

				significantly associated with death >1 hour from the onset of symptoms, dyspnea within 7 days of death, and overt heart failure within 7 days of death.
9	×	ventricular tachyarrhythmias	no antiarrhythmic drug treatment (ICD) vs. D,l-sotalol	During follow-up, 25 patients (53.2%) in the ICD-only group had a VT/VF recurrence in comparison to 15 patients (28.3%) in the sotalol group and 15 patients (32.6%) in the ICD/sotalol group (p=0.0013).
14	-	Tachycardia, Ventricular	implantable cardiac, defibrillator right coronary artery bypass grafting, cardiac transplantation	The episodes of ventricular tachycardia were refractory to aggressive medical management and implantable cardiac defibrillator placement. A Heartmate left ventricular assist device was implanted, in combination with isolated right coronary artery bypass grafting, which abolished any further episode of ventricular tachycardia. The patient successfully underwent cardiac transplantation 79 days later.
15	○	coronary disease, ventricular tachycardia	ICD vs. conventional treatment	The average survival for the defibrillator group over a 4-year period was 3.66 years compared with 2.80 years for conventionally treated patients.
16	○	Tachycardia, Ventricular, Ventricular Fibrillation	ICD vs. antiarrhythmic drug therapy	Overall survival was greater with the implantable defibrillator, with unadjusted estimates of 89.3 percent, as compared with 82.3 percent in the antiarrhythmic-drug group at one year, 81.6 percent versus 74.7 percent at two years, and 75.4 percent versus 64.1 percent at three years (P<0.02).
17	△	left ventricular dysfunction	ICD & CABG vs. no antiarrhythmic treatment	No difference was seen in the history of myocardial infarction (83%), congestive heart failure (50%), or atrial (11%) or ventricular (17%) arrhythmias between the two groups.
18	△	Ventricular Dysfunction, Left	ICD & CABG	During an average follow-up of 32±16 months, there were 101 deaths in the defibrillator group (71 from cardiac causes) and 95 in the control group (72 from cardiac causes). The hazard ratio for death from any cause was 1.07 (95 percent confidence interval, 0.81 to 1.42; P=0.64). There was no statistically significant interaction between defibrillator therapy and any of 10 preselected base-line covariates.
19	○	nonsustained ventricular tachycardia, coronary disease	Automatic Defibrillator Implantation vs. antiarrhythmic drug	Three-year total survival was comparable in group 1 (70%) and in group 2 (81%), but sudden cardiac death mortality tended to be lower in group 1 versus group 2 (0 vs 9%, p = 0.09). Patients receiving class III

				antiarrhythmic therapy had significantly higher 3-year all cause (40%, $p = 0.04$) and sudden death (25%, $p = 0.06$) mortality than patients receiving beta blockers (17% and 8% respectively) or no antiarrhythmic drug therapy (4% and 0%, respectively).
20	-	ventricular arrhythmias	ICD vs. antiarrhythmic drug therapy (AVID trial)	Although 14% of registry patients received neither ICD nor antiarrhythmic drug therapy, ICDs were no more frequently used in the registry patient than antiarrhythmic drugs (45% for ICD vs 42% for drugs). Thus, randomized AVID patients have very similar clinical characteristics, cardiac history, and presenting arrhythmias as to nonrandomized eligible patients.
21	-	ventricular arrhythmias	ICD vs. antiarrhythmic drug therapy (AVID trial)	There is a striking absence of any attempt at chronic therapy to prevent cardiac arrest in most patients with a prior ventricular tachycardia or ventricular fibrillation.
22	○	ventricular arrhythmia, coronary disease	ICD vs. conventional medical therapy	During an average follow-up of 27 months, there were 15 deaths in the defibrillator group (11 from cardiac causes) and 39 deaths in the conventional-therapy group (27 from cardiac causes) (hazard ratio for overall mortality, 0.46; 95 percent confidence interval, 0.26 to 0.82; $P=0.009$).
25	○	Ventricular Tachycardia, Ventricular Fibrillation	ICD vs. antiarrhythmic drugs and guided by electrophysiological (EP)	Fifteen patients died, 4 in the early ICD group and 11 in the EP-guided strategy group ($P = .07$).
ACP 1	○	coronary disease at high risk for ventricula arrhythmia	ICD vs. conventional therapy	15 patients (16%) who received an ICD died compared with 39 patients (39%) who received conventional therapy ($P = 0.009$). Regression analysis showed that mortality was not associated with anti-arrhythmic medications, including amiodarone, β -blockers, other cardiac medications, or any baseline characteristic ($P > 0.2$ for all interactions).
2	△	sudden death at the time of coronary artery bypass graft (CABG) surgery	ICD (+) vs. (-)	Prophylactic implantation of a cardioverter-defibrillator at the time of coronary artery bypass graft surgery did not improve survival of patients at high risk for sudden death.
3	△	ventricular fibrillation , ventricular tachycardia (VT)	ICD vs. amiodarone	Patients in the ICD group appeared to have a lower mortality rate relative to those in the amiodarone group, but the differences were not statistically

