Early Identification of Poorly Performing Implants in Michigan with the Example of One Manufacturer

Nicholas Blair Frisch[1], Michael A Masini[2], Huiyong Zheng, Richard E Hughes[3], Brian Richard Hallstrom[4], David C Markel[5]
[1]Orthopaedic Surgery, Ascension Providence Rochester Hospital, [2]Ann Arbor Orthopaedic Specialists, [3]University of Michigan, [4]Univ Of Michigan Med Ctr, [5]Ascension Providence Hospital - MSUCHM

INTRODUCTION:

Arthroplasty registries play a critical role in improving the quality of care for patients and performing post-market surveillance of medical devices. Without a global infrastructure for identifying outlier implants, it falls to each individual registry to report on implant performance in its annual report and/or publish in peer-reviewed literature. When an implant appears to have worse performance than other similar implants, the registry can potentially protect patients from further use of that implant by reporting their results. This paper reports the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) findings specific to the Biomet Vanguard XP bicruciate-retaining total knee implant and explores opportunities to improve the timeliness and reliability of reporting.

METHODS:

Data collected by MARCQI's 2019 report covered MARCQI activities from 2/15/2012 through 12/31/2018 and included the use of the Biomet Vanguard XP implant. Demographic data were analyzed using Chi-squared and independent two-group *t*-tests to determine if there were differences in cases between Vanguard XP and all other implants. The cumulative percent revision (CPR) was computed from the survival function, S(t), using CPR(t)=100*(1-S(t)). The S(t) was estimated using the Kaplan-Meier method. A log-rank test was used to assess differences in the CPR curve for the Vanguard XP and all other implants. A Cox proportional hazards model was also used to assess the impact of age and sex on the hazard function for revision. The comparative group used was all other TKA implants. Cumulative sum (CUSUM) charts adapted for arthroplasty were constructed for each individual surgeon in MARCQI.

RESULTS:

There were 148,832 knee arthroplasty cases in the MARCQI registry. When cases containing unknown/missing data and deaths were excluded, there were 507 that used a Vanguard XP implant combination and 134,605 cases that used other implants (Figure 1). The unadjusted cumulative percent revision (CPR) curve up to five years postoperatively (Figure 2) for the Vanguard XP differed from the CPR curve for all other implants in MARCQI (P<0.0001). The hazard ratios for the three factors included in the Cox proportional hazards model were all significantly different from unity: implant (2.76, 1.98 – 3.86, 95% CI), sex (0.80, 0.74 – 0.85, 95% CI), and age (0.96, 0.96 – 0.97, 95% CI). The top three reasons for revision were pain, arthrofibrosis, and aseptic loosening (Table 1). All of the surgeons who used the Vanguard XP experienced higher failure rates than before they used the implant.

DISCUSSION AND CONCLUSION:

Arthroplasty implant registries have a critical role in identifying and reporting implant outcomes. The increased coverage of registry reporting is important going forward as practices and implant usage vary. The timing of reporting is important, as is the development of thresholds and benchmarks for reporting in collaboration with industry could potentially save patients from the morbidity caused by implants that do not perform as well as anticipated. The Vanguard XP experienced higher early failure rates than other TKA implants within the MARCQI registry.

Figure 1: Flow diagram of cases used in analysis.

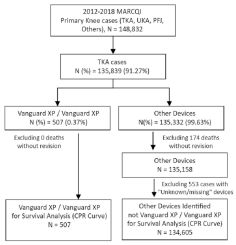

Figure 2: Cumulative percent revision (CPR) for the Vanguard XP to five years following primary procedure with shaded 95% confidence intervals.

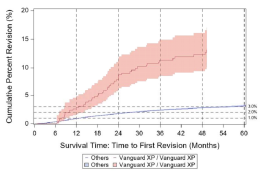

Table 1: Reason for revision for Vanguard XP implant.

	Overall		Revised within 2 years		Revised after 2 years	
Reason for revision	Frequency	Percent	Frequency	Percent	Frequency	Percent
Pain	16	36.4	14	48.3	2	13.3
Arthrofibrosis	9	20.5	6	20.7	3	20.0
Aseptic loosening	8	18.2	4	13.8	4	26.7
Dislocation/instability	7	16.0	3	10.3	4	26.7
Joint infection	3	6.8	1	3.5	2	13.3
Extensor mechanism failure	1	2.3	1	3.5	0	0