

DIRECT HIS-BUNDLE PERMANENT PACING AS AN ALTERNATIVE TO CONVENTIONAL RIGHT VENTRICULAR APICAL PACING: A PILOT STUDY IN ZAGAZIG UNIVERSITY CARDIAC ELECTROPHYSIOLOGY LABORATORY.

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ABSTRACT

Aim: was to evaluate the feasibility of direct his bundle pacing (DHBP) as one of the physiological pacing approaches in our EP lab.

Methods: All suitable patients admitted for permanent pacemaker implantation, between January and June 2013, were given a trial for DHBP. Using his bundle (HB) recording through a quadripolar catheter as an electrical and radiological guidance, custom shape stylet was used to direct an active fixation lead to the target position; a pacing protocol was applied to insure pure HB capture. A matching group of patients with apical right ventricular pacing (ARVP) were used as control, to assess the feasibility of DHBP technique.

Results: Pure DHBP was successful in 12 out of 32 patients 38%.The DHBP procedure was costly when compared to ARVP in total procedure time (94.7±30.4 vs. 43.2±17.4 minutes), fluoroscopy time(35.2±10.9 vs. 10.1±3.6 minutes), patient x-ray exposure (34.1±7.8 vs. 11.9±4.9 Gy Cm²)and acute pacing threshold (2.1±0.6 vs.0.6±0.4 V). But in the other hand it was better in paced QRS width (76.8±14.8 vs. 193.9±35.8 ms.), patients' exercise capacity as percentage of achieved METS from Max METS for age (75.5±8.7 vs.54.9±8.7%). the DHBP procedure time was progressively shorter indicating a steep learning curve.

Conclusion: Although DHBP has many technical difficulties, it can be achieved with a reasonable coast in our EP lab with a demonstrable benefit, and a steep learning curve.

Keywords: direct his bundle pacing, apical right ventricular pacing, physiological pacing, pacemaker, paced QRS duration, and active fixation lead.

INTRODUCTION

The introduction of cardiac pacing in clinical practice led to logical concerns about the possible impact of the stimulation site on cardiac function. Key studies in the sixties, however, showed that atrial, right ventricular, and left ventricular pacing produced no short term differences in ventricular physiology either in patients with or without heart disease. These studies appeared to close the subject, and the problem of cardiac pacing was reduced to one of finding both identifying easiest access point which produced fewest complications. ^[1, 2] Two decades later, the technique was shown to be associated with several deleterious physiological effects, including asymmetrical ventricular hypertrophy, ventricular dilatation ^[3], myofibrillar disarray ^[4], increase in myocardial concentrations of catecholamines ^[5], and alterations in myocardial perfusion ^[6], the clinical deleterious effect was obvious in the DAVID ^[7]and in the MOST^[8] trials. Non apical right ventricular pacing (ARVP) was extensively studied with no encouraging results, the ROVA study, did not show any improvement in quality of life or ventricular contraction when non apical pacing sites were used

^[9]. If the aim is to mimic physiological activation patterns, the HB undoubtedly provides the ideal site. The first set of data comes from a team in Pennsylvania ^[10], showed that Long-term, direct his pacing results in a reduction of left ventricular dimensions and improved cardiac function in patients with atrial fibrillation and dilated cardiomyopathy. During the last decade there was much work done in the field of DHBP, to extend the indications ^[11-16] and to improve the technique^[17-20]. But inspite of these efforts, DHBP is still great in theory, but difficult in practice^[21]. The aim of this study was to assess the feasibility of direct DHBP in our EP lab using simple readily available techniques, and to compare the short term effect on exercise capacity of the patients.