				significant (P = 0.14 for all-cause mortality; P = 0.09 for death from arrhythmia)
4	△	resuscitated ventricular fibrillation (VF)、ventricular tachycardia (VT)	ICD vs. amiodarone	Over 6.3 years, mean survival was 4.58 years in the ICD group and 4.35 years in the amiodarone group (difference 0.23 y, 95% CI -0.09 to 0.55 y). Mean duration of the initial hospital stay was longer for the ICD group (4.7 d in intensive care and 12.0 d on the ward) than for the amiodarone group (2.0 d in intensive care and 8.3 d on the ward).

○：対比療法に対し効果を認めた △：有意な差を認めない ×：対比療法より治癒成績が悪かった -：判断できない

(3) 安全性・信頼性
特に記載が無かった。

(4) 患者QOL

QOLについての記載が1件あり、死亡率のみの評価でなくQOLを加えるとICDの費用対効果は有利になったとしている。

抄録 No	ICD の評価	疾病 名称	技術	QOL
MED 25	○	Ventricular Tachycardia, Ventricular Fibrillation	ICD vs. antiarrhythmic drugs and guided by electrophysiological (EP)	Because effectiveness aspects other than mortality are not incorporated in this ratio, other factors related to quality of life were used as qualitative measures of cost-effectiveness. If quality-of-life measures are taken into account, the cost-effectiveness of early ICD implantation was even more favorable.

○：対比療法に対し効果を認めた △：有意な差を認めない ×：対比療法より治癒成績が悪かった -：判断できない

(4) コストベネフィット

ハイリスクな心室性不整脈患者のためにはICDは\$23,000 per life-yearの節約になるという論文と、

早期のICD移植が\$11,315 per patient per yearの節約となるというものがあつた。

抄録 No	ICD の評価	疾病 名称	技術	コスト

MED 15	○	coronary disease, ventricular tachycardia	ICD vs. conventional treatment	Accumulated net costs were \$97,560 for the defibrillator group compared with \$75,980 for individuals treated with medications alone. The resulting incremental cost-effectiveness ratio of \$27,000 per life-year saved compares favorably with other cardiac interventions. Sensitivity analyses showed that the incremental cost-effectiveness ratio would be reduced to approximately \$23,000 per life-year saved if transvenous defibrillators were used instead of the older devices, which required thoracic surgery for implantation.
25	○	Ventricular Tachycardia, Ventricular Fibrillation	ICD vs. antiarrhythmic drugs and guided by electrophysiological (EP)	The cost-effectiveness ratios were \$63 and \$94 for the early ICD and EP-guided strategy groups, respectively, per patient per day alive. This amounts to a net cost-effectiveness of \$11,315 per patient per year alive saved by early ICD implantation.

○：対比療法に対し効果を認めた △：有意な差を認めない ×：対比療法より治癒成績が悪かった -：判断できない

B. その他

ICD 治療結果を直接評価してはいないが、dispatcher assistance の効果を試験したもの、除細動閾値やエネルギーレベル、電極リード、刺激の方法に関するもの、class IC の坑不整脈 (propafenone) による閾値への影響の試験等の論文が見られた。

