

					<p>pacing had AF (relative risk [RR] 0.54, 95% CI 0.33 to 0.89, P = 0.01)† and more patients who received atrial pacing were free from thromboembolic events (RR 0.47, CI 0.24 to 0.92, P = 0.02)† and chronic AF (RR 0.35, CI 0.16 to 0.76, P = 0.004)† than those who received ventricular pacing.</p>
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○：評価する

また、治癒性についてまとめてみると、評価するが 17 件に対し、評価しないが 7 件、差がないとするのが 3 件であった。以下表にまとめる。

文献 No	結果	疾病名称	対比技術	治癒性
MED 1	○	sleep apnea syndrome	atrial overdrive pacing vs pacemaker(-)	In patients with sleep apnea syndrome, atrial overdrive pacing significantly reduces the number of episodes of central or obstructive sleep apnea without reducing the total sleep time.
MED 3	○	sinus bradycardia	interatrial septum pacing (IASP) vs right atrial appendage pacing (RAAP)	Rate-adaptive IASP at the triangle of Koch is more effective than RAAP in preventing PAF in patients with sinus bradycardia. In our sample of patients no additional clinical benefit is furnished by the CAP algorithm.
MED 5	○	atrial fibrillation	dual-site RA pacing vs high right atrium pacing	Dual-site RA pacing with continued sinus overdrive prolonged the time to AF recurrence and decreased AF burden in patients with paroxysmal AF. The absence of a major impact on symptom control suggests that pacing should be used as an adjunctive therapy with other treatment modalities for AF.
MED 12	○	atrial flutter	procainamide pretreatment vs digoxin pretreatment	In group A, sinus rhythm in 13 patients and atrial fibrillation in 14 patients, arrhythmia remained unchanged in the 3 remaining patients; in group B, sinus rhythm appeared in 19 and atrial fibrillation in 5, and no change was observed in the remaining 2 patients
MED 26	○	Pacemaker patient	AV interval pacing	variations in the AV interval during atrial pacing have significant effects on LA function.
MED 31	×	paroxysmal atrial fibrillation	atrial overdrive pacing vs pacemaker(-)	atrial overdrive pacing, achieved by increasing the atrial base rate, has no incremental benefit in the suppression of paroxysmal atrial fibrillation when compared to rate responsive pacing with a base rate of 60 bpm.
MED 34	○	Atrial Fibrillation	biatrial pacing vs pacing (-)	Biatrial pacing significantly reduced both monitored (13.8% versus 38.5%, P:=0.001) and clinical (10.8% versus 33.8%, P:=0.002) episodes of AF. Median ICU (19 versus 24 hours, P:=NS)
MED 50	×	drug refractory AF	DDD pacing vs conventional right atrial (RA) pacing and a	Pacing (either type) at a base rate of 70 beats/min has an antifibrillatory effect when compared with inhibited pacing at 40 beats/min.

			control period of inhibited pacing	
MED 54	×	antiarrhythmic drug-refractory PAF	atrial pacing vs pacing(-)	The time to first recurrence of sustained PAF, the interval between successive episodes of PAF, and the frequency of PAF were compared in intention-to-treat analysis.
MED 66	○	paroxysmal AF	DDI pacing vs VDI pacing	This trial was designed after pilot studies showed dual site pacing to be safe, feasible and preliminary results suggested increased maintenance of sinus rhythm with atrial pacing.
MED 78	○	chronic atrial fibrillation	accelerometer-controlled VVIR Dash Intermedics pacemaker vs a vibration piezoelectric controlled VVIR Sensolog III Siemens pacemaker	During daily activities, accelerometer-driven pacemakers seem to provide a heart rate response closer to that of healthy controls. Our new mathematical analysis is a simple and reproducible method for evaluating and quantifying the efficacy of any sensor-driven pacemaker.
MED 105	△	pacemaker patient	rate adaptive pacing(VVIR) vs fixed rate pacing	However, patient selection for rate adaptive single chamber pacing should be made with caution, since the objective benefit of restoring normal chronotropy may subjectively be negligible for most patients.
MED 58	○	obstructive hypertrophic cardiomyopathy (HC)	pacing on vs Patients paced in inactive and active modes.	The LV outflow tract gradient increased significantly after inactivation of pacing in all patients (22 +/- 21 mm Hg to 47 +/- 21 mm Hg). Thus, AV synchronous pacing effectively relieves symptoms and reduces the LV outflow tract gradient in patients with obstructive HC.
MED 62	×	chronic atrial tachyarrhythmia and complete AV block	right ventricular outflow tract (RVOT) pacing vs right ventricular apical pacing (RVA)	Within the limits of this study, no symptomatic improvement or hemodynamic benefit was noted after three months of RVOT pacing, by comparison with RVA pacing.
MED 20	×	congestive heart failure	optimal medical therapy plus dual chamber pacemaker vs optimal medical therapy	At a 6 month follow-up, 7/19 patients in Group 1 had died compared with 5/19 patients in Group 2. During follow-up, there were few significant changes in evaluated parameters except for mitral regurgitation time, which was prolonged in Group 1 and shortened in Group 2. The systolic left ventricular diameter shortened significantly only in Group 2
MED 22	○	paroxysmal atrial fibrillation	three mode switching algorithm	The more sensitive onset criteria for detection of atrial tachyarrhythmias were associated with lower frequency and severity of symptoms.
MED 68	○	high degree AV block	randomly programmed to upper tracking	Carriers of dual-chamber pacemakers with no or mild heart failure (Weber A/B) benefit from higher programmed upper rates. In contrast,