PATIENTS AND METHODS

All patients admitted to cardiac EP lab, Zagazig University hospitals for permanent pacemaker implantation -according to the Guidelines for cardiac pacing and cardiac resynchronization therapy- ^[22] between January and June 2013, were included in the study. A trial was made to implant a HB electrode, if the trial failed, the electrode was implanted in the right ventricular apex -according to

our EP lab protocol for preparation and preforming single chamber pacemaker implantation-^[23]. All patients were provided with VVIR pulse generators (with an activity sensor which is used to measure the patients' movement and to determine the appropriate pacing rate, programed at the same upper sensor rate). Patients with successful HB implantation were compared with a matching group of patients with an electrode implanted in the right ventricular (RV) apex. Signed informed consent was obtained from all patients. HB localization: HB recording was obtained using a quadripolar catheter with 2-5 mm electrode spacing introduced from the left femoral vein and advanced to the right atrium under fluoroscopy, the catheter was positioned in the anatomical position of the HB in the superior septal aspect of the TV, by advancing the catheter to the RV in right anterior oblique (RAO) projection and applying a clock wise torque and confirming the septal position in left anterior oblique (LAO) projection. Recording from the catheter is displayed on the cardiolab EP recording system (GE healthcare, WI, USA); electric stimulation was delivered to the catheter using EPS320 Cardiac Stimulator (Micropace Inc., CA, USA). If HB recording was obtained pacing was started at 4v at 50ms pulse width to capture the heart, 12 lead ECG simultaneously recorded should show a QRS width less than 120ms, or the output was reduced until loss of capture or QRS width reduced, if loss of capture occurred before reduction in QRS width, the catheter is slightly moved and the same pacing protocol is repeated. If no HB recording obtained the same pacing protocol is repeated. Once stable pacing is obtained at a pacing rate of 70/min the pacing rate was increased to 140/min and one to one conduction confirmed, the pacing threshold is determined, with 3 V or less at 50 ms is considered acceptable. A screw-in active fixation lead is used 52 cm, active fixation Tendril SDX, St Jude leads (St Jude, Minneapolis, MN, USA), it was introduced through the left subclavian vein, a custom shaped style is preloaded in the lead with two curves, the first curve is big to access the superior aspect of the TV, and the second curve is smaller and orthogonal to the first one to access the septal aspect of the valve. The lead was manipulated to aim at the recording tip of the quadripolar catheter. To confirm the position of the pacing lead unipolar recording was obtained from the tip, and the previous pacing protocol was repeated using the

pacing electrode. Once acceptable the screw was protruded to fix the lead in position. The pacemaker was programed to sense the patients QRS and not the P wave-if any- by adjusting the sensing threshold. Fluoroscopy time and exposure was noted, skin to skin time was noted. If the time from procedure start exceeded 120 minutes without achieving endpoints of paced narrow QRS in an acceptable pacing threshold the lead was fixed to the RV apex. After one month of implantation, an exercise ECG was done, to determine exercise capacity of the patients, measured in maximum metabolic equivalents (METS) which can be achieved by the patient, the percentage of METS achieved from the maximum calculated METS for age was calculate. Patients were excluded if they cannot exercise on a treadmill or having a comorbidity that may affect the exercise capacity. The patients were followed-up for 3 months to detect any complications. Statistical methods: All data were analyzed using SPSS software statistical package for social science version 16 (SPSS, Inc. Chicago, IL, USA). Results were presented as mean value \pm SD for continuous variables and as frequency (%) for categorical variables. Data were tested for normality using Kolmogorov-Smirnov test. Means were compared in independent groups using Student t-test or Mann-Whitney test.

RESULTS

Between January and June 2013, 83 pacemakers were implanted, among them, 32 patients were included in the study, with success to capture the HB achieved in 12 patients (38%). Control group of 12 patients with matching demographic and clinical characteristics were selected from pacemaker clinic, there were four females in each group (36%) $p=0.67$. table 1 shows demographic and clinical characteristics of the 24 patients.

When we compared procedure time, DHBP procedure was twice as long as ARVP (218%), fluoroscopy time was more than triple in DHBP pacing (350%), patient exposure-using reduced sittings (low details, 7.5 frames/second)-was nearly triple ARVP (309%), QRS width during DHBP was 40% of that during ARVP, pacing threshold in DHBP was 3.5 times higher than ARVP with the screw-in, which remained higher after one month and after 3 months, but followed the usual course of pacing threshold (initial elevation after one month and stabilization at a lower chronic pacing threshold later on), R wave amplitude in DHBP was 67% of

the R wave amplitude in ARVP. There was 29% reduction of the pacing threshold when the screw was out, compared to the screw-in in the HB lead. As shown in table2.