抄録 No	評価	疾病名称	技術	治癒性
MED 1	○	ventricular fibrillation (VF) cardiac arrest	dispatcher assistance (+) vs. (-)	The participants who received dispatcher assistance were more likely to correctly deliver a shock with the AED during the simulated VF cardiac arrest (91% vs 68%, p = 0.001).
2	○	Cardiovascular Diseases	left pectoral subcutaneous array lead vs. endocardial right ventricular defibrillation lead	In ACAT I, stored energy at DFT decreased from 13.1+/-7.7 J (active can) to 9.6+/-6.1 J (three-finger array lead) (P = 0.04), impedance decreased from 53+/-8 ohms to 40+/-6 ohms (P < 0.0001). Omitting the middle finger of the array lead, stored energy at DFT increased by 0.9 J (P = 0.47) and impedance by 2 ohm (P < 0.0001).
5	○	ventricular fibrillation	defibrillation threshold (DFT) was evaluated in a step-down protocol (15, 10, 8, 5 J)	The DFT+ in the study group was 9.6 +/- 3.2; in control group 10.1 +/- 3.5 J. At a mean follow-up of two years there was no significant difference between the two groups concerning the incidence of sudden cardiac death (2.4% in the study group vs. 3.8% in the control group).
12	△	Tachycardia, Ventricular, Ventricular	single-pass transvenous endocardial	In summary, both leads were safe and efficacious in the detection and treatment of ventricular tachyarrhythmias. There were no

		Fibrillation	ICD lead, Endotak DSP vs. conventional lead	differences between the DSP and control groups regarding short- or long-term lead related complications.
23	○	Arrhythmia, Coronary disease	The DFT was 8.4 +/- 3.2 J with the active shell vs. 13.1 +/- 6.9 J with the lead alone	The DFT was 8.4 +/- 3.2 J with the active shell, compared with 13.1 +/- 6.9 J with the lead alone (p < 0.01). This reduction was greatest in those patients with higher thresholds with the lead-alone configuration and resulted in DFT < or = 15 J with the active shell configuration in all patients.
24	○	Tachycardia, Ventricular, Ventricular Fibrillation	Propafenone 450 mg/day or 675 mg/day vs. placebo + ICD	There was no statistically significant difference between implantation and pre-discharge defibrillation thresholds in the three groups (Group 1: [mean +/- SE] 11.0 +/- 1.3 vs. 12.1 +/- 1.5 J; Group 2: 11.5 +/- 1.1 vs. 13.6 +/- 1.3 J; Group 3: 12.5 +/- 1.2 vs. 13.3 +/- 1.6 J), and no significant difference between treatment groups was found with a 0.86 power to detect a 5-J difference between groups.

○：対比療法に対し効果を認めた △：有意な差を認めない ×：対比療法より治癒成績が悪かった -：判断できない

5 - 3 - 1 4 Embolus Detection

MEDLINE 9 件の論文の要点を記す。

ドプラーソノグラフィーで計測した結果、体外循環中の脳の微小血栓数は大動脈カニューラ位置に依存することが分かった。(MED-1)

頸動脈内膜摘除後の脳内の栓子を抗血小板薬品で減少させたが、超音波栓子信号は有効性評価に応用できる。(MED-2)

心臓弁膜手術後の栓子カウントは冠動脈バイパス手術後より多いが、神経行動学的副作用は認められなかった。(MED-3)

心肺バイパス中に使用する、遠心ポンプとローラーポンプとの比較試験で、血球のダメージの差、血栓、塞栓等で観察したが差が無かった。(MED-4)

肺塞栓症診断についてスパイラルCTと肺換気灌流シンチグラム造影で比較実験した。差がなかったが、スパイラルCTは他の病変の兆候を検出できる。(MED-5)

下肢外傷患者の血栓塞栓症予防のための aspirin と clivarin の投与試験。(MED-6)

塞栓検出を応用して脳血管障害患者の塞栓予防に aspirin と ticlopidine を比較したが差が認められなかった。(MED-7)

急性肺塞栓症の検出のために換気、灌流、胸部X線写真の3つのマッチした異常を予測値として評価した。(MED-8)

心臓弁手術中に空気塞栓を防止するため、2次元の経食道心エコーで泡を監視し効果が認められた。(MED-9)

(1) 技術適用疾病

MEDLINE における技術適用疾病名称は、heart disease, thromboembolic disease, Heart Valve Diseases, Coronary Artery Disease, pulmonary embolism, lower extremity injuries, cerebrovascular disease, prevention of cerebral embolic ischemic events, acute pulmonary embolism である。