			rates of 110, 120, and 130 bpm	patients with more advanced heart failure (Weber C/D) improve aerobic capacity with lower programmed upper rates. This may be caused by exercise-induced ischemia in group I as indicated by stress echocardiography.
MED 18	○	Brady-Tachy Syndrome	DDDR + CAP pacing vs DDDR pacing	78 % of patients in DDDR pacing and 73 % in DDDR + CAP pacing (p=n.s.) were free from symptomatic paroxysmal atrial fibrillation recurrences. The number of premature atrial complexes per day decreased during DDDR + CAP from 2665±4468 to 556±704 (p<0.02).
MED 23	○	risk of stroke	ventricular pacemaker vs physiologic pacemaker	The annual rate of stroke or death due to cardiovascular causes was 5.5 percent with ventricular pacing, as compared with 4.9 percent with physiologic pacing (reduction in relative risk, 9.4 percent; 95 percent confidence interval, -10.5 to 25.7 percent [the negative value indicates an increase in risk]; P=0.33).
MED 81	×	atrioventricular(AV) block sick sinus syndrome(SSS)	physiologic pacemaker vs ventricular pacemaker	At the end of follow-up, we reported 29 cases of cerebral ischemia: 9 patients had AV block while 20 had SSS (p < 0.05). Comparing the different pacing modalities, there was an increase in the incidence of stroke in patients receiving ventricular pacing (p < 0.05).
ACP-J 3	△	symptomatic bradycardia	physiologic (dual-chamber or atrial) pacing, vs ventricular (single-chamber) pacing	Physiologic pacing was no more effective than ventricular pacing for reducing stroke and cardiovascular mortality.
CCTR 1	○	sick sinus syndrome	single chamber atrial pacing vs ventricular pacing	After 5.5 years follow-up, all-cause mortality, cardiovascular deaths, atrial fibrillation, thromboembolism, and heart failure were significantly less in the atrial group. AV block occurred in four patients in the atrial group.

○ : 評価する △ : 差がない × : 評価しない

(3)安全性・信頼性

文献 No	結果	疾病名称	対比技術	安全性・信頼性
MED 52	○	post operative atrial fibrillation (AF)	right atrial pacing vs biatrial pacing, no atrial pacing	Continuous right or biatrial pacing in the postoperative setting is safe and well tolerated.
MED 107	○	pacemaker patient	DDD mode 80ppm vs DDD mode	Ventricular function and preload decreased overnight (PM vs AM) with both pacing regimens.

			50ppm	Stroke volume (SV) (61 mL vs 53 mL) and ejection fraction (EF) also fell (0.56 vs 0.53) in the morning.
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○：評価する

(4)患者 QOL

rate smoothed atrial pacing（身体的限界を改善）、multisite biventricular pacing（患者 QOL の改善）、ventricular pacing は dual chamber pacing に比較して移植の QOL を改善、multisite biventricular pacing（入院率の改善）に対し、「dual chamber pacing は 65 才以上の患者には移植の複雑さがあり、解決策はない」、「dual chamber pacing の重傷度低減はより調査が必要」と有効性を認めない報告もある。

MED No	結果	疾病名称	対比技術	患者 QOL
MED 25	○	atrial arrhythmias	overdrive pacing + Rest Rate vs DDDR	Overdrive pacing + Rest Rate was well tolerated and associated with a slight improvement in quality of life.
MED 30	△	drug refractory paroxysmal atrial fibrillation	multisite atrial pacing vs right atrial pacing	Quality of life is equally improved with either pacing strategy, with no differences between them.
MED 7	○	atrial fibrillation (AF)	DDD mode with the rate-smoothing algorithm (RSA)	One quality-of-life instrument detected a significant improvement in the "physical limitations" domain with the rate-smoothing mode.
MED 79	○	sinus-node dysfunction	dual-chamber pacing. vs ventricular pacing	Quality of life improved significantly after pacemaker implantation (P<0.001), but there were no differences between the two pacing modes in either the quality of life or prespecified clinical outcomes (including cardiovascular events or death). The implantation of a permanent pacemaker improves health-related quality of life. However, the quality-of-life benefits associated with dual-chamber pacing as compared with ventricular pacing are observed principally in the subgroup of patients with sinus-node dysfunction.
MED 94	△	severe symptoms of hypertrophic obstructive cardiomyopa	DDD pacing vs AAI pacing	Quality-of-life score and exercise duration were significantly improved from the baseline state after the DDD arm but were not significantly different between the DDD arm and the backup AAI arm.

		thy		
MED 97	○	high grade AV block and chronic or persistent paroxysmal atrial fibrillation	Dual sensor VVIR mode pacing vs no rate response, activity sensing	Overall, chronotropic response was best with dual sensor pacing during standardized daily activity protocols and during the standard car journey.
MED 102	○	high degree AV block	programmed AV delay between 100 and 250 ms on quality-of-life vs dual chamber pacemaker	the effect of AV delay programming on the patient's quality-of-life has been less well studied.

