Feasibility, Safety And Efficacy Of Left Bundle Branch Pacing In Octogenarians

Shunmuga Sundaram[1], Dasarath Boppana[1], Mahesh Kumar[1], Giridhar Muthu[1], Vijesh Anand[1], and Suryakumar Balasubramanian[1]

[1]Velammal Medical College Hospital and Research Institute

May 6, 2020

Abstract

Background: Left bundle branch pacing (LBBP) provides physiological pacing at low and stable threshold. The safety and efficacy of LBBP in elderly population is unknown. Objectives: Our study was designed to assess the safety, efficacy and electrophysiological parameters of LBBP in octogenarian ([?]80 years) population Methods: All octogenarians requiring permanent pacemaker implantation for symptomatic bradycardia and heart failure were prospectively enrolled. Echocardiography, electrocardiography and pacing parameters were recorded. Results: LBBP was successful in 10 out of 11 patients. Mean age 82.1 ± 2.5 yrs. Male 7 patients. Follow up duration 4.7 months (range1-7months). Indication for pacing included atrioventricular (AV) block 5 patients, Left bundle branch block (LBBB) with low ejection fraction (EF) 4 patients, sinus node dysfunction in 1. LB lead placement fluoroscopic time was 17.9 minutes. QRS duration reduced from 145.9 ±27.7ms at baseline to 107.1 ±9.5ms after LBBP (p value0.00001) LV ejection fraction increased from 47.6 % to 55.9 % after LBBP (p value0.017). Pacing threshold was 0.58 ± 0.22V and sensed R wave 17.35 ± 6.5mV and it remained stable during follow up. LBBB with low EF patients also showed similar reduction in QRS duration along with improvement in LVEF. No major complications noted Conclusion: LBBP is a safe and effective strategy (91% acute success) of physiological pacing in elderly patients. LBBP also provided effective resynchronization therapy in our small group of elderly patients. The pacing parameters remained stable over a period of 7 months follow up.

Introduction:

Physiological pacing offers the advantage of capturing His-purikinje system directly thereby achieving synchronized ventricular contraction[1]. Deshmukh et al[2] first showed the feasibility of permanent his bundle pacing (HBP). Although HBP offers the most physiological form of pacing, it has some inherent limitations. Huang et al[3] reported direct capture of left bundle (LB) by deep septal pacing as an alternative to overcome the limitations of HBP. Though the safety of LBBP has been established by several studies, the data for elderly population is lacking. This paper describes the feasibility, safety and electrophysiological properties of left bundle branch pacing in octogenarians.

Materials and Methods:

This is a prospective, single center, observational study conducted in our institute from march 2019 to march 2020 after getting approval from the institutional ethical committee. Patients provided written informed consent regarding LBBP as a non-standard approach. All patients aged between 80-89 years who were planned for permanent pacemaker implantation for symptomatic bradyarrhythmia and those with left bundle branch with low left ventricular ejection fraction (LVEF) requiring cardiac resynchronization therapy (CRT) were included in the study. Patients who refused for the therapy were excluded.

Intracardiac electrograms along with 12 lead electrocardiography (ECG) were continuously recorded (Workmate Claris, Abbott, Plymouth, MN). The procedure was done as described by Huang et al[4] using C315 sheath and 3830 SelectSecure^{tm} lead (Medtronic, Minneapolis, MN). In brief, the pacing lead was placed deep inside the septum at a site 1-1.5cm below the His bundle (fig 1A). LB capture was confirmed by presence of right bundle branch delay pattern (qR in lead V1) along with any one of the following criteria (a) presence of LB potential (b) Non-selective to selective LB capture during unipolar threshold measurement (fig 1B) (c) short and constant peak left ventricular activation time (pLVAT) <80ms. (d) programmed stimulation from the pacing lead to show change in QRS morphology, duration and axis

Patients baseline characteristics and indications for pacing were documented. ECG, electrophysiological and pacing parameters were recorded. LVEF was measured by modified simpson's method. Follow up was done in device clinic at the end of 15 days, one month and subsequently every 2 months.

Statistical analysis:

Continuous variables are reported as mean ± SD (standard deviation) and compared with Student's t-test and categorical variables with Chi-Square test. P value of <0.05 was considered as significance.

Results:

Among the 93 patients who had undergone successful LBBP during the study period, 11 satisfied the inclusion criteria. Successful LBBP could be performed in 10 out of 11 patients (91% acute success rate). In one patient with AV block, lead could not be penetrated deep and conventional RV lead was placed. Baseline and procedural characteristics are shown in table 1. Mean age of the study population was 82.1 ± 2.5 years. 6 patients were men and 5 had associated coronary artery disease. The indication for pacemaker implantation was AV block in 5 patients (50%), LBBB with low EF in 4 patients (40%) and symptomatic sinus node dysfunction in one patient. The baseline QRS duration was 145.9 ± 27.7ms. Pre-procedural echocardiography showed mean EF of 47.6 ± 11.2% and septal thickness of 11.1 ± 0.7mm. The mean duration of follow up was 4.7 ± 1.9 months

