Two years experience in pacemaker implantation in AL-Kadhemia university hospital and review of its indications and related early complications.

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سنتا خبرة في زرع النابض الكهربائي القلبي في مستشفى الكاظمية الجامعي وتبيان دواعي الزرع ومضاعفاته الأولية

الخلاصة

تمهيد: يزرع أكثر من ٤٠٠٠٠ نابض سنويا في العالم ، وتتم هذه العملية في مختبر القسطرة أو في غرفة الأشعة السنية، تحت التخدير الموضعي. ويدخل إلى الوريد تحت الترقوي بطريقة سلدنجر.ويبقى المريض في المستشفى ليلة واحدة بعدها.

الأهداف: لتوثيق سنتين من الخبرة في زراعة النابض الكهربائي في م. الكاظمية الجامعي ل ٢٩٠ مريضا،موضحا دواعي الزرع والمضاعفات الأولية.

الطرق: درست حالات ٢٩٠ مريضا (رجعيا)زرع فيهم ٣٠٢ نابضا، لداعي انحصار الحزمة القلبية الكامل خاصة مع توسع في QRS.(عند١٨٠ مريضا). زرع هذه النوابض فريق طبي متخصص بإشراف الأستاذ الدكتورعمار الحمدى من الفترة ٨\٢٠٠٣-٨\ ٢٠٠٥.

النتائج: ١٧٠ مريضا كانوا رجالا(معدل أعمارهم ٧٥ سنة)؛والمتبقي منهم ١٢٠ مريضا) كن نساء(ومعدل اعمارهن٦٢ سنة).وكان العرض الشائع هو فقدان الوعي المؤقت(١٣٥ مريضا)،ونوبات من الدوخة(٨١ مريضا).وأشار فحص الصدى القلبي غالبا إلى توسع البطين الأيسر (١٨ مريضا)، وتوسع الأذين الأيسر(٣٢ مريضا)،وقلة حركة احد الجدر للبطين الأيسر(١٥ مريضا). وكان أهم دواعي الزرع هو انحصار الحزمة القلبية الكامل(عند٢٢١ منهم)،ومرض العقدة (٤٥ منهم).زرع نابض مؤقت ل ٦٢ مريض VVI(٢٢٨ مريضا)،وDDDالجيبية(عند٤٥ منهم).أكثر صنفين زرعا هما عانوا من بطئ النبض(<٣٠ ن.ف.د)،من ضمنهم حالتان طارئتان.استفيد من نظام ولتر لتخطيط القلب المتحرك في مقاربة٤٨ مريضا كان يعانى من حالات متكررة وغير مفسرة لفقدان الوعي المؤقت،ولتوثيق حالات التسارع الاذينى ،والتوقف الجيبى ،ولإسقاط احتمالية التسارع البطينى.كذلك،ساعد جهاز فحص الكهربائية الفسلجية في مقاربة ٤ مرضى عانوا من حالات متكررة وغير مفسرة لفقدان الوعي المؤقت(إن كان فحص الهولتر سلبيا).إن أهم واخطر المضاعفات كان التهاب الجيب الجراحي (عند ١٣ مريضا)، أزيل ١٢ صندوقا مع وادٍ بنجاح بواسطة قوة ساحبة تزداد تدريجيا وبحذر وبمراقبة المنظار الوجى.وأزيل بسلاسة ٥ نوابض قديمة (من نوع سورين) لانتهاء بطاريتها،وزرعت نوابض بديلة لهم،لكن قطع عمدا أدين مع تثبيت الأجزاء العازلة.ثلاث حالات تبعتها تجمع دموي كمضاعفات أولية ،عولج تحفظيا بالسحب الابرى.أجريت ٤ ترقيات إلى DDD.للصنف (لنوع سورين) من VVI

ABSTRACT

Background: More than 400000 pacemakers are implanted each year. Subclavian vein is accessed by Seldinger technique This procedure is accomplished in catheterization laboratory or x-ray room, under local anesthesia;. Generally patients stay in hospital for one night.