After one month of implantation, calculated metabolic equivalents (METS) achieved by the patients, during symptom limited exercise stress

test, was compared between the two groups, DHBP patients achieved more METS when compared to Max METS for the age as shown in table3.

Learning curve was steep, with improvement in the procedure duration over time, figure (1).

During the period of follow-up there were no cases of loss of capture or lead dislodgment.

Table1:demographic and, clinical and echocardiographic characteristics of the patients

	DHBP	ARVP	t	P
Age (years)	58.4±6.8	59.3±8.2	-0.28	0.78
BMI	28.5±3.5	29.6±4.9	-0.54	0.59
Heamoglobin(gm/dl)	11.4±1.8	11.1±1.5	0.61	0.43
LVEDV (ml)	84.9±12.1	83.7±11.6	0.24	0.81
LVESV (ml)	31.5±7.6	32.2±8.9	-0.18	0.85
EF (%)	63.9±6.1	61.9±8.1	0.42	0.68

Table2: Intra-procedural data comparison

	DHBP	ARVP	t	P
Procedure time (minutes)	94.7±30.4	43.2±17.4	4.87	<0.001
Fluoroscopy time (minutes)	35.2±10.9	10.1±3.6	7.22	<0.001
Patients exposure (Gy cm ²)	34.1±7.8	11.9±4.9	7.94	<0.001
QRS duration (ms)	76.8±14.8	193.9±35.8	-10.0	<0.001
Pacing threshold screw out(V)	2.1±0.6	0.6±0.4	6.54	<0.001
Pacing threshold screw in(V)	1.5±0.5			
Pacing threshold one month(V)	2.3±1.3	1.2±0.6	3.56	<0.001
Pacing threshold 3 months(V)	1.2±0.7	0.7±0.3	4.46	<0.001
R wave amplitude (mV)	5.2±2.0	7.7±1.9	-2.91	<0.001
Lead impedance (ohms)	361.4±55.1	555.7±60.1	-7.84	<0.001

Table3: Exercise ECG data comparing both groups

	DHBP	ARVP	t	P
Max. METS for age	10.2±0.68	10.1±0.83	0.27	0.74
% of achieved METS form MAX METS for age	75.5±8.7	54.9±8.7	5.52	<0.001

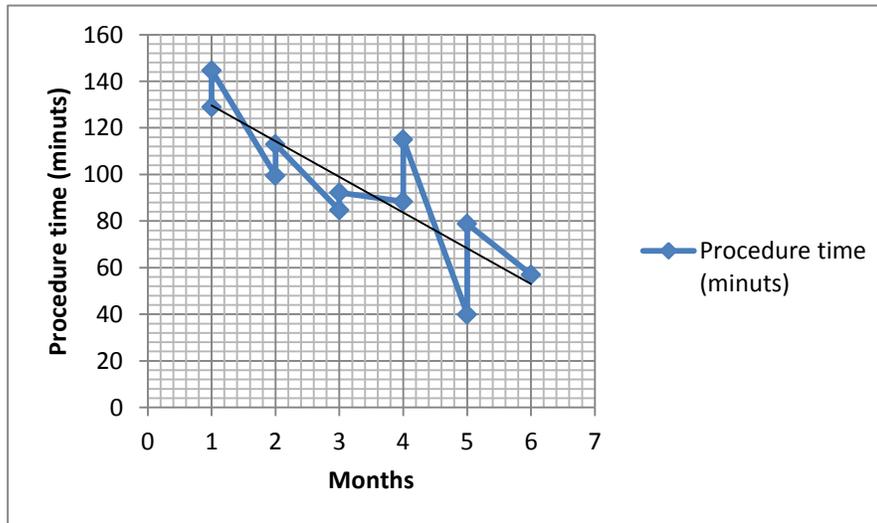


Figure (1): Linear regression plot showing the total procedure time of DHBP in each of the months of the study.

