

(4) 患者QOL

両項目とも特に触れたものは無かった。

(5) コストベネフィット

2件が触れており、臨床的結果は同等であるからコスト増になる stent は不要だとするもの、臨床成績は良いがコストがかかると指摘したものである。

No	Stent の評価	運用コスト系
21	×	an ideal result without the use of stents appears to be practicable in many of these patients, with consequent cost savings.
34	×	the stent group was higher than the balloon-angioplasty group at a cost of an additional 2085 Dutch guilders (US\$1020) per patient.

○：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. Direct stenting(3件)

Balloon の予備拡張なしに stent を挿入する direct stenting について3件の抄録があり、いずれも予備拡張有りと比較して、生存率、再発率、影響性に対して有意差が無く、安全でコストも低いという結果を得ている。

(1) 技術適用疾病

疾病は coronary artery disease, angina pectoris で、balloon 予備拡張の有無の比較をしたものである。

(2) 診断・治癒能力

下表のように同等の結果を得たとしている。

抄録 No	Direct stent の評価	生存率、再発率、影響性
MED 1	△	No difference in major adverse cardiovascular events was found at 6-month follow-up.
3	△	Stent implantation was successful without predilatation in 192 of the 197 group I patients (97.5%), and with predilatation in 197 of the 199 group II patients (99%). No in-hospital stent thrombosis or death occurred.

11	○	At 6-month follow-up, the incidence of major adverse cardiac events including death, angina pectoris, myocardial infarction, congestive heart failure, repeat angioplasty, or coronary artery bypass graft surgery was 5.3% in DS+(direct stent) and 11.4% in DS-(with predilatation)
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### (3) 安全性・信頼性

X線撮影時間、コントラスト剤投薬の削減が得られ安全であるとしている。

No	Stent の評価	安全性
MED 1	○	direct stenting used less contrast (92.7 +/- 43.1 mL vs 117.4 +/- 61.0 mL, P =.04), and less fluoroscopy time (7.5 +/- 3.9 minutes vs 11.6 +/- 8.3 minutes)
3	○	The feasibility and safety of direct stenting of selected and non-complex coronary lesions is confirmed.

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### (4) 患者QOL

特に記述は無かった。

### (5) コストベネフィット

コスト上の有効性を述べたものが1件あり、direct stenting は予備拡張付に比べて安価であるとしている。

抄録 No	Direct stenting の評価	コスト
11	○	Compared with DS-, DS+ conferred a dramatic reduction in procedure-related cost (\$956.4 +/- \$352.2 vs \$1,164.6 +/- \$383.9, p <0.0001) and duration of the procedure (424.2 +/- 412.1 vs 634.5 +/- 390.1 seconds, p < 0.0001).

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## C. stent と抗血栓剤、抗血小板剤、抗凝結剤の併用

### (1) 技術適用疾病

Coronary disease, angina pectoris, myocardial infarction そして unstable angina and

non-ST-segment elevation myocardial infarction , stent 後の血栓予防について試験している。

(2) 診断・治癒能力

Stent と併用する抗血栓剤、抗血小板剤、抗凝結剤の効果を試験したもの16件の内、併用の効果を認めた論文が12件、認めないもの3件、どちらもいえないもの件であった。抗血小板グリコプロテイン抑制剤、cilostazol + aspirin、abciximab、fluvastatin、aspirin+ ticlopidine 併用は効果が認められ、Nadroparin、xemilofiban、Tirofiban (対AMI) 併用では効果を認めない結果が出ている。抗血小板剤療法と抗凝血剤療法を比較した2件では、いずれも抗血小板剤療法の効果を認めている。

No	薬剤併用の評価	疾病名称	併用技術・薬剤	救命率・生存率 再発率・予防率・影響性・安全性
MED 15	○	Coronary Disease	platelet glycoprotein IIb/IIIa inhibitors	The key 30 day endpoint was reduced, from 10.5% to 6.8%( the composite of death, myocardial infarction, or urgent target vesselRevascularisation)
20	△	Coronary Disease	Nadroparin with a microporous catheter	Intramural delivery of nadroparin with a microporous catheter after stent deployment was feasible and safe but had no effect in reducing restenosis or the occurrence of major adverse clinical events over 6 months.
24	△	Coronary Disease	xemilofiban	Death, myocardial infarction, or urgent revascularization occurred within 182 days 13.5%(placebo), 13.9%(20mg of xemilofiban)
25	○	Coronary Disease	cilostazol plus aspirin vs. ticlopidine and aspirin	As a poststenting antithrombotic, C+A is as effective as T+A in preventing major cardiac events including stent thrombosis, and safer in that it does not cause neutropenia despite the fact that there is no statistical difference in the incidence of adverse effects and complications.
27	○	Coronary Disease	Abciximab vs. heparin	The use of abciximab reduced the composite adverse event rate to 3.7% (76% absolute reduction)
28	○	Coronary Disease	Stent+ abciximab, stent + placebo, balloon+ abciximab	6ヵ月間の死亡又は心筋梗塞： 11.4% (stent and placebo) 5.6% ( stent and abciximab) 7.8% ( balloon and abciximab)
29	○	Coronary Disease	fluvastatin	a significantly lower incidence of total death and myocardial infarction was observed in six patients (1.4%) in the fluvastatin group and 17 (4.0%) in the placebo group
32	○	Coronary Disease	Aspirin+ ticlopidine, aspirin alone,	The primary end point was observed in 38 patients: 20 (3.6 percent) assigned to receive aspirin alone, 15 (2.7 percent) assigned to receive aspirin and warfarin, and 3

