Prosthetic Valve Leaflet Perforation resulting in Critical Aortic Insufficiency: A Rare Late Complication after use of COR-KNOT

Sankalp P. Patel[1], Robert J. Cubeddu[1], Stephen E. D'Orazio[1], and Brian J. Solomon[1]

[1]NCH Healthcare System

August 2, 2022

Abstract

The implementation of automatic fasteners such as the Cor-knot ® device (LSI Solutions, Inc.) has revolutionized the field of minimally invasive valvular surgery. Nonetheless, paravalvular regurgitation, valvular embolization, and early leaflet perforation are all potential complications which may occur. Late manifestations of leaflet perforation (>5-year post-implantation) are rare. Herein, we discuss a patient who underwent remote Trifecta ® (St. Jude, Inc.) surgical aortic valve replacement (SAVR) presenting with symptomatic critical aortic regurgitation secondary to leaflet perforation from automatically fastened metallic Cor-knot ® sutures.

Prosthetic Valve Leaflet Perforation resulting in Critical Aortic Insufficiency: A Rare Late Complication after use of COR-KNOT®

Sankalp P. Patel D.O.[1], Robert J. Cubeddu M.D.[2], Stephen E. D'Orazio M.D.[3], Brian J. Solomon M.D.[3]

1. Department of Graduate Medical Education, NCH Healthcare System
2. Department of Structural Heart Disease, President NCH Heart Institute, NCH Healthcare System
3. Department of Cardiothoracic Surgery, NCH Heart Institute, NCH Healthcare System

Disclosures : The authors have nothing to disclose

Funding: No funding was provided for this report

Conflicts of Interest: None

Corresponding Author:

Sankalp P. Patel

Address: 311 9th St. N, Naples, FL 34102

Ph: (239) 624-0940

Fax: (239) 624-0941

Email: Sankalp.Patel@nchmd.org

Twitter: @SankalpPatelDO

Abstract : The implementation of automatic fasteners such as the Cor-knot® device (LSI Solutions, Inc.) has revolutionized the field of minimally invasive valvular surgery. Nonetheless, paravalvular regurgitation, valvular embolization, and early leaflet perforation are all potential complications which may occur. Late manifestations of leaflet perforation (>5-year post-implantation) are rare. Herein, we discuss a patient who underwent remote Trifecta® (St. Jude, Inc.) surgical aortic valve replacement (SAVR) presenting with

symptomatic critical aortic regurgitation secondary to leaflet perforation from automatically fastened metallic Cor-knot® sutures.

Introduction : Cor-knot® has facilitated a significant reduction in cardiopulmonary bypass and aortic cross-clamp times in comparison to manual hand-tied knots[1]. This has led to a revolutionary change in the discipline of minimally invasive valve surgery through mitigation of numerous bypass-related complications. The long-term complications of utilizing the automatic fastening device itself remain poorly understood, given most occur acutely. We describe a patient who underwent placement of a 23mm St. Jude Trifecta® aortic bioprosthesis, fastened with Cor-knot® sutures, presenting to our center 6 years later with severe, symptomatic bioprosthetic valvular regurgitation. The purported mechanism is secondary to leaflet erosion and consequential perforation due to the protruding automatically fastened metallic knots.

Case Report : A 70-year-old male (weight: 85kg, BMI: 28 kg/m^2) with history of aortic stenosis underwent SAVR in 2015 at an outside hospital, 6 years prior to his presentation to our facility. He was noted to have no evidence of coronary disease and underwent successful implantation of a 23mm St. Jude Trifecta® bioprosthetic aortic valve at the outside center. Given use of a minimally invasive technique, the aortic prosthesis was secured with the Cor-knot® automatic fastening device. He presented to our institution in 2021, over 6 years after his initial SAVR, complaining of dyspnea on exertion which had worsened over the course of several weeks. His vital signs on arrival were significant for elevated blood pressure of 163/78 mmHg, revealing a widened pulse pressure. He underwent a two-dimensional transthoracic echocardiogram (TTE), revealing an LVEF (left ventricular ejection fraction) of 40-45%, mild to moderate mitral valve regurgitation, and an abnormally functioning bioprosthetic aortic valve. Dimensionless index via doppler interrogation was noted to be 0.34, however pressure half-time was noted to be less than 250 milliseconds, thus quantifying severe transvalvular aortic regurgitation. Given reduced LVEF, he underwent cardiac catheterization with unremarkable coronary occlusion noted. Subsequent transesophageal echocardiogram (TEE) was performed to elucidate true severity of bioprosthetic valve dysfunction and confirmed compromised severe transvalvular aortic insufficiency with revelation of a torn non-coronary leaflet (Video 1). Surgical removal of the malfunctioning bioprosthetic valve and redo-SAVR was planned the following day. The patient was brought to the operating suite in a fasted state and prepped and draped in usual sterile fashion. He was cannulated for cardiopulmonary bypass without complication. Re-do aortotomy was planned a quarter centimeter above prior aortotomy line with extension across the noncoronary sinus and coronary ostial cardioplegia was needed given severity of aortic insufficiency. Upon initial visual observation, decision was made to proceed with an aortic root enlargement to facilitate placement of a properly sized valve via a Manougian approach, which proceeded to occur in uncomplicated fashion. Exposure of the 23mm St. Jude Trifecta® aortic valve ensued in the interim, confirming suspicion on TEE. A large circular hole was observed in the left coronary leaflet and another large similar sized hole was seen in the noncoronary leaflet (Figure 1). Both holes corresponded to inward facing metallic Cor-knot®fastened knots, likely precipitating leaflet perforation. Uncomplicated valve resection followed thereafter along with completion of annular enlargement, with post-explant visualization of the St. Jude Trifecta® better unveiling the 2 separate perforations created in the left and non-coronary cusps, aligning with the position of metallic fastened knots (Figure 2A and 2B). A 23mm On-X® (CryoLife, Inc.) mechanical valve was implanted in the aortic position. After confirming successful valve placement, a bovine pericardial patch was utilized to close the aortotomy and routine weaning of bypass ensued followed by decannulation. The patient was brought back to our cardiovascular intensive care unit and follow-up echocardiogram showed a well-seated mechanical aortic valve without significant valvular or paravalvular regurgitation (Video 2).