Aim of study: To register 2 years experience of Pace maker (PM.) implantation in Al-Kadhimiah University hospital in 290 patients, emphasizing its indications and related complications.

Patients and methods: 290pat. had been retrospectively reviewed for 302 implanted PM. devices, mainly due to Complete heart Block(CHB) with wide QRS. (180 pat.). 302 PM. devices were implantedn AL-Kadhemiah university hospital by an experienced medical team, supervised by Prof. Dr. Ammar Al- Hamdi in a period of 2 year, from 8\2003-8\2005.

Results**:** 170 of them were males (mean age 75 years); the remaining 120 pat. were females (mean age: 62 years). Their main chief complaint was syncope (135 pat.) , and dizzy spells (81 pat). Their main Echo. findings were dilated LV. (18 pat.), dilated LA. (32 pat.), and LV. wall hypokinesia (15 pat.). The main indication for implantation was CHB. (221), and SND. (45). The main implanted mode was DDD. (228) and VVI. (45). Temporary PM. has been indicated in 62 pat. presented with bradycardia with ventricular rate ≤30 bpm. (including 2 emergency procedures). Ambulatory Holter monitoring was useful in approaching recurrent unexplained syncope in 48 pat, especially to document atrial- tachycardia, sinus pauses, and to exclude ventricular arrhythmia. EPS. was helpful in approaching 4 pat. with unexplained recurrent syncope (with nondiagnostic Holter). Main and serious complication was pocket –related infection (13), 12 of their lead systems and boxe had been successfully removed by cautious gradually increasing pulling force under fluoroscopy. 5 old pacing systems were smoothly extracted due to End Of Life (EOL) of Sorin™, and new systems were reimplanted, but 2 lead coils

were cut with ligation of insulating part. 3 procedures were early complicated by hematoma, managed by simple needle aspiration. System upgrading was performed in 4 Sorin™ reimplanted systems (from VVI. to DDD.)

Conclusions: Temporary PM. implantation is not essential, except in those presenting with ventricular rate ≤30 bpm. 24 hour ambulatory ECG. monitoring is of paramount importance in approaching pat. with recurrent unexplained syncope, especially in suspected Sinus Node Dysfunction (SND).. Diabetes mellitus(DM.) was the main pat. - related risk factor to PM. infection.

Key wards: Syncope, Bradycardia, ECG., Holter, PM., Indications, Complications.

Introduction

More than 400000 pacemakers are implanted each year [(1).] Pacemaker is composed of pulse generator (battery, output, sensory, timing, telemetry, micro processor, and sensor circuits), and lead system (terminal pin connecter, lead body consists of coiled insulation, stimulating and sensory electrodes, and fixation device which is either passive or active types).

Pre operation issue include: history, physical examination, informed consent; pre procedural data include: 12 lead ECG. \CBP. \ESR., renal function test, FB. Sugar, echo. heart study, medication review especially for warfarin which should be discontinued 3dayes before.[(1,,2,3)]

Patient preparation include: Nothing by mouth 6hours before, IVF. might be indicated to prevent dehydration which has potential hazards during procedure. Set IV. line ipsilateral to the site of planned implantation. Shave the area and wash it with iodine solution above the nipple to the angle of jaw, and from sternum to axillary line[1,2,3].

Post- operative issues include: PA. CXR for documentation of lead position, their connection and pneumothorax, Evaluate pacing\sensory thresholds and lead impedance before discharge. Discharge instructions include pat. education about signs of infection\ bleeding and avoiding heavy lifting especially forceful abduction at ipsilateral side[1,2,3].

Implantation technique issues: Subclavian vein is accessed by Seldinger technique, 2 leads can be inserted through one incision.