			aspirin+ warfarin	(0.5 percent) assigned to receive aspirin and ticlopidine (P=0.001 for the comparison of all three groups).
36	○	Coronary Disease	Stent+ abciximab, stent + placebo, balloon+ abciximab	The main outcomes that occurred less with abciximab were death and large myocardial infarction--7.8% in the placebo group, 3.0% for stent plus abciximab (p<0.001), and 4.7% for balloon angioplasty plus abciximab (p=0.01).
37	△	unstable angina pectoris or acute myocardial infarction	Tirofiban	At 6 months the composite end point (either death from any cause, new myocardial infarction, bypass surgery for angioplasty failure or recurrent ischemia, repeat target vessel angioplasty or stent insertion for actual or threatened abrupt closure) occurred in 1,070 placebo group patients (27.1%) and 1,071 tirofiban group patients (24.1%, p = 0.11)
39	○	Coronary Disease	aspirin+ ticlopidine, aspirin, ticlopidine	Between days 1 and 14, we observed a significant decrease in collagen-induced platelet aggregation in group A (62.2+/-2.5% versus 36.9+/-3.1%), whereas an increase was seen in group B (58.3+/-2.5% versus 67.7+/-3.2%) and no change was seen in group C (P<.0001).
42	○	ischemic heart disease,	Cilostazol vs. aspirin	The restenosis rate was 26.8% in the aspirin group, compared with 8.6% in the cilostazol group; this difference was statistically significant.
44	△	unstable angina or acute myocardial infarction	Tirofiban	The primary composite end point at 30 days was reduced from 12.2% in the placebo group to 10.3% in the tirofiban group, a 16% relative reduction (P=.160). However, 2 days after angioplasty, the tirofiban group had a 38% relative reduction in the composite end point (P< or =.005), largely because of a reduction in nonfatal myocardial infarction and the need for repeat angioplasty.
49	○	Coronary Disease	antiplatelet therapy vs. anticoagulant therapy	Of the patients assigned to antiplatelet therapy, 1.6 percent reached a primary cardiac end point, as did 6.2 percent of those assigned to anticoagulant therapy (relative risk, 0.25; 95 percent confidence interval, 0.06 to 0.77).
ACP 4	○	acute myocardial infarction	antiplatelet therapy vs. anticoagulant therapy	Clinical events AP 3% (抗血小板) AC 21% (抗凝固)
CDSR 1	○	unstable angina	GP IIb/IIIa blockers	血小板グリコプロテインIIb/IIIaブロッカーはPTCA後の30日後死亡率と30日後、6ヵ月後の死亡率または心筋梗塞の発生は減じたが、不安定なアンギナと non-ST-segment elevation 心筋梗塞の死亡率は下げない。

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- (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。

#### D. PTCA と冠動脈バイパス CABG との比較

PTCA と冠動脈バイパス CABG との比較に関するものは 5 件であったが、high-risk 患者でも CABG と同様の生存率を得て PTCA が代替治療になるとするものがある一方で、死亡率、stroke 率は同じ、或いは優れているが再施行率が高いとするものが 3 件あり、評価は分かれている。

(1) 適用疾病

refractory myocardial ischemia, multivessel coronary artery disease, myocardial infarction, coronary artery disease である。

(2) 診断・治癒能力

抄録 No	PTCA の CABG に対する評価	疾病名称	技術	救命率・生存率	再発率・予防率
MED 6	○	refractory myocardial ischemia	PTCA vs. CABG	The 30-day survivals for CABG and PCI were 95% and 97%, respectively. Survival rates for CABG and PCI were 90% versus 94% at six months and 79% versus 80% at 36 months	
9	△	multivessel disease	coronary-artery stenting vs. CABG	At one year, there was no significant difference between the two groups in terms of the rates of death, stroke, or myocardial infarction.	16.8 percent of those in the stenting group underwent a second revascularization, as compared with 3.5 percent of those in the surgery group
13	△	multivessel coronary artery disease	