(5)コストベネフィット

なし

B. Pacing mode (31件)

(1) 技術摘要疾病

先に記した疾病名に対する pacing mode の臨床効果、pacing mode 間の比較等詳細に記述されている。例えば VVIR 又は VVI は患者の運動期間及び QOL を著しく改善する、DDD は hypertrophic obstructive cardiomyopathy 患者、特に老患者の QOL を改善するが、dilated cardiomyopathy 患者には期待外れの効果である、DDI は recurrent vasovagal syncope 患者の失神の再発を減少する、DDIR 又は DDI は sick sinus syndrome の心房細動発作を減少する等々である。

また VVIR→DDDD は VVIR に耐えられない患者の QOL を改善し、DDD→VVI は childhood neurally mediated syncope による失神に効果があり、また sinus node の chronotropic failure で患者の生理的心臓刺激の順化を DDD、VVIR、DDDR で比較評価した場合、DDDR が他の 2 者に比べ心肺能力を改良、生活 QOL の質を向上させる効果がある。但し、心肺能力を回復させない場合は DDDR でプログラムされてはならないとのコメントが付いている。

その他 DDDR と DDIR の比較では、heart block と paroxysmal atrial tachyarrhythmias 患者に総合的 QOL に差はない、また DDD と VVIR の比較では DDDmode で心肺機能と QOL に快適感が増大する傾向にあるが、両者特に差はない臨床評価もある。

(2)診断・治療能力

治癒性でみると、失神の再発や閉塞性の減少、薬物療法より優れている等の有効性評価の一方、「heart block 患者に対する DDDD の効果は期待外れ」、「VVI&VVIR pacing は効果があったが全ての運動要領が測定できたわけではない」との評価もある。

文献 No	結 果	疾病名称	对比技術	治愈性
MED 9	○	recurrent vasovagal syncope	Permanent cardiac pacing vs medical treatment	DDD pacing with rate-drop response function is more effective than beta-blockade for the prevention of syncopal recurrences in highly symptomatic vasovagal fainters with relative bradycardia during tilt-induced syncope.
MED 17	○	heart disease	conventional DDD vs ELA medical mode-switch algorithm	The analyzed DDD/AMC mode-switch algorithm leads to a significant reduction of ventricular pacing in patients with spontaneous AV conduction or with only paroxysmal AV block. Thereby the battery lifetime is prolonged and the incidence of complications due to ventricular pacing can be reduced.
MED 21	○	paroxysmal atrial fibrillation	DDDR pacing vs DDD pacing	The patients were less symptomatic with the DDDR mode. The number of mode-switch activations compared with symptomatic episodes of PAF confirmed the high rate of asymptomatic PAF episodes in patients with brady-tachy syndrome.
MED 33	×	Sick Sinus Syndrome	DDDR pacemaker vs VVIR pacing	MOST will fill the clinical need for carefully designed prospective studies to define the benefits of dual-chamber versus single-chamber ventricular pacing in patients with SSS. Thus the final results of MOST should be clinically generalizable.
MED 37	○	tilt-positive cardioinhibito ry neurally mediated syncope	DDI pacemake vs pacemaker(-)	One patient (5% in the pacemaker arm experienced recurrence of syncope compared with 14 patients (61%) in the no-pacemaker arm (P=0.0006). In the no-pacemaker arm, the median time to first syncopal recurrence was 5 months, with a rate of 0.44 per year.
MED 36	○	atrial tachyarrhyth mia	DDDR pacing vs VDD pacing	A total of 1,636 detections of PAF were recorded in patients preablation. Only 48 episodes (2.9%) were characterized as false-positive detections; 25 episodes (1.5%) were classified as oversensing, and 23 episodes (1.4%) were classified as competitive atrial pacing. A total of 3,061 detections of PAF were recorded postablation. Only four episodes (0.1%) were classified as oversensing.
MED 44	×	atrial arrhythmia	atrial overdrive pacing vs atrial overdrive + propafenone	In DDD paced patients, the overall effect of propafenone during atrial overdrive is variable. Propafenone may increase the proportion of asymptomatic atrial arrhythmia episodes. A proarrhythmic effect of propafenone was documented (aggravation of atrial arrhythmias). These results need to be confirmed by further larger randomised studies.
MED	○	severe childhood	DDD pacing vs VVI pacing	Permanent pacing is an effective treatment for children with severe neurally mediated

47		neurally mediated syncope		syncope and reflex anoxic seizures. VVI is as effective as DDD in preventing syncope and seizures.
MED 48	○	atrioventricular synchrony	DDD pacing vs VVI pacing	After long-term VVI pacing, ERPs at all 4 atrial sites increased significantly in a nonuniform fashion in association with biatrial dilatation. PWD and cSNRTs also prolonged significantly. With the reestablishment of AV synchrony, ERPs, PWD, cSNRTs, and biatrial dimensions returned to baseline levels. In the 12 patients who underwent long-term DDD pacing from baseline, no significant changes in atrial electrophysiology.
MED 49	○	chronic atrial fibrillation	VVI pacing vs DDD pacing	Chronic loss of AV synchrony induced by VVI pacing is associated with mechanical remodeling of the left atrium, which may reverse after the reestablishment of AV synchrony with DDD pacing. This process may be partly responsible for the higher incidence of thromboembolism observed in patients undergoing VVI pacing compared with AV sequential pacing.
MED 60	×	dilated cardiomyopathy	Dual-chamber DDD pacing vs pacing(-)	Three more patients died 6 months after (between sixth and twelfth month of follow-up), due to refractory heart failure; 1 patient dropped out because his pacemaker was programmed in VVI mode at low rate, due to intolerance of DDD pacing. Among the other 4 patients no clinical and laboratory parameters were significantly different after 1 year of follow-up.
MED 64	×	pacemaker dependent patients	VVI vs VVIR pacing	VVIR pacing improved some but not all measures of exercise capacity.
MED 71	○	cardioinhibitory vasovagal syncope	DDI pacing vs DDD pacing	These data suggest that DDD pacing with rate drop response function is effective in cardioinhibitory vasovagal syncope and may be preferable to DDI pacing with rate hysteresis.
MED 85	○	pacemaker patient	three different pacing mode(VVIR, DDD and DDDR)	Single chamber ventricular pacing was associated with enhanced spontaneous systemic platelet activation compared with physiological dual chamber pacing. This was related to the loss of atrioventricular synchrony rather than to the underlying cause of bradycardia, lack of rate response, or coexisting arrhythmia. This abnormality may be associated with increased thromboembolism and was correctible by an appropriate pacing mode prescription and possibly antiplatelet treatment.
MED 89	○	sick sinus syndrome	DDIR pacing vs DDI pacing	DDIR vs DDI significantly improves short- and long-term haemodynamic performance. Dual chamber pacing shows a significant reduction of paroxysmal atrial fibrillation

