THE RATE OF CIED INFECTION BY SEVERITY: EVIDENCE FROM A LARGE US PAYER DATABASE

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OBJECTIVE: To estimate the incidence, severity and annual healthcare cost for cardiac implantable electronic device (CIED) recipients experiencing a CIED related infection during the first year following their CIED procedure.

METHODS:

- This analysis used data from MarketScan® Commercial Claims and Medicare Supplemental database (Truven Health Analytics, New York, NY) from 2009 to 2012.
- Inclusion and Exclusion Criteria:
  - Patients with a record of a complete CIED implant (initial or replacement) or generator replacement only (replacement), (Figure 1) determined by ICD-9 and CPT codes were included.
  - Patients included in this analysis were: permanent pacemakers (PPM), implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy defibrillators or pacemakers (CRT-D and CRT-P).
- Continuous medical and prescription enrollment were required for 6 months prior to the first record of an implant. (Figure 2)
- Patients were excluded if there was a record of a major cardiac surgery during their index implant procedure.
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CLASSIFICATION OF INFECTIONS:

- CIED infections were classified based on ICD-9 codes into four mutually-exclusive severity categories:
  - Severity Group 1: infection not managed in an inpatient setting or no infection removal.
  - Severity Group 2: infection managed in an inpatient setting but no infection removal.
  - Severity Group 3: infection managed by an inpatient or outpatient setting and no infection removal.
  - Severity Group 4: infection managed with implant removal and severe exacerbation.

- Infection rates and annual expenditures by severity were estimated separately for both the initial and replacement cohorts.
- Kaplan Meier models were utilized to generate survival curves and product limit estimates for annualized rate of infection for the period up to 365 days post index implant.
- Least-squared means from gamma link-log regression models were used to estimate the incremental annual expenditures for the four severity categories as well as the no infection group for each cohort.

RESULTS:

- Of the 50,031 (N=40,418 initial and N=9,617 replacement) patients with CIED implant procedures, 1,306 (n=654 initial and N=652 replacement) patients had at least one ICD or generator replacement during the index for the initial implant cohort. (Table 1)
- Patients in the initial and replacement cohorts who experienced a CIED infection were younger and more likely to have had their index implant in an inpatient setting than those that did not experience an infection. (Table 1)
- Implantation of permanent pacemakers (PPM) occurred in approximately half of the implants in each cohort. (Table 1)
- Average time from implant to infection was 61.8 (SD 76.0) days for patients in the initial cohort and 48.7 (SD 67.5) days for patients in the replacement cohort. (Table 1)
- In the replacement cohort, 36% of patients diagnosed with CIED infection had a record of a prior CIED infection. (Table 1)
- Estimated annual infection risk for the patients in the initial implant cohort was 1.18% compared to 2.37% for the patients in the replacement implant cohort. (Figure 3)
- Among patients with CIED infection, Severity Group 1 infections made up 38.4% of the initial and 47.2% of the replacement implant cohort. While the most severe infections (Severity 4) were found in approximately 3% of the initial implant cohort. (Table 2)
- Estimated incremental expenditures for any infection compared to no infection for initial and replacement infections are shown in Figure 4.
- Estimated incremental expenditures by Severity Group of infection for patients in the initial implant cohort at 1 year were: $15,651; $204,077; $43,929; and $279,744. (Figure 5A)
- Estimated incremental expenditures by Severity Group of infection for patients in the replacement implant cohort at 1 year were: $26,837; $45,541; $46,759; and $82,606. (Figure 5B)

CONCLUSIONS:

- CIED infections present a substantial healthcare burden for payers, irrespective of severity of clinical presentation and management strategy (implant removal vs. retention).