Guide wire is inserted; Introducer with its dilator is inserted over guide wire (GW.), GW. is removed; the lead is inserted into its final site observed by fluoroscopy; the

created pocket should be large enough of pacing\ sensing thresholds are taken using PM. System analyzer (PSA.); it is worth taking time during the implantation to get capture threshold possible. Plug the lead into PM., put the box in the pocket, suture it. This procedure is accomplished in catheterization laboratory or x-ray room, under local anesthesia; Generally patients stay in hospital for one night.

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Patients and methods:

Consecutive 290 pat. had been studied retrospectively from 8\2003- 8\2005, for their made of presentations, indications for PM. implantation, early and late complications; the implantation had been performed by specialized medical team supervised by Prof. Dr. Ammar Al- Hamdi,

mainly performed by Dr. Nazar Al-Chalabi MD. in CCU in AL-Kadhimiah university hospital; medical files included in formations about duration and made of presentation, associated co morbidities, multiple surface ECG s, Holter monitoring, electro- physiology study report, with review of their medications. 302 pulse generators and its related lead system were implanted for

290 patients (including 5 re- implanted pat. for end of life (EOL.)). Follow up (FU.) periods were variable, depending on the presence of new pat. complaints; but usually were scheduled 7-10 days after implantation, then 2 month apart; it is performed in an active PM. clinic, supervised by Dr. AL-Hamdi or the implanting physician; it is accomplished by examining the pocket wound for healing\ infection\ hematoma, and removing silk sutures; then reviewing PM. parameters especially pacing and sensing thresholds, lead impedance, battery status, lower pacing rate, rate modulation mode, and sensor function. These all were accomplished after reviewing surface ECG. looking for intrinsic rate\ rhythm, and status of pacing\ sensing PM. function.

Results

290 Pat. had been studied; 7 of them were males (59%), aging 60-88 years (mean age: 75 years); and the remaining were females (41%), aging 45-75 years (mean age: 62 years); their modes of presentation were variable, mainly recurrent syncope and dizzy spells. (see table 1).

Table1: Predominant mode of presentation in 290 implanted patients

Mode of presentation	NO. Of Pat.	% To total 290 Pat.
Recurrent syncope	١٣٥	%٥٥ .٤٦
Dizzy spells	٨١	%٣١ .٢٧
Palpitation	٢٧	%٣ .٩
Nocturnal fit	١	%٣ .٥
Bradycardia during induction of anesthesia	١	%٣ .٥

Their co- morbidities were variable, mainly hypertension, angina, myocardial infarction, and heart failure (see table 2)

Table2: Co- morbidities in 290 implanted patients

Co morbidity	NO. of Pat.	% of total 290 pat.
Hypertension	٧٨	%٨ .٣٣
Heart failure	٢٣	%٦ .١٨

Angina pectoris	٤٢	%٩.١٧
Old myocardial infarction	١٢	%١.٤
Diabetes mellitus	٣٥	%٦.١٢
Old mw stroke	٩	%١.٣
Chronic Obstructive Pulmonary Disease	١٠	%٩.٣

No associated co- morbidities were recorded in 52 Pat.

Their ECG. findings were variable, or intermittent; main patterns with P was ≤ 60 bpm. was sinus bradycardia of Tachy-brady cardia; while main patterns with QRS. ≤ 40 BPM. was complete heart block (CHB.) with wide QRS. (the reverse is true), or Sinus bradcardia of Sinus Node Dysfunction (SND.); while the main pattern with QRS. 40-60 bpm. was Mobitz II; However, main pattern with QRS. ≥ 60 bpm. was Trifascicular block (see table 3).