				recurrence, regardless of rate responsiveness.
MED 90	○	paroxysmal atrial tachyarrhythmias	three pacing modalities DDDR and VVIR(IVR)	DM is the pacing mode of choice of patients with paroxysmal atrial tachyarrhythmias. With optimal programming, inappropriate mode switching and tracking of atrial tachyarrhythmias was very uncommon.
MED 92	×	carotid sinus syndrom	VVI pacing vs DDI pacing	Elderly patients with carotid sinus syndrome are likely to develop symptomatic hypotension following VVI pacing.
MED 93	○	complete AV block (CAVB)	fixed rate pacing vs ventricular rate-responsive pacing(VVIR)	Compared with VVI and VVIR 130, VVIR 110 was associated with an increased peak oxygen uptake and a higher oxygen uptake at anaerobic threshold The atrial rate during exercise expressed as a percentage of the expected maximal heart rate was lower in VVIR 110 than in VVI or VVIR 130 There was no significant in cardiac output at peak exercise between VVIR 110 and VVIR 130.
MED 95	○	complete AV block (CAVB)	VVI pacing vs VVVI pacing, DDD pacing	beat-to-beat blood pressure variability was related to symptomatic intolerance of VVI pacing and may have potential utility as an aid to diagnosis or as a predictor of pacemaker
MED 96	○	sick sinus syndrome	DDDR pacing vs VVIR pacing, DDD pacing	DDDR pacing proved to be better than VVIR and DDD in patients with sick sinus disease and chronotropic incompetence angina pectoris
MED 100	○	chronotropic incompetence	DDD pacing vs DDDR pacing	the results of paired metabolic exercise tests with the Dromos DR and Ergos TC 03 pulse generators demonstrate a clear clinical benefit using the accelerometer-based sensor in the CI patient
MED 104	○	bradycardia	rate adaptive ventricular pacing(VVIR) vs fixed rate pacing(VVI)	Rate adaptive ventricular pacing can significantly improve the exercise capacity and cardiac output in patients with bradycardia. The increment of exercise cardiac output in VVIR mode is mainly dependent upon the pacing rate
CCTR 4	○	pacemaker patient	DDD mode vs VVI mode	Atrial pacing at physiological rates does not trigger the release of ANF.
MED 35	○	hypertrophic obstructive cardiomyopathy	pacemaker in active mode(DDD with optimized short AV delay) vs pacemaker in the inactive mode(AAI)	Subjective improvements in the quality-of-life of patients was measured using a specially developed questionnaire. These findings justify, by all means, the intention to implant a DDD pacemaker in older patients. In younger and/or such patients with elevated pressure gradients, the results of ongoing randomized studies comparing myectomy, PTSMA and pacing have to be considered.

○ : 評価する △ : 差がない × : 評価しない

(3)安全性・信頼性

「sick sinus syndrome における DDD pacing は一時的 AAI pacing と比較して MBF を減らす」、「ペーシングの数値は自動/手動で変わらない」、「DDD pacing mode から VVI pacing mode に帰るとより耐性がます」、「DDD pacing mode と心機能の関係で新しい知見が得られた」等の4件の有効性評価が記述されている。

文献 No	結果	疾病名称	対比技術	安全性・信頼性
MED 40	○	sick sinus syndrome (SSS)	DDD pacing vs AAI pacing	Myocardial blood flow at rates 60 and 90 beats per min did not differ between the AAI and DDD groups.
MED 43	○	AV block	Automatic mode switching from DDD(R) to DDI(R) or VVI(R) vs mode switching from DDD(R) to VVI(R)	Percentage changes of respiratory gas exchange measurements were significantly larger (O ₂ consumption: -8.2 +/- 5.0% vs. -0.6 +/- 7.2%; ventilatory equivalent of CO ₂ exhalation: 5.3 +/- 4.9% vs. 1.5 +/- 4.3%; respiratory exchange ratio: 7.0 +/- 2.2% vs. 3.5 +/- 3.0%; end-tidal CO ₂ : -5.7 +/- 2.9% vs. -1.8 +/- 2.7%; all P < 0.01) and the increase in subjective assessment of the effort tended to be higher (mean increase on Borg scale: 1.6 +/- 1.9 vs. 1.1 +/- 1.8, P = 0.07) after heart rate unadjusted than after adjusted mode switching.

(4)患者 QOL

「VVIR pacing mode + HBA, VVI Pacing mode + 心房間薬は運動期間と QOL を改善する」、「VVIR pacing mode から DDDR pacing mode への変更は老患者の QOL を改善する」、「DDIR pacing mode と DDDR pacing mode は患者 QOL に差はない」に対し、「VDD pacing mode は心房センシングのロスで運動期間の減少と主観的重傷度が増加する」との評価もある。

文献 No	結果	疾病名称	対比技術	患者 QOL
MED 10	×	complete AV block	single lead VPP pacemaker	atrial undersensing of > 10% in patients with single lead VDD pacing was associated with a decrease in exercise duration and increase in the subjective severity score.
MED 24	○	Atrial Fibrillation	HBA + VVIR pacemaker vs atrioventricular modifying drug + VVI pacemaker	significantly improved in both treatment arms for the modified Karolinska questionnaire (KQ) (Med +50% v HBA +50%, p = NS) and the Nottingham health profile (NHP) (Med +40% v HBA +20%, p = NS).

