QOL) survey to assess the quality of life for patients who underwent robotic repair versus patients who underwent traditional repair (Suri et al., 2012). A postsurgical QOL survey was mailed to 202 patients who underwent CMVR or RMVR between January 2008 and November 2009. The QOL survey consisted of the Duke Activity Status Index, Short Form-12 Item Health Survey, and

Linear Analogue Self-Assessment Frequency for chest pain and fatigue; these components measure pain and activity levels post-surgery. In both surgical approaches, patients scored excellent results in the QOL survey. However, patients who underwent robotic repair scored slightly higher in the QOL survey versus patients who underwent the traditional repair (Suri et al., 2012).

The results of this study show that patients who receive RMVR may experience higher levels of life satisfaction post-surgery compared with patients who receive the traditional approach. Specifically, patients who underwent RMVR may experience lower pain associated with recovery and even a faster recovery time.

Conclusion

The aim of this literature review is to address how the implementation of RMVR affects surgical outcomes for patients with degenerative mitral valve disease. The surgical outcomes discussed from primary literature include mitral valve durability, hospital stay time, CB and XC time, stroke risk, mortality risk, and quality of life. From analyzing the surgical outcomes of RMVR, the literature suggests that RMVR has acceptable surgical outcomes for patients, and sometimes superior outcomes when compared with the conventional approach.

Echocardiographic data from studies strongly support that RMVR has acceptable short term and long-term mitral valve durability, indicating the repair can be done successfully through the robotic approach. In addition to quality repairs, the mortality risk through RMVR is acceptable and similar to mortality risks associated with the traditional approach. These results suggest that patients who undergo RMVR are not at a higher risk of death.

However, assessing the CB and XC times show that the RMVR is associated with much longer procedural times. Although longer CB and XC times increase the risk for stroke, the risk for stroke is acceptable for RMVR and similar to the stroke risk associated with the traditional

approach. Essentially, the longer procedural time with RMVR is not enough to increase the risk for stroke, suggesting patients who undergo RMVR are not at a higher risk for surgical complications.

The literature also shows that patients who undergo RMVR experience superior recovery times. This is possible since the RMVR uses a thoracotomy to reach the heart while the traditional approach uses a more invasive sternotomy. In addition to superior recovery times, patients who undergo RMVR seem to experience a higher quality of life when compared with the traditional approach based off survey questionnaires. These components strongly suggest that patient may be able to return to daily level of activities much sooner if they undergo RMVR.

Overall, the implementation of robotic assisted mitral valve repair maintains and improves surgical outcomes in patients with degenerative mitral valve disease. From analyzing the literature, none of the studies examined the mitral valve durability of patients greater than 5 years post-operation. To better understand whether RMVR has acceptable surgical outcomes for patients in the long term (>5 years), a study should be done to compare echocardiographic outcomes of patients who underwent RMVR and CMVR. The results of this study will indicate which procedure provides superior repairs, and an indication of how effective RMVR is for patients in the long term. The procedure with superior repairs will provide patients with longer lasting mitral valves, which is essential for basic heart function and day to day activities. The long-term durability of a repair can help influence which approach is implemented more at hospital centers, which could greatly impact cardiovascular outcomes for patients.

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