DISCUSSION

We succeed in 38% of our trials to establish a successful DHP, the most common cause of failure that we could not achieve a QRS width less than 120ms, the second most common cause was the inability to fix the lead in the target position, or the instability of the position, the third most common cause was the inability to maintain one to one conduction at a rate less than 140/minute. Deshmukh & Romanyshyn^[24] used the same technique and achieved a success rate of 72% but they did not have a time limit, Cantu et al.^[25] achieved 64% success with using a special steerable catheter, Catanzariti et al.^[26] achieved 95% success using steerable catheter and coronary sinus catheter as a landmark, it seems that a well-equipped EP lab with experienced staff can have an essential rule in increasing the success rate, in the other hand, some of the previous authors considered a para-his pacing –with QRS wider than 120ms- as a successful HB pacing, which was not the case in our study, as we only accepted pure HB capture with QRS duration < 120ms.

Average total procedure time (skin to skin time) was 94.7±30.4 vs. 43.2±17.4 minutes and average fluoroscopy time was 35.2±10.9 vs. 10.1±3.6 minutes, for DHBP and ARVP respectively, The most significant challenge encountered was the inability to precisely direct the stylet-controlled lead tip to the small (2-mm diameter) target, especially

during cardiac contraction and relaxation. Moreover, difficulty was frequently encountered when attempting to engage the screw into the membranous septum. Gross dislodgment of the lead tip requiring multiple attempts was a common occurrence that could be attributed to initial lack of experience and lack of active lead steering which necessitate many trials to refine the shape of the stylet and directing the tip of the electrode to a suitable position for pacing and fixation. Cantu et al.^[25] median fluoroscopy time was 16 minutes for DHBP and 17 minutes for para-his pacing. Catanzariti et al.^[26] Mean procedural and fluoroscopy exposure times were 135.7 ± 18.1 min (range 106 –147) and 10.2 ± 4.1 min, respectively, they used additional coronary catheter for land marking. Kronborg et al.^[27] Mean implantation time was 85±31 min, mean fluoroscopy time was 23±13 min, and mean position attempts of the HB lead was 8±5. Total procedure time in our study was progressively shorter reflecting the steep learning curve of the procedure.

Pacing parameters were acceptable. As most of the authors set a target pacing threshold of 2.5 V, we decided to increase it to 3V as the first cases showed a good capture between 3V and 2.5V but not below 2.5V, which was reduced when the screw was protruded. Cantu et al.^[25] reported nearly similar parameters; QRS duration was 99±19 ms. the acute HB threshold at 0.5 ms was 1.7±1.2v. Catanzariti et

al. [26] Pacing thresholds, impedance and sensed potentials of the HB lead, recorded 30–60 min after lead fixation and at the last follow-up examination, were 1.61 ± 0.55 and 1.71 ± 0.92 V at a pulse width of 0.5 ms, 552 ± 89 and 525 ± 101 ohm, 4.32 ± 2.77 and 4.17 ± 3.63 V, respectively. The pacing threshold in our study dropped to similar limits after fixation of the lead, but we preferred to report the pre-fixation values to try making the procedure faster, by skipping many trials of fixing and unfixing the lead, the chronic pacing threshold was nearly the same as the acute pacing threshold, with the usual elevation at one month of implantation, in some of our patients, we had to increase the factory default pacing voltage to achieve a safety margin of double the pacing threshold.

The marked improvement in exercise capacity observed using symptom limited exercise testing to measure the Max. achievable METS and correcting it as a percentage of the MAX predicted METS for age was agreed by Deshmukh & Romanyshyn [24] using the LV pressure-volume curves recorded improvement in patients with DHBP, in the same study there was a marked improvement in cardiopulmonary testing parameters in patients with DHBP vs. ARVP. In the other hand Padeletti et al. [28] demonstrated no improvement in LV pressure-volume curves when measured during acute pacing from different sites including DHBP. In the first study the patients baseline EF was much lower than the second study, furthermore the second study adopted only the acute effect of pacing, while the first one like in our case demonstrated the chronic effect of HB pacing, and its expected-as proved by the first study- that increase in the stroke volume with less oxygen consumption is the direct cause of increased exercise capacity even in patients with normal LV systolic function.