MED 38	○	patients intolerant to VVIR pacing.	DDDR pacing vs VVIR pacing	significant improvements in quality of life after crossover to DDDR pacing strongly favors dual-chamber pacing compared with single-chamber ventricular pacing in elderly patients requiring permanent pacing.
MED 55	×	heart block and paroxysmal atrial tachyarrhythmias	DDIR vs DDDR	Overall the QOL score was not different between the modes.
MED 101	○	complete AV block (CAVB)	DDD pacing vs VVIR pacing	Overall quality-of-life and cardiovascular symptoms did not significantly differ, though three patients felt discomfort during VVIR mode.
MED 108	○	atrial arrhythmias	DDD pacing vs DDDR pacing	These objective results were confirmed by the quality-of life assessment due to a symptom questionnaire.

○：評価する △：差がない ×：評価しない

(5)コストベネフィット

なし

C、pacing therapies (13 件)

(1) 技術摘要疾病

ペースメーカー移植は患者の健康に関連した生活の質を改善する。疾病名とその改善効果を列挙すると、carotid sinus syndrome（老患者における転倒を減らす）、chronic heart failure（患者の QOL の改善）、chronic atrial fibrillation（患者の QOL と運動機能の改善）、obstructive hypertrophic cardiomyopathy（患者に対してプラシーボ効果を与える）、obstructive hypertrophic cardiomyopathy（患者の失神再発防止）等々である。一方では老患者に対する dual chamber pacemaker 移植の複雑さを調査し、臨床的解決策は見出せないとの評価もある。

(2)診断・治療能力

pacing は投薬より有効、発作に対し物理療法より有効等の有用性評価に対し、「心臓病にたいする薬物治療と年齢の相関は 75 才を越えると負の相関」との評価もある。

文献 No	結果	疾病名称	対比技術	治療性
MED 2	×	congestive heart failure	cardiac resynchronization therapy	Cardiac resynchronization therapy may lead to a reduction in LV volumes in patients with advanced HF and conduction disturbances. Volume nonresponders have significantly higher baseline LVEDV.
MED	×	Carotid sinus syndrome	dual-chamber pacemaker implant vs	There is a strong association between non-accidental falls and

4			pacemaker(-)	cardioinhibitory CSH. These patients would not usually be referred for cardiovascular assessment. Carotid sinus hypersensitivity should be considered in all older adults who have non-accidental falls.
MED 46	○	chronic atrial fibrillation	Group I : AV node ablation and pacemaker implantation associated with discontinuation of rate-control medications vs Group II : AV node ablation and pacemaker implantation without discontinuation of antiarrhythmic rate-control drugs Group III : pacemaker implantation without performing AV node ablation and continuing rate-control medical therapy	At the 1- and 6-month evaluation, the patients in group 1 showed a significant improvement of left ventricular ejection fraction, quality of life, and activity scores. The exercise duration and the maximal VO2 consumption, however, did not change significantly. A slight improvement of the quality of life and physical activity scores was observed in the group undergoing AV node ablation without withdrawal of medications. However, no significant changes were observed in the group receiving only the pacemaker without modification of medical therapy and with intact AV node conduction.
MED 57	×	congestive heart failure (CHF)	Pacing vs pacing(-)	results of a first interim analysis showed trends toward improvement in all primary and secondary endpoints during the pacing periods compared with no pacing.
MED 63	○	vasovagal syncope	Pacemaker therapy vs pacemaker(-)	The baseline tilt-table test showed a slowest heart <60/min or longest heart period >1000 ms in 60% of no-pacemaker patients and 72% of pacemaker patients. There was a marked reduction in the postrandomization risk of syncope in pacemaker patients. The primary outcome was the first recurrence of syncope.
MED 74	○	pacemaker patient	activity sensing(ACT), Qtsensing, or dual sensing (ACT=QT)	he data indicate that the mechanisms responsible for the increase Qc during exercise were different for ACT versus ACT = QT or QT sensor-driven pacing.
CCTR 2	○	pacemaker patient	single-chamber ventricular dual-chamber pacemakerspacemakers vs	The implantation of a permanent pacemaker improves health-related quality of life. The quality-of-life benefits associated with dual-chamber pacing as compared with ventricular pacing are observed principally in the subgroup of patients with sinus node

				dysfunction.
CCTR 6	○	hypertrophic obstructive cardiomyopathy	pacing on vs pacing off	Pacemaker therapy is of clinical and haemodynamic benefit for patients with hypertrophic obstructive cardiomyopathy, left ventricular outflow gradient at rest over 30 mmHg who are symptomatic despite drug treatment.

○：評価する △：差がない ×：評価しない

(3)安全性・信頼性

なし

(4)患者 QOL

文献 No	結果	疾病名称	対比技術	患者 QOL
MED 15	○	congestive heart failure,	uni- or biventricular pacing therapy	Chronic improvement by prolongation of the 6-minute-walk-test by 60 meters, an improvement of O2 uptake by 23% at exercise, and improvement of quality of life score and NYHA classification.
MED 16	○	heart failure, intraventricular conduction delay	active atrioventricular pacing vs inactive pacing	quality-of-life score improved by 32 percent (P<0.001), peak oxygen uptake increased by 8 percent (P<0.03), and active pacing was preferred by 85 percent of the patients (P<0.001) hospitalizations were decreased by two thirds (P<0.05),
MED 56	○	pacemaker patient	pacing on vs pacing(-)	Quality of life was evaluated after the first study period in 40 patients.
MED 65	×	Cardiac Pacing	DDDR pacing vs VVIR pacing	A prospective trial to evaluate quality of life in dual chamber pacemaker recipients age 65 years or older randomized to DDDR versus VVIR programming.
MED 84	○	hypertrophic obstructive cardiomyopathy	Pacing vs pacemaker activated vs non activated	Quality of life assessment with a validated questionnaire objectivated the subjective improvement.

