Practice-specific process improvement interventions in diagnosis and adoption of pacemaker therapy in SND patients: Results from IMPROVE Brady study.

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**Introduction:** Utilization of pacemaker therapy for guideline indicated patients with sinus node dysfunction (SND) remains low in developing geographies. The aim of the IMPROVE Brady study was to evaluate the care pathways of bradycardia patients and to assess if a specific process improvement intervention could increase the adoption of guideline based therapy in this patient population.

**Methods:** IMPROVE Brady was a quality improvement initiative conducted at ten centers in India and Bangladesh for patients with SND. This prospective, multicenter study enrolled patients in two phases sequentially (Phase I and II) with a heart rate of ≤50 beats per minute presenting with symptoms including syncope, dizziness, and/or dyspnea. Patients were followed to identify the proportion diagnosed with symptomatic SND who received pacemaker therapy (IPG device). In Phase I, physicians assessed and treated subjects per standard care practice at their center. Prior to enrollment of Phase II, the investigators completed an educational workshop and were given access to the IMPROVE Brady toolkit (including patient and physician educational tools) to create a practice-specific process improvement intervention. The prespecified primary objectives were to evaluate the impact of the intervention on (1) the diagnosis of SND and (2) whether SND subjects receive an indicated IPG device.

**Result:** A total of 978 patients were enrolled, 508 in Phase I and 470 in Phase II, and followed for 8.9 ± 10.7 months. They were 57.7 ± 14.8 years of age, 75% were male, and 92% had completed at least primary education. The study met both of its prespecified primary objectives. An SND diagnosis was made in 409 (87%) patients in Phase II compared to 368 (72%) patients in Phase I, showing a significant increase in diagnosis (P<0.001). Pacemaker (IPG device) implantation increased significantly in Phase II compared to Phase I: 32% (n=130) vs 17% (n=63, P<0.001). Syncope and presyncope symptoms recorded at the baseline visit increased the probability of an SND diagnosis and subsequent IPG implant in both phases (P<0.001). A lower heart rate increased the probability of an SND diagnosis (P<0.001) while more advanced age increased the probability of receiving an IPG (P<0.001), in both phases. Of the patients that declined an IPG, 41% of them were due to insurance or cost barriers and this was unaltered by the intervention.
Conclusion: A process improvement initiative conducted at centers across South Asia significantly increased both the diagnosis of SND and subsequent treatment with guideline indicated pacemaker therapy. Diagnosis of SND and pacemaker implantation improved overtime despite similar insurance and cost constraints.