The fluoroscopic time for LB lead placement was 17.9 ± 8.2 minutes. Non-selective to selective LB capture could be demonstrated during unipolar threshold measurement (fig 1B). LB potential was noted in one patient as other patients had either AV block or complete LBBB. QRS duration was reduced to 107.1 ± 9.5ms (measured from the onset to the end) (p value 0.00001). The pLVAT as measured in lead V5 (from pacing spike to peak of R wave) was 72.2 ± 5.3ms. The unipolar pacing threshold was 0.58 ± 0.22V at 0.5ms pulse width. The mean R wave amplitude was 17.35 ± 6.6mV. The unipolar pacing impedance was 773.6 ± 112.9ohms. All 4 patients with LBBB and low EF had complete correction of LBBB at low and stable threshold (fig 1C and 1D). No acute procedural complications noted.

Follow-up

All patients had minimum of one month follow up. The mean follow-up duration was 4.7 ± 1.9 months (range 1-7 months). The pacing threshold remained stable at 0.525 ± 0.07V at 0.5ms pulse width and sensed R wave amplitude 15.6 ± 7.3mV during follow up (table 2). The unipolar pacing impedance decreased to 663.1 ± 57.9ohms (p value 0.002). Echocardiography showed significant improvement in LV ejection fraction from 47.6 ± 11.2% to 55.9 ± 5.4% (p value 0.017). The length of the lead inside the septum was 10.3 ± 0.82mm. There was no acute or late lead dislodgement. There were no episodes of thrombo-embolism, pocket infection or mortality.

Cardiac re-synchronization therapy

Four patients had undergone LBBP done for LBBB with low LVEF. The QRS duration was reduced from 169.7 ± 13.3ms to 111.5 ± 13.4ms and LVEF improved form 37.5 ± 8.8% to 51.5 ± 4.4% along with improvement in the NYHA functional class.

Discussion:

Huang et al[3] in 2017 first reported LBBP as a safe alternative to HBP to provide low and stable threshold in patient with heart failure and LBBB. Though multiple studies are available[5,6], there is no published data on safety of LBBP in elderly patients. In this paper we have shown that LBBP could be successfully done in 10 out of 11 patients without any procedural complication. LBBP could reduce the QRS duration from 145.9 ± 27.7ms to 107.1 ± 9.5ms (p value 0.00001). LV ejection fraction improved from 47.6 ± 11.2% to 55.9 ± 5.4% (p value 0.017) during follow up. The lead parameters remained stable during follow up (table 2). All these findings are comparable to the published studies by other authors on LBBP[5,7,8]

Generally, CRT trials have excluded very old patients (>80 years old) and little data exist on outcomes of CRT in elderly[9]. Rigot et al[10], in a retrospective study showed that the response to CRT was not compromised in patients aged >75 years with 14% mortality at the end of one year. Achilli et al[11] showed 2.4% LV lead dislodgement in patients aged >80 years undergoing CRT. Though similar clinical efficacy was noted as compared to those under 80 years, 17.3% mortality occurred during follow up of 12 months. LBBP could be safely done as an alternative for cardiac re-synchronization therapy in our small cohort aged [?] 80 years. We could also show significant reduction in QRS duration along with improvement in LVEF in these patients. With the stable lead parameters and less procedural complication rate, LBBP has the potential to be an excellent alternative to CRT in elderly patients.

Limitations

This is a single center, prospective, observational study involving small number of patients aged more than 80 years (n=10). This data cannot be extrapolated to the general population. The long-term safety data of LBBP is yet to be available.

Conclusion:

Left bundle branch pacing is a safe strategy of physiological pacing in octogenarians and we could show significant reduction in QRS duration and improvement in LV ejection fraction. LBBP provides effective resynchronization therapy in elderly population as shown in our small group of patients. Further prospective, multicenter, randomized controlled trials will be required to assess the long safety of LBBP.