○：評価する ×：評価しない

(5)コストベネフィット

なし

D. pacemakers (23 件)

(1) 技術摘要疾病

pacemaker 機器に関する改良や新技術の臨床テストが報告されている。疾病名称に相

当するのが機器の仕様・機能で Long-term thresholds、chronotropic incompetence、periodic reprogramming、automatic threshold evaluation、frequency of oversensing、automatic rate response optimization 等が評価の対象である。

適用療法に相当するのが機能・機能部品であり、報告されている評価結果を列挙すると、insulative coating (新しい pulse generator では不要)、membrane leads (電気生理学的特性が重要)、autosensing (定期的感度チェックが不要)、new accelerometer-based pacemaker (明瞭な臨床利点を示す)、steroid-eluting electrode (耐用性 20 年)、permanent pacing leads (非ステロイド系心内膜リードが支配的)、pulse generator longevity (低出力化により長寿命化)、pacemaker telemetry (不整脈に対する潜在的データ源) 等がある。

(2)診断・治療能力

文献 No	結果	疾病名称	対比技術	治癒性
MED 6	○	Sick Sinus Syndrome	lower output 2.5V vs normal output 3.5V	Programming to a lower output slightly increased projected pacemaker longevity compared to the nominal 3.5-V setting. Longevity increased for 5% in patients with single and for 14% in dual chamber pulse generators.
MED 8	×	atrial fibrillation	pacemaker telemetry vs pacemaker telemetry	Pacemaker telemetry is a potentially important source of data on cardiac arrhythmias. Further studies are required to define the limitations of these data in specific devices before they can be interpreted with confidence.
MED 11	○	pacemaker patient	the extrathoracic subclavian approach vs the cephalic approach	Lead placement was accomplished in 99 of the 100 patients randomized to the extrathoracic subclavian vein approach as compared to 64 of 100 patients using the cephalic approach. In addition to a higher initial success rate, the extrathoracic subclavian vein medial approach was determined to be preferable as evidenced by a shorter procedure time and less blood loss. There was no difference in the incidence of complications.
MED 14	○	pacemaker patient	high impedance ventricular leads(Cap Sure Z) vs conventional leads(Cap Sure SP)	The use of a high resistance lead for ventricular pacing appears to result in a clinically relevant extension of generator longevity.
MED 69	○	Cardiac Pacing	the 6 Fr approach vs the 2 Fr approach.	he results of this study show that the use of 2 Fr electrode catheters reduces the rates of entry site and catheter manipulation related complications during EPS. Despite their small size, these

				catheters allow quick and precise positioning of the electrode.
MED 73	○	sick sinus syndrome	single-chamber atrial pacing vs single-chamber ventricular pacing	During follow-up (mean, 5.5+/-2.4 years), there was no change in PQ interval in either group and no change in atrial stimulus-Q intervals or Wenckebach block point in the atrial group. Four of 110 patients in the atrial group developed grade 2 to 3 AV block that required upgrading of the pacemaker (0.6% per year). Two of these 4 patients had right bundle-branch block at pacemaker implantation.
MED 82	×	pacemaker patient	rate response optimization(OPT) vs fixed activity rate response programming(FIXED)	As only 1 (3%) patient had complaints related to the activity rate response and fixed rate response programming according to clinical judgement already resulting in symptom-free DDDR pacing, no differences could be detected between the fixed rate response programming and rate response optimization.
MED 32	○	pacemaker patient	autocapture or pulse output automatically adjusted vs autocapture off, fixed output parameters	We performed a 6-month follow-up measuring stimulation threshold by means of the VARIO test and Autocapture test, evoked response signal, and R wave signal. The mean R wave was 15.77 +/- 3.5 mV at the end of the follow-up for group I, and 14.91 +/- 6.8 mV for group II (P = NS). The measured evoked response at the end of the follow-up was 9.25 mV in Group I and 8.48 mV in Group II (P = NS).
CCTR 7	○	chronotropic incompetence (CI)	DDDR mode vs DDD mode	In conclusion, the results of paired metabolic exercise tests with the Dramas DR and Ergos TC 03 pulse generators demonstrate a clear clinical benefit using the accelerometer-based sensor in the CI patient.
CCTR 8	○	pacemaker patient	rate adaptive vs rate adaptive(-)	By calculating the quotient of the signal's duration above and below zero baseline, a reliable discrimination between walking upstairs and downstairs was possible. A correction of the Leaky integrator signal by the new quotient yielded a more adequate rate adaptation to walking up and downstairs to represent at the patient's daily life activities