Discussion:

The Cor-knot® device is an automated titanium suture fastening device manufactured to knot and cut sutures throughout minimally invasive valve surgeries in which manual ties may be unfeasible. In addition to offering a convenient, expedited suturing solution which decreases aortic cross-clamp and cardiopulmonary bypass time, the Cor-knot® system has been shown to be just as durable, if not more durable, than manually hand-tied sutures[2]. Though shown to be a safe, viable alternative to manual knot-tying, long-term

complications of the fastening device remain poorly understood. The St. Jude Trifecta® aortic bioprosthesis was implemented in our patient in 2015; recent data has demonstrated this valve has necessitated reintervention more often than other bioprostheses[3]. Whether the durability of the Trifecta® valve contributed to the perfectly round perforations in both leaflets is unable to be determined, but it can be presumed that bioprosthetic valve deterioration may have had a role. Severe transvalvular aortic regurgitation after implementation of a Trifecta® (St. Jude, Inc.) prosthesis in conjunction with the Cor-knot® has been scarcely reported. Several reports exist demonstrating severe bioprosthetic transvalvular regurgitation from a similar causative mechanism in other SAVR prostheses, though the patients within these reports presented within 20 months of valve replacement[4,5]. As highlighted within these reports, we believe the mechanism of leaflet failure in our patient was due to repetitive trauma suffered by the leaflet as it consistently flapped against the Cor-knot®.

Conclusion :

Our report serves to highlight an underreported and poorly understood mechanism of bioprosthetic aortic regurgitation secondary to leaflet trauma from an automated titanium fastening device. We recommend operators to remain vigilant of this complication before utilizing artificial knot-fastening systems and to orient knots away from imposing neighboring leaflet impedance.

References:

1. Sazzad F, Xian OZ, Ler A, Guohao C, Swee KG, Kofidis T. Incidence of valvular regurgitation and leaflet perforation by using automated titanium fasteners (CORKNOT®) in heart valve repair or replacement: less usual than reported. *J Cardiothorac Surg* . 2021;16(1):163. Published 2021 Jun 7. doi:10.1186/s13019-021-01512-z
2. Sazzad F, Ler A, Kuzemczak M, Ng S, Choong AMTL, Kofidis T. Automated Fastener vs Hand-tied Knots in Heart Valve Surgery: A Systematic Review and Meta-analysis. *Ann Thorac Surg* . 2021;112(3):970-980. doi:10.1016/j.athoracsur.2020.08.117
3. Biancari F, Valtola A, Juvonen T, et al. Trifecta Versus Perimount Magna Ease Aortic Valve Prostheses. *Ann Thorac Surg* . 2020;110(3):879-888. doi:10.1016/j.athoracsur.2019.12.07
4. Balan R, Mogilansky C, Larsen AL, Massoudy P. Severe aortic regurgitation after implantation of a sutureless valve prosthesis using an automatic knot fastener device. *Interact Cardiovasc Thorac Surg* . 2017;25(1):153-154. doi:10.1093/icvts/ivx069
5. Brescia AA, Bolling SF, Patel HJ. Valvular Regurgitation After Implantation of Prostheses Secured With Cor-Knot Automated Fasteners. *Ann Thorac Surg* . 2017;103(6):e491-e492. doi:10.1016/j.athoracsur.2016.11.035