(2) 診断・治療能力

診断系の正確性では、脳の微小血栓数 2 件、シンチグラフの検出限界に触れたもの 1 件、血栓信号の再現性に触れたもの 1 件の記載があった。

早期診断性では、血栓信号の周波数が卒中発作再発のリスクを予知する、スパイラルCTと肺換気灌流シンチグラム造影の診断性、急性肺塞栓症の予測等に関するものがある。

抄録 No	診断能力 の評価	治療能力 の評価	疾病 名称	技術	診断系 (診断の正確性、早期診断性)・治療性
MED 1	○	○ elongated cannula	heart disease	short aortic cannula vs. elongated one	The number of high-intensity transient signals (HITS) was 994 +/- 2118 (mean +/- SD) for the short cannula group and was significantly lower with the elongated cannula (223 +/- 208; p < 0.02).
2	○ Doppler ultrasou nd	○	Thrombo -embolic disease	L-arginine vs. S-nitro -soglutath ione, placebo	median number of embolic signals, placebo 44.7 (6 to 778), L-arginine 9.5 (0 to 225), and GSNO 0.8 (0 to 8). Frequency of embolic signals predicts risk of stroke recurrence.
3	○ Doppler ultrasou nd	△	Heart Valve Diseases, Coronary Artery Disease	CABG vs. cardiac valve operations	There were no significant differences between patients undergoing valve and coronary operations in neurobehavioral outcomes, strokes, transient ischemic attacks, or deaths.
4	× Doppler ultrasou nd	△	Coronary Artery Disease	centrifugal pump vs. roller pump	In contrast, TAT and F1 + 2 formation did not differ between the groups, and neither did the total embolus count of both Doppler systems. Embolus counts did not correlate with TAT or F1 + 2 formation.
5	○	-	pulmonar y embolism	spiral CT pulmonary angiograp hy vs. ventilation -perfusion scintigrap hy	It was possible to make a confident diagnosis in a significantly larger proportion of patients when SCTA was used as the initial investigation (35/39, 90%) compared with using VQS first (21/39, 54% P<0.001).
6	-	○	lower extremity injuries	Aspirin vs. clivarin	Deep vein thrombosis occurred in 9 patients (6.3%) with clivarin prophylaxis and in 7 patients (4.8%) treated with Aspirin. In both groups, no clinically significant side effects of the medications were observed.
7	○ Transcra nial Doppler monitori ng	△	cerebrova scular disease, preventio n of cerebral embolic ischemic events	Aspirin vs. ticlopidine	The correlation between the number of emboli under the two medications was high. The highest number of embolic signals was found in high grade carotid stenosis.
8	-	-	acute	ventilation	Positive predictive values of triple-matched defects

			pulmonary embolism	/perfusion vs. chest radiographic defects	in the upper plus middle zones, 1 of 27 (4%), were less frequent than in the lower zones, 13 of 57 (23%) (p < 0.05).
9	○	-	Heart Valve Diseases	Doppler ultrasonic (+) vs. (-)	The incidences of microbubbles and retained air were 57% and 43% in group 1, and 62% and 38% in group 2 respectively (ns).

○：対比療法に対し効果を認めた △：有意な差を認めない ×：対比療法より治癒成績が悪かった -：判断できない

(3) 安全性・信頼性

(4) 患者QOL

(5) コストベネフィット

特に記載が無かった。

6. 考察とまとめ

本年度は、循環器系治療機器を中心に検討した。

医療機器は薬剤と多くの点で相違するが、今回 RCT に基づき医療機器に関する evidence 情報を収集し、機器毎の疾病横断的データベース化の見通しを得た。

医療機器の RCT データの現存数は多く、その処理にはデータマイニングの様な自動化検出ソフトが必要である。一方で、安全性・信頼性、QOL に関する RCT データが少ないことに対する対策が必要であるとも考えている。

また、RCT による evidence 情報は医療機器（技術）に関する臨床ニーズを顕在化するという意味が大きく、機器開発の効率化・適正化に役立つモデルも今後検索及び検討する必要がある。

今後、医療機器に関する evidence 情報のデータベース化を拡大し、臨床的に有効で、効率的な医療機器開発を無駄なく実施する基盤を作る可能性が示され、データベース化枠組みの基礎を築くことが出来た。

次年度以降は、対象領域を脳神経系、整形外科系、消化器系へと分野を拡げながら、医療機器技術を中心とした EBM データベースの実現化に向けた調査研究を行うこととする。