○ : 評価する × : 評価しない

(3)安全性・信頼性

安全性評価として、「皮膜のないリード」、「二極敷き心臓内ペースングリード」、「自動感度調整敷きペースメーカー」が、また信頼性の評価として「二極式皮膜窒化膜電極の

電機生物学的性能]、「steroid eluting 冠状静脈洞リード（移植後2週間で安定）」等が記述されている。

文献 No	結果	疾病 名称	対比技術	安全性・信頼性
MED 51	○	pacemaker patient	steroid lead design vs steroid lead design	Stable VTH was reached 2 weeks after implantation, and no transient rise in threshold was observed. Safe and efficient pacing at low pulse amplitudes were achieved with both leads.
MED 29	○		J-shaped atrial lead vs straight atrial lead	The J-shaped lead may have a somewhat higher malfunction rate. The J-shaped lead seems to be more stable.
MED 27	○	Heart Failure	steroid-eluting coronary sinus lead	Pacing threshold stabilized 2 weeks after lead implantation and sensing threshold remained stable from the time of implant.
MED 42	○	pacemaker patient	Uni- pacing vs bipolar pacing	Mean pacing thresholds determined with the automatic pacemaker function were not different from the manually measured values.
MED 53	○	patients with chronically implanted pacemaker leads	Laser-assisted pacemaker lead extraction vs nonlaser lead extraction	Complete lead removal rate was 94% in the laser group and 64% in the nonlaser group ($p = 0.001$). A successful lead extraction significantly reduced for patients randomized to the laser tools, 10.1 +/- 11.5 min compared with 12.9 +/- 19.2 min for patients randomized to nonlaser techniques ($p < 0.04$).
MED 67	○	Cardiac Pacing	bipolar lead vs unipolar lead	The frequency of oversensing can be significantly reduced by defining an optimal sensitivity setting using simple isometric maneuvers.
MED 70	○	Cardiac Pacing	Passive fixation leads vs conventional bipolar pacing lead	Two lead failures ThinLine coradial bipolar leads are safe and effective for cardiac pacing and sensing. overall handling characteristics good to excellent
MED 72	○	Cardiac Pacing	ion exchange lead in steroid vs without steroid, control	ion exchange membrane effective in reducing the chronic pacing threshold
MED 86	△	pacemaker patient	insulative coating of the IPG vs uncoating	An insulative coating for pacemakers does not appear to alter sensing performance
MED 99	○	pacemaker patient	Autosensing adjusted sensitivity with the recommended 2:1 safety margin vs	Compared with the recommended 2:1 sensing safety margin, the Autosensing feature performed equal to manual programming in preventing episodes of under/oversensing, and was better for atrial undersensing during

			experienced atrial myopotential oversensing	sleep.
MED 103	○	pacemaker patient	steroid eluting electrods	Extrapolation of the line of best fit suggests that about 20% of the steroid is still present at 10 years and 18% at 20 years.

○：評価する △：差はない

(4)患者 QOL

なし

(5)コストベネフィット

ペースメーカー電極はパルス発生器の構造も進歩しており、絶縁コートはコストアップにつながるの必要ない等々。

文献 No	結果	疾病 名称	対比技術	コストベネフィット
MED 51	○	pacemaker patient	steroid lead design vs nonsteroid lead designs.	The tip design, independently of the steroid additive, prevented any energy-consuming increases in the voltage threshold.
MED 98	○	pacemaker patient	membrane electric lead vs bipolar endocardial leads	The reliability and effectiveness of the pulse generator-lead system allowed for consistent pacing at very low outputs and safety preserved at a programmed output only 0.3 V above the capture threshold.
MED 106	○	pacemaker patient	sintered platinum leads, activated pyrolytic carbon leads, and vitreous carbon leads	(5) in the absence of other differences, cost can be the deciding factor in lead selection.

○：評価する

D、その他（16件）

(1) 技術摘要疾病

pacemaker の基礎データとなる心拍数、不整脈、レートコントロール等の実験報告や診断機器での解析評価、「症候性の SSS 患者に対するペースメーカー治療とチオフィリンの効果の比較」及び、「心臓薬物投与と年齢の相関」等の一般論等々である。

(2) 診断・治療能力

文献 No	結 果	疾病 名称	对比技術	治癒性
MED 13	○	rapid VT	Antitachycardia pacing vs shock	In rapid VTs one attempt of ATP may be suitable as an additional therapy option during ICD capacitor charging to avoid painful shocks without compromise of safety. Thus, future ICDs should implement the option of ATP during charging of capacitors.
MED 28	×	heart failure	Multisite ventricular pacing	The PEA sensor is a promising tool for long-term hemodynamic monitoring and serial evaluation of the effects of multisite ventricular pacing in heart failure patients.
MED 39	×	pacemaker patient	heparin initiation 6h vs heparin initiation 24h	Warfarin therapy or no anticoagulation is associated with only a 2% to 4% risk of pocket hematoma formation.
MED 41	○	sustained ventricular tachyarrhythmias	antiarrhythmics versus implantable defibrillators (AVID) vs antiarrhythmics	Actuarial survival was 0.86 (95% confidence interval [CI] 0.85 to 0.88), 0.79 (95% CI 0.78 to 0.81), and 0.72 (95% CI 0.70 to 0.74) at 1, 2, and 3 years. mortality rates of patients with sustained ventricular tachyarrhythmias remain high. Well-tolerated ventricular tachycardia in patients with structural heart disease does not carry a significantly better prognosis than ventricular tachyarrhythmia with more severe hemodynamic consequences.
MED 45	○	Atrial fibrillation	atrioventricular junction ablation	successful in 155 (99%) of 156 patients Escape rhythm present in 104 patients (67%) after radiofrequency ablation. The escape rate ranged from 11 to 65 beats/min (mean 39 +/- 10 beats/min). Only 49 patients (31%) had an escape rate >=40 beats/min. Of the 104 patients with an escape rhythm, 53 patients (51%) had a QRS.
MED 61	○	heart disease	use of cardiac medications vs	Older age is a significant independent negative correlate of evidence-based cardiac medication use in this cohort.
MED7 5	○	heart failure and chronic atrial fibrillation	atrioventricular junction ablation and VVIR pacemaker (Abl+Pm) vs pharmacological (drug) treatment	lower scores in palpitations (-78%; P=0.000) and effort dyspnea (-22%; P=0.05) than the 26 of the drug group. Lower scores, although not significant, were also observed for exercise intolerance (-20%), easy fatigue (-17%), chest discomfort (-50%), Living with Heart Failure Questionnaire (-14%), New York Heart Association functional classification (-4%), and Activity scale (-12%).