Table 3: Presentations of ECG. Patterns of 290 implanted patients

ECG. Pattern	No. of patients	Presentation	No. of patients
P≤60 bpm.	٤٢	Sinus bradycardia of Tachy-brady	٢٩
		Sinus brady. Of SND.	١٢
		Congenital CHB.	(missed) ١

Atrial fibrillation (AF.)	٣٣	Chronic persistent AF.	٣١
		Paroxismal AF.	٢
QRS≤40 bpm.	١٧٤	CHB. With wide QRS.	١٣٧
		Brady. Of Tachy- brady.	٢٢
		Sinus brady. Of SND.	١٢
		EOL.	٥
QRS. 40-60	٣٥	MobitzII	٢٣
		Sinus brady. Of SND	١٢
QRS≥60 bpm.	٤٢	Trifasicular block	١٤
		Sinus pause of SND.	٨
		Carotid sinus hypersensitivity	١
		Unexplained syncope	١
Wide QRS.	١٥٦	CHB.	١٣٧
		Trifasicular block	١٤
		EOL.	٥
CHB. with narrow QRS.	٢٢		

Total number of implanted devices were 302 (290 patients with, 12 reimplanted infected devices, and the main mode of implanted PM. was DDD.) (see table 4).

TABLE 4: Modes of 290 implanted devices.

	No. of devices	% of total 302 devices
Mode.		
DDD.	٢٢٨	%٥ .٧٥
VDD.	٢٩	%٦٥ .٩
VVI.	٤٥	%٩ .١٤

This table includes 5 boxes were reimplanted due to EOL (Sorrin^{TM}) presented with their original complaints (syncope\ dizzy spells) with ECG. showed CHB. in 4patients reimplanted with DDD., AF. with CHB. In the 5th one reimplanted with VVI.

The indications of PM. implantation were variable, mainly were CHB., SND. (see table 5).

Table5: Indications of 302 implanted PMs., according to ACC\AHA guidelines in 1998.

Indications	No. of implanted .PMs	to total %290 pat.
CHB.	٢٢١	76%
SND.	٤٥	15%
MobitzII	٢٣	8%
Trifascicular block	١٤	5%
Unexplained syncope	١	0.3%

CHB. was including 6 cases with intermitant CHB.

45 patients had SND. with variable presentations, mainly Tachy –brady. (see table 6).

Table 6: Presentation modes of 45 implanted patients with SND.

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Mode of presentation	No. of implanted PMs	%of total 290 pat.
Tachy- brady. syndrome	٣٥	%١٢
Sinus brady ≤40	١٢	%٤
.Sinus pause≥3 sec	٨	%٢
Chronotropic incompitance	١ (missed)	%٠.٣

Ambulatory ECG (Holter monitoring) was helpful in ranking 48 patients for PM. implantation mainly when SND. was suspected (see table7).

Table 7: Indications of Holter monitoring in 48 implanted patients.

	Indications
No. of patients	
٤٥	Suspected SND. to document sinus pauses >3 sec. and to correlate between symptoms and timing of .pauses
٢	Syncope not proved to be due to Atrio-ventricular block to exclude ventricular tachycardia
١	Evaluation of resumed recurrent syncope after PM. implantation to exclude myopotential inhibition, PM. Mediated tachycardia (PMT.), to

	assist in the reprogramming to Rate – Response and Mode-switching after device dysfunction

Less commonly, invasive EPS. was helpful in 4 pat. in making decision for PM. implantation, especially for recurrent unexplained syncope (see table 8).

Table 8: EPS. indications in 4 implanted pat.

No. of pat.	Indications
٢	Syncope not proved to be AVB., with normal HV. Interval; to exclude VT. (after non diagnostic Holter monitoring)
١	Carotid sinus stimulation –induced ventricular asystole. 3 sec. with normal HV. interval, and no pacing –induced HV. prolongation in unexplained syncope
١	Markedly prolonged HV. interval ≥ 100 ms. in unexplained syncope.

2 cases of recurrent junctional SVT., refractory to anti arrhythmic drugs (AAD.) had undergone EPS. for ablating fast limb of AVN. reentry circuit, complicated by late CHB., thence DDD. had been required.

PM. implantation is regarded as very low risk outpatient surgical procedure, undertaken by a cardiologist or trained physician in X ray room or catheterization laboratory.

