Patients' Experience after Cryoballoon Ablation Under Moderate Sedation and General Anesthesia

Youssef Jalloul¹ and Marwan Refaat¹

¹American University of Beirut Medical Center

May 6, 2020

In 1999, Paul Myles et al. published an important paper outlining the details of a novel assessment tool to measure patients' quality of recovery (QoR) post-anesthesia and surgery.[1] The following year, Paul Myles et al. published another article outlining the QoR-40. This study, as well as multiple other studies, further studied QoR-40's validity, reliability, internal consistency, test-retest reliability, inter-rater reliability, and split-half coefficient. [1–3] It can be completed in a relatively short period (around five minutes). [3,4] However, its administration by the investigators provides more complete and timely data as compared to self-administration.[4] It has been translated into multiple languages and validated by these languages as well.[5] However, even though the QoR-40's score has a maximum score of 200 with a range of 160, the minimal clinically important difference is only 4.8 units to translate into clinically relevant change. The difference between the mean QoR-40 scores post-cardiac surgery (with and without complications) was only four units while maintaining a wide standard deviation within groups. [5,6] QoR's utility lies in its correlation with patient satisfaction as well as with another measure of patient well-being, the quality of life (QoL) score.[3] Furthermore, the QoR-40's score three days post-cardiac surgery correlated well with the SF-36's measure of QoL 3 months after the operation. Hence QoR-40 is helpful in assess patient's short-term prognosis. [7] These findings hold even three years after the operation; however, the correlation level does decrease. [8]

In this issue of the journal of cardiovascular electrophysiology, Wasserlauf et al. utilized the QoR-40 to measure the impact of the anesthesia used during cryoballoon ablation of paroxysmal atrial fibrillation.[9] Catheter ablation has become a common procedure for the management of paroxysmal atrial fibrillation with minor procedural complication. [10,11] Patients undergoing cryoballoon ablation for atrial fibrillation experience less pain than radiofrequency ablation. [12]

Multiple sedative modalities can be utilized for cardiac catheter ablation. One modality is the use of a light anesthetic: It alerts the physician of patient discomfort, it comforts the physician and nursing staff and carries a lower risk of drug overdose. However, it does increase the patients' intraoperative motion. [13] Other modalities include general anesthesia and deep sedation. However, it should be noted that conscious sedation does carry a risk of hypoventilation and aspiration. [14] In a previous study, no significant difference in complication rate was present following ventricular tachycardia ablation during minimal as compared to deep sedation. [15] Also, in another study, patients undergoing percutaneous epicardial access (for ventricular tachycardia or premature ventricular complex) had similar complication rates regardless of whether they did the procedure under general anesthesia or moderate/deep sedation. [16] Furthermore, in a study by Tang et al., patients who underwent non-conscious sedation during catheter ablation for atrial fibrillation had more transient anesthetic complications as compared to conscious sedation. However, these two groups did not reveal a difference in the procedure-related complication/success rates. [17] Finally, Wasserlauf et al. found moderate sedation to carry a lower procedure time without jeopardizing the complication and recurrence rate up to a median follow-up duration of 0.9 years. This paper studied patients undergoing cryoballoon

ablation for paroxysmal atrial fibrillation. [18]

Given the previously reported evidence supporting the use of conscious anesthesia during atrial fibrillation catheter ablation, Wasserlauf et al. set on a task to expand our knowledge of patients' tolerance of moderate sedation during cryoballoon ablation. [9] Consequently, they studied patients undergoing cryoballoon ablation for paroxysmal atrial fibrillation under general anesthesia or moderate sedation. Within 24 hours after the procedure, patients would provide the QoR-40 and their likelihood to recommend the procedure and sedation method. The mean QoR-40 was greater than 180 in the two groups with a difference of less than 5 unites. Furthermore, the difference in the QoR-40 scores was not statistically significant. [9] These scores were better than scores observed by Myles in minor surgeries (178 ± 17) and cardiac surgeries without complications (176 ± 16). [6] Moreover, patients reported a high satisfaction rate with a high likelihood to recommend the procedures (83% and 89%) and a high likelihood to recommend the sedation method (94% and 85%) depending on the sedation method (general anesthesia and moderate sedation respectively). However, the difference was not statistically significant. [9] This result is similar to a previous study that found that 96% of patients would recommend radiofrequency ablation for atrial fibrillation. [19] What these results mean is that they support the use of moderate sedation as compared to general anesthesia, given the similar patient experience, but different procedure time, expense, and possible complications from general anesthesia. [9]

This study, however, does have limitations. It was a single-center non-randomized study. The QoR-40 has sections that are heavily dependent on the medical center and staff; hence this is an important issue to consider. Furthermore, the assignment to anesthesia groups was not standardized, and the decision was dependent on physician and patient preference. Though understandable, the physician preference can be made to be dictated by a predefined set of criteria to minimize nonrandom assignment. Finally, we note that the QoR-40 scores presented by Wasserlauf et al. were the means and standard deviations. [9] When calculating the 95% confidence intervals of the difference of the mean QoR-40 scores of the two groups, we find that there is no statistically significant difference between the two groups.