MED 76	○	pacemaker patient	pacing at the right ventricular outflow tract (RVOT) vs the RV apex (RVA)	subtle improvements in diastolic and systolic function with pacing in the RVOT and at combined sites in the RV compared to traditional RVA pacing.
MED 77	○	refractory atrial fibrillation	Exercise performance with an upper rate , programmed to 220-age vs upper rate of 120 beats/min	Programming the upper rate of rate adaptive pacemakers based on the age of the patient improves exercise performance and exertional symptoms during both low and high exercise workloads as compared with a standard nominal value of 120 beats/min.
MED 87	△	paroxysmal atrial fibrillation (AF)	atrioventricular junction ablation and pacemaker implantation vs pharmacological treatment	The discontinuation of drug therapy exposes patients to further recurrences of paroxysmal AF and the risk of developing permanent AF. In patients with paroxysmal AF not controlled by pharmacological therapy, Abl+Pm treatment is highly effective and superior to drug therapy in controlling symptoms and improving quality of life.
MED 88	○	pacemaker or implantable defibrillator	medial approach vs lateral approach	Initial success was achieved in each of 25 patients randomized to the medial approach compared with 18 of 24 patients randomized to the lateral approach to the axillary vein (75%). In addition to a higher initial success rate, the medial approach was determined to be preferable as evidenced by a shorter lead placement time, a smaller number of contrast injections, and a reduced requirement for additional micropuncture guidewires.
MED 91	○	symptomatic SSS	dual-chamber rate-responsive pacemaker therapy vs no treatment, oral theophylline	DM is the pacing mode of choice of patients with paroxysmal atrial tachyarrhythmias. With optimal programming, inappropriate mode switching and tracking of atrial tachyarrhythmias was very uncommon.
ACP-J 1	○	severe recurrent vasovagal syncope	dual-chamber pacemaker with rate-drop response vs acemaker(-)	Patients in the pacemaker group had a lower rate of recurrence of syncope ($P < 0.001$) (Table) and a greater time to syncope (112 vs 54 d, $P < 0.001$) than those in the control group. A permanent dual-chamber pacemaker reduced the recurrence of syncope, but not presyncopal events, in patients with severe recurrent vasovagal syncope.
ACP-J 2	○	recurrent vasovagal syncope	paroxetine hydrochloride vs placebo	Patients in the paroxetine group had a lower rate of recurrent syncope { $P = 0.002$ }* and a trend toward a lower rate of positive tilt-table test results than did patients in the placebo group { $P = 0.08$ }* (Table).
CCTR 3	○	pacemaker patient	Mixed venous oxy-hemoglobin saturation (M(v)O ₂)	This small trial shows that the area under the curve of capillary blood cell velocity increases in hypertensive patients treated

			senso vs sensor(・)	with both losartan/losartan-HCT and amlodipine compared with baseline values.
CCTR 5	○	drug refractory atrial fibrillation (AF) and atrial flutter (AFI)	DDDR pacing vs VVIR pacing	We suggest that an assessment of the frequency and duration of AF paroxysms should be part of the work-up before AV node ablation and pacemaker implantation in order to make the best selection of patients for MS DDDR

○：評価する △：差がない ×：評価しない

(3)安全性・信頼性

なし

(4)患者 QOL

なし

(5)コストベネフィット

なし

5 - 3 - 1 3 Implantable Cardiac Defibrillator

MEDLINE 25 件、ACP-Journal Club 4 件の論文が検索された。

A、ICD 治癒成績に関するもの

ICD (Implantable Cardiac Defibrillator)の治癒成績についての評価は 18 件あった。

(1) 技術摘要疾病

18 件の対象疾患は ventricular arrhythmias, cardiac arrest, ventricular fibrillation, arrhythmic and nonarrhythmic cardiac deaths, tachycardia ventricular, ventricular dysfunction left, coronary disease at high risk for ventricula arrhythmia, sudden death at the time of CABG である。

(2) 診断・治療能力

坑不整脈剤等に対する ICD の効果を認めた論文は 7 件見られた。しかし、CABG 時の ICD 使用が死亡率を 45%下げたとする論文がある一方で死亡率を下げないとする論文が 3 件見られた。また、D,l-sotalol の方が ICD より再発率が低いとするもの 1 件、amiodarone と比較して有効でないとする論文が 2 件見られた。

AVID に関する解説的論文が 2 件あった。

抄録 No	ICD の評価	疾病名称	技術	治癒性
MED 3	○	ventricular arrhythmias, cardiac arrest	ICD vs. antiarrhythmic drug therapy	Overall survival was higher, though not significantly, in patients assigned to ICD than in those assigned to drug therapy (1-sided P=0.081, hazard ratio 0.766, [97.5% CI upper bound 1.112]). In ICD patients, the percent reductions in all-cause mortality were 41.9%, 39.3%, 28.4%, 27.7%, 22.8%, 11.4%, 9.1%, 10.6%, and 24.7% at years 1 to 9 of follow-up.
6	-	Ventricular Fibrillation	ICD vs. antiarrhythmic drug therapy	Since publication of the Multicenter Automatic Defibrillator Implantation Trial (MADIT) in 1996, indications for implantation of implantable cardioverter defibrillators (ICDs) have expanded.
7	○	arrhythmic and nonarrhythmic cardiac deaths in the CABG Patch Trial	ICD therapy (+) vs. (-)	Cumulative arrhythmic mortality at 42 months was 6.9% in the control group and 4.0% in the ICD group (P=0.057). Cumulative nonarrhythmic cardiac mortality at 42 months was 12.4% in the control group and 13.0% in the ICD group (P=0.275). Death due to pump failure was