The incidence of complications is variable depending on its severity, timing from implantation, and whether mechanical or electrical issues being blamed. The main and serious complication in this series was infection of the box and \ or the lead system; There was no mortality, but the morbidity was significant (only one of the 13 infected pockets had been cured by prolonged IV

. antibiotic course with local dressings; that case was presented as early cellulites). Hence, strict sterile precaution is essential in all cases (undertaken by all medical implanting personnel).

Timing of infection (from date of implantation) was regarded as late (1-6 months) in 12 pat. scheduled for reimplantation, 8 of them were diabetics (type II) with poor glycemic control (P value was <0.001) indicating that diabetes is a significant risk factor for development of infected implanted PM. system (see table 9 and 10) .

Table 9: Pat. Criteria of 12 pocket infection

No. of pat.	Pat. criteria
٨	Elderly, diabetic, late presentation, all had low body weight
٢	Elderly, not diabetic, late presentation, both had low body weight

٢	Normal body weight, not diabetic, no special reason, late presentation, might be due to tight subcutaneous pocket

	Diabetes	No Diabetes
Infected system	8	4
Not infected system	27	263
P value	<0.001	Chi^2: 36.997

Table 10: Infected PM. systems vs. Diabetes as a risk factor.

Infected boxes of these pat. were easily removed, and lead extraction was successful in 8 cases, and was accomplished by continuous gradually increasing pulling force under fluoroscopy, with great care and precaution. Any increasing persistent resistance is an absolute indication to stop trying pulling and abandon the lead extraction procedure, and an indication for referral to a more specialized centre.

The remainder 4 cases, hence, were referred to specialized centre outside country (for laser ablative technique). Another 2 re implanted cases (from 5 re implanted cases due to EOL.) were unsuccessful (Sorin™) and lead systems were abandoned by special technique after insuring that the system was not infected, this technique can be summarized as follows: cut the lead at its proximal end—pull the metal core as far as possible, but with great care – cut the metal core emerging from that proximal end of insulating part of the lead—pull the insulating part at its proximal end (with great care) – tightly legate it by several non absorbable silk 1-0 sutures to

subcutaneous tissue plane.

Hematoma of the created pocket developed early (within 2 weeks) in 3 cases; needle aspiration was regarded as diagnostic and therapeutic measure, with no resumption of those hematomas.

No recorded case of clinically significant pneumothorax at inter-\post- operative period.

No recorded case of PM. Syndrome that mandated upgrading of VVI. to DDD. 5 cases were re implanted due to EOL., presented with resumption of their original complaints, all of them were of Sorrin ™, re implanted with new PM. Boxes;3 of them had upgrading from VVI. to DDD.; the remaining 2 cases had chronic persistent AF. with CHB.; hence, only the box generator of VVI. was re implanted. Their date of implantation ranged from 6-10 years before start of this study. Re implantation in these pat. had no special complication apart from finding special lead head adaptor suitable for the old Sorin™ lead system.

Temporary PM. was implanted in 62 pat. presented with ventricular rate <30 bpm. (including 4 emergency procedures during threshold testing of permanent PM. during implantation.

DISCUSSION

Syncope is a common medical problem, accounting 6% of general medical admission. It is defined as sudden transient loss consciousness with associated loss of postural tone, recovery is spontaneous, without neurological deficit, and not requiring cardioversion [1,4]. Syncope in elderly is frequently multifactorial (drugs, ischemia, anemia, and decrease in barorecepter sensitivity) [5]. Elderlies constitute the main bulk in this study; pediatric age group is not presented here. There is a trend towards delayed diagnosis of advanced conductive heart disease in pat. presented with dizzy spells [6,7], could be explained by physicians unfamiliarity to relate these spells to abnormal heart rhythm (not infrequently misdiagnosed as vertigo, anemia, hysteria, cervical osteoarthrosis, among others).