Figures and tables

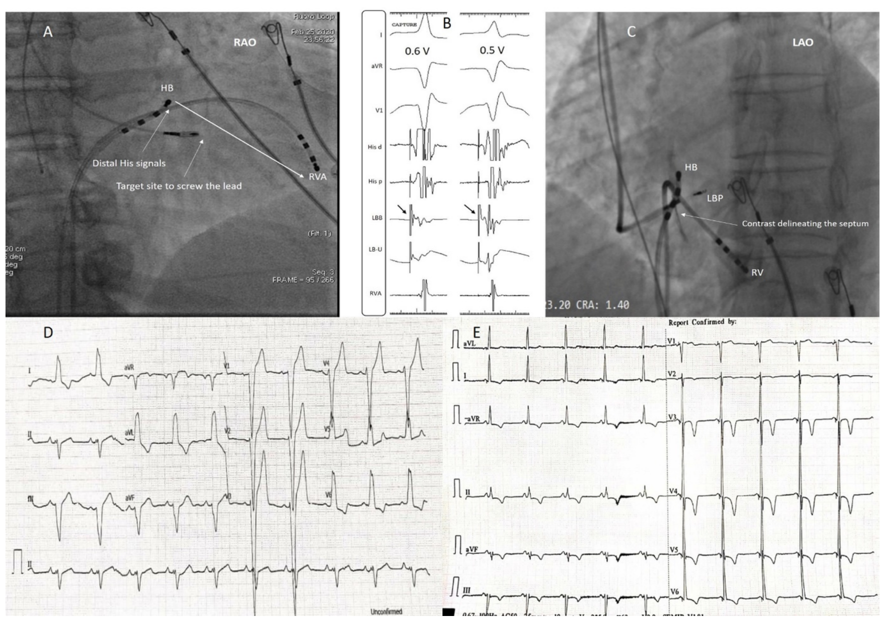

Fig 1. LBBP for LBBB with low LVEF. A- RAO view showing the target site for the lead placement – 1.5cm below distal His bundle (HB) along an imaginary line to RV apex (RVA). B – Non selective to selective LB capture as output reduced from 0.6V to 0.5 V. Note the distinct LB lead electrogram after the pacing spike while selective capture along with change in QRS morphology from QS to rSR in V1. C – Sheath angiography in LAO view showing the depth of the lead (LBP) inside the septum. D – Baseline ECG showing complete LBBB with QRS duration of 160ms. E- ECG after LBBP showing narrow QRS with T wave memory

Total number of patients
Successful LB pacing Male Female
Follow up (months)
Age in years
Coronary artery disease
Pre-procedure – ECG and ECHO QRS duration (milliseconds) LV ejection fraction (%) Septal Thickness (mm)
Left ventricular function Ejection fraction <50% Ejection fraction >50%
Pacing indications AV block LBBB with Low EF Sinus node dysfunction
Procedural parameters LBBP fluoroscopy time (minutes) Unipolar pacing threshold (@0.5ms pulse width) Unipolar pacing
Safety Parameters Acute lead dislodgement Late lead dislodgement Late rise in threshold by >1V Thrombo-embolic episod

Table 1: Baseline and procedural characteristics of the study population

	At implantation	Follow up (1-7 months)	*P Value*
Pacing Parameters Threshold (Unipolar;0.5ms pw) R wave (mV) Pacing Impedance (ohms)	0.58 ± 0.22 V 17.35 ± 6.5 mV 773.6 ± 112.9 ohms	0.525 ± 0.07 V 15.65 ± 7.3 mV 663.1 ± 57.9 ohms	0.23 0.26 **0.002**
ECG – QRS duration (Pre and Post)	145.9 ± 27.7ms (Pre)	107.1 ± 9.5 ms (post)	**0.00001**
Echocardiographic Paraemters LV ejection Fraction Worsening of Tricuspid regurgitation	47.6 ± 11.2% –	55.9 ± 5.4% Nil	**0.017**

Table 2: Follow up data of pacing and echocardiographic parameters

References

1. Vijayaraman P, Chung MK, Dandamudi G, et al. His bundle pacing. J Am Coll Cardiol 2018;72: 927–47.
2. Deshmukh P, Casavant DA, Romanyshyn M, AndersonK. Permanent, direct His-bundle pacing: a novel approach to cardiac pacing in patients with normal His-Purkinje activation. *Circulation* 2000;101:869–77
3. Huang W, Su L, Wu S, et al. A novel pacing strategy with low and stable output: Pacing the left bundle branch immediately beyond the conduction block. Can J Cardiol 2017;33:1736. e1–3.
4. Huang W, Chen X, Su L, et al. A beginner's guide to permanent left bundle branch pacing. Heart Rhythm 2019;16:1791-6
5. Vijayaraman P, Subzposh FA, Naperkowski A, et al. Prospective evaluation of feasibility, electrophysiologic and echocardiographic characteristics of left bundle branch area pacing. Heart Rhythm 2019;16:1774–1782.

6. Zhang J, Wang Z, Cheng L, et al. Immediate clinical outcomes of left bundle branch area pacing vs conventional right ventricular pacing. Clin Cardiol 2019; 42:768–773.
7. Li X, Li H, Ma W, et al. Permanent left bundle branch area pacing for atrioventricular block: Feasibility, safety, and acute effect. Heart Rhythm 2019;16:1766–1773.
8. Li Y, Chen k, Dai Y, et al. Left bundle branch pacing for symptomatic bradycardia: Implant success rate, safety, and pacing characteristics. Heart Rhythm 2019;16:1758–1765.
9. Senni M, Tribouilloy CM, Rodeheffer RJ, et al. Congestive heart failure in the community. A study of all incident cases in Olmsted County, Minnesota, in 1991. Circulation 1998;98:2282–9.
10. Rigot LC, Cornille AL, Ollitrault P et al. Predictors of clinical outcomes after cardiac resynchronization therapy in patients [?]75 years of age: a retrospective cohort study. BMC Geriatr 2019;19:325
11. Achilli A, Turreni F, Gasparini M, et al. Efficacy of cardiac resynchronization therapy in very old patients: the Insync/Insync ICD Italian Registry. Europace 2007;9:732-8