In conclusion, Wasserlauf et al. have added to our knowledge of cryoballoon ablation under moderate sedation which might become the more frequently adopted anesthesia strategy during AFib cryoablation.

References:

- 1. Myles PS, Hunt JO, Nightingale CE, et al. Development and psychometric testing of a quality of recovery score after general anesthesia and surgery in adults. Anesth Analg. 1999;88(1):83-90. doi:10.1097/00000539-199901000-00016
- 2. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S. Validity and reliability of a postoperative quality of recovery score: The QoR-40. Br J Anaesth. 2000;84(1):11-15. doi:10.1093/oxfordjournals.bja.a013366
- 3. Gornall BF, Myles PS, Smith CL, et al. Measurement of quality of recovery using the QoR-40: A quantitative systematic review. Br J Anaesth. 2013;111(2):161-169. doi:10.1093/bja/aet014
- 4. Gower ST, Quigg CA, Hunt JO, Wallace SK, Myles PS. A comparison of patient self-administered and investigator-administered measurement of quality of recovery using the QoR-40. Anaesth Intensive Care. 2006;34(5):634-638. doi:10.1177/0310057x0603400514
- $6. \ Myles\ PS.\ Clinically\ Important\ Difference\ in\ Quality\ of\ Recovery\ Scores.\ Anesth\ Analg.\ 2016;122(1):13-14.\ doi:10.1213/ANE.000000000001060$
- 7. Myles PS, Hunt JO, Fletcher H, Solly R, Woodward D, Kelly S. Relation between quality of recovery in hospital and quality of life at 3 months after cardiac surgery. Anesthesiology. 2001;95(4):862-867. doi:10.1097/00000542-200110000-00013

- 8. Myles PS, Viira D, Hunt JO. Quality of life at three years after cardiac surgery: Relationship with preoperative status and quality of recovery. Anaesth Intensive Care. 2006;34(2):176-183. doi:10.1177/0310057x0603400220
- 9. Wasserlauf, Jeremiah; Kaplan, Rachel; Walega, David; Arora, Rishi; Chicos, Alexandr; Kim, Susan; Lin, Albert; Verma, Nishant; Patil, Kaustubha; Knight, Bradley; Passman R. Patient-Reported Outcomes After Cryoballoon Ablation Are Equivalent Between Moderate Sedation And General Anesthesia. J Cardiovasc Electrophysiol. 2020.
- 10. Chung MK, Refaat M, Shen WK, Kutyifa V, Cha YM, Di Biase L, Baranchuk A, Lampert R, Natale A, Fisher J, Lakkireddy DR. Atrial Fibrillation: JACC Council Perspectives. J Am Coll Cardiol. Apr 2020; 75 (14): 1689-1713.
- 11. D'Avila A, Ptaszek LM, Yu PB, Walker JD, Wright C, Noseworthy PA, Myers A, Refaat M, Ruskin JN: Left Atrial-Esophageal Fistula After Pulmonary Vein Isolation. Circulation May 2007; 115(17): e432-3.
- 12. Attanasio P, Huemer M, Shokor Parwani A, et al. Pain Reactions during Pulmonary Vein Isolation under Deep Sedation: Cryothermal versus Radiofrequency Ablation. PACE Pacing Clin Electrophysiol. 2016;39(5):452-457. doi:10.1111/pace.12840
- 13. Defaye P, Kane A, Jacon P, Mondesert B. Cryoballoon for pulmonary vein isolation: Is it better tolerated than radiofrequency? Retrospective study comparing the use of analgesia and sedation in both ablation techniques. Arch Cardiovasc Dis. 2010;103(6-7):388-393. doi:10.1016/j.acvd.2010.06.004
- 14. Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design. Heart Rhythm. 2012;9(4):632-696.e21. doi:10.1016/j.hrthm.2011.12.016
- 15. Wutzler A, Mueller A, Loehr L, et al. Minimal and deep sedation during ablation of ventricular tachycardia. Int J Cardiol. 2014;172(1):161-164. doi:10.1016/j.ijcard.2013.12.175
- 16. Killu AM, Sugrue A, Munger TM, et al. Impact of sedation vs. general anaesthesia on percutaneous epicardial access safety and procedural outcomes. Europace. 2018;20(2):329-336. doi:10.1093/europace/euw313
- 17. Tang RB, Dong JZ, Zhao W Du, et al. Unconscious sedation/analgesia with propofol versus conscious sedation with fentanyl/midazolam for catheter ablation of atrial fibrillation: A prospective, randomized study. Chin Med J (Engl). 2007;120(22):2036-2038. doi:10.1097/00029330-200711020-00018
- 18. Wasserlauf J, Knight BP, Li Z, et al. Moderate Sedation Reduces Lab Time Compared to General Anesthesia during Cryoballoon Ablation for AF Without Compromising Safety or Long-Term Efficacy. PACE Pacing Clin Electrophysiol. 2016;39(12):1359-1365. doi:10.1111/pace.12961
- 19. Ezzat VA, Chew A, McCready JW, et al. Catheter ablation of atrial fibrillation Patient satisfaction from a single-center UK experience. J Interv Card Electrophysiol. 2013;37(3):291-303. doi:10.1007/s10840-012-9763-5