Palpitation mainly was presenting SND. (especially Tachy- brady.). SND. mainly was presented as chronic persistent AF. (in 32 pat.) with brady. ≤ 40bpm., while 22 pat. diagnosed with CHB. presented with narrow QRS (supra- hisian AVB.).

The most physiological implanted mode was DDD. \VDD. (257 devices). The advantage of VDD is its requiring only one lead The remaining implanted mode was VVI. mode (45 devices) mainly in pat. presenting with Tachy- brady.

EPS. was useful in 4 pat. to elucidate syncope mechanism and to exclude VT. if clinically expected. All pat. had echo. heart study. Echo is of low yield unless history and examination revealed evidence of structural heart diseases [1,8] (detected only 80 sfinding).

Careful carotid sinus massage (CSM.) should be applied to pat. presenting with dizzy spells or syncope especially if these were unexplained and recurrent in elderly pat. [9]

Unstable pat. always should be admitted to hospital and temporary PM. Be implanted

The risk to the pat. of sudden lack of out put (op.) causing asystole can be prevented by placing temporary PM. in pat. who were PM. dependant (occurred in 62 pat. presented with bradycardia and ventricular rate ≤30 bpm., including 2 emergency inra-operative temporary PM. implantation.

Criteria of PM. dependence include no escape rhythm (asystole), or VT. (pause dependant), and CHB. with drady. ≤30 bpm. . [2,10]

All implanting staff must wear scrub clothes, hats, and masks. The risk of infection is high in the prolonged operation (>72 hours) [3,11]. Infection incidence in published literature is <2% [3,12], but the morbidity is high [3,13]. If there is active infection at surgical pocket, the re- implantation procedure is deferred until the pat. is afebrile and no longer septic; mainly due to Staphylococcus aurous. Acute infection of PM. pocket might behave like an abscess; if this drains through the skin: chronic draining sinus develops [3]. Treatment of infected box (diffuse cellulites\infected erosion \developing abscess) consisted of parenteral empiric antibiotics, removal of implanted device (including the device), debridement of all inflammatory tissue (if any), abandonment of infected pocket, and re implanting in contra lateral side [3,14].

The most successful treatment of hematoma is immediate pocket exploration; while needle aspiration decompress the pocket but doesn't remove the clot; furthermore, repeated needle aspiration increase the risk of infection[3].

No reported penetration case in this series (presenting itself as exit block, loss of sense, pacing threshold elevation, and diaphragmatic stimulation) [3].

VVI. should be followed twice in the first 6 months, then every 12 months; while DDD. \ VDD. should be followed twice in the first 6 months, then once every 6 months [2].

CONCLUSIONS

1: PM. implantaton is safe outpatient surgical procedure without reported mortality.

2: Temporary PM. implantation is not essential, except in those presenting with ventricular rate ≤30 bpm.

3: PM. clinic is essential for pat. –implanting physician contact, and for systematic follow- up.

4: 24 hour ambulatory ECG. monitoring is of paramount importance in approaching pat. with recurrent unexplained syncope(especially in suspected SND.).

5: EPS. is helpful as a last available resort in approaching pat. with recurrent unexplained syncope with non diagnostic Holter monitoring.

6: Diabetes mellitus is the main pat. - related risk factor to PM. infection.

7:Lead explanation can be accomplished by continuous gradually increasing pulling force under fluoroscopy with great care and precaution, only by experienced operator.

النتائج: إن زرع النابض المؤقت غ ر ضروري، إلا عند المرضى ذوى التباطؤ القلبي >٣٠ ن.ف.د. وان تخط ط القلب المتحرك ذو فائدة كب رة في مقاربة المرضى الذ ن عانون من حالات متكررة وغ ر مفسرة من فقدان الوعي المؤقت، خاصة عند الاشتباه بمرض العقدة الج ب ة.وان داء السكركان أ[a]م عامل خطورة لالت اب النابض المزروع.

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