CONCLUSION

In conclusion, this study demonstrated the difficulties accompanied with DHBP, in the other hand the great benefits gained from this approach including; avoiding the established deleterious ARVP; and the acute gain in exercise capacity, which will be reflected as an improvement in the life style

STUDY LIMITATIONS

The small number in addition to the short period of follow-up was the main limitations of this study, but we considered it as a pilot study to test the acute feasibility of the DHBP in our EP lab. The lack of

hemodynamic confirmation of superiority of the DHBP to ARVP was another limitation, but we are planning to include a larger number of patients in a study which will include invasive and non-invasive hemodynamic comparison.

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تنظيم القلب الدائم عن طريق ضفيرة هس كبديل عن التنظيم التقليدي من قمة البطين الايمن: دراسة تجريبية في مختبركهروفسيلوجية القلب
بجامعة الزقازيق

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يعد تنظيم القلب فسيولوجيا (اقرب الي التنظيم الطبيعي) من أهداف اختصاصيو كهربية القلب، وخصوصا بعد التقارير المبكره عن الآثار الضارة لتنظيم القلب عن طريق قمة البطين الايمن، وبسبب صعوبات فنيه لم يلق التنظيم الفسيولوجي شعبية واسعة. هدف هذه الدراسة هو تقييم فعالية تنظيم القلب عن طريق ضفيرة هس.

الاساليب: تمت محاولة زرع منظم ضربات قلب عن طريق ضفيرة هس لجميع المرضى المناسبين، المحولين لزرع منظم ضربات قلب في الوحدة بين شهري يناير ويونيو 2013 ، مستخدمين تسجيل ضفيرة هس عن طريق قسطرة رباعية كدليل كهربى واشعاعى، واستخدم سلك معاد تشكيله لتوجيه الكترود ذو تثبت ايجابي الي مكان ضفيرة هس، واستخدم بروتوكول تنظيمي لضمان التنظيم الانتقائي لضفيرة هس، وقد ادرجت مجموعة اخري من المرضى ذوي خصائص مشابهة ممن نظم القلب عندهم عن طريق قمة البطين الايمن لاستخدامهم كمجموعة حاكمه.

النتائج: لقد نجحنا في تحقيق التنظيم عن طريق ضفيرة هس في 12 مريضا من اصل 32 مريضا (38%)، وقد بلغ اجمالي وقت الاجراء (94.7 ± 30.4 مقابل 43.2 ± 17.4 دقيقة) لكل من التنظيم عن طريق ضفيرة هس في مقابل التنظيم عن طريق قمة البطين الايمن، و اجمالي وقت التعريض للاشعة السينية (10.9±35.2 في مقابل 3.3±10.1 دقيقة)، و اجمالي جرعة الاشعة للمريض (7.8 ± 34.1 مقابل 4.9 ± 11.9 جراي لكل سم²)، كما بلغت عتبة التنظيم (0.6±2.1 مقابل 0.4±0.6 فولت)، وفي الجانب الاخر تحسن تناسق القلب حيث بلغ اتساع موجة الكيو ار اس (14.8±76.8 في مقابل 35.8±193.9 مللي ثانية) في كل من التنظيم عن طريق ضفيرة هس و التنظيم عن طريق قمة البطين الايمن علي التوالي. كما وصلت نسبة ما يستطيع المريض تحقيقه من مكافئات الجهد منسوبة الي الحدود القصوي بالنسبة للسنة (8.7±75.5 مقابل 8.7±54.9 في المائة)، كما كان منحنى التعلم سريعا في خلال فترة الدراسة.

نستخلص من الدراسة: انه بالرغم من الصعوبات الفنيه التي تواجهنا اثناء تنظيم القلب عن طريق ضفيرة هس الا ان النتائج تستحق العناء ومما يشجع علي الاستمرار في هذا النهج منحنى التعلم السريع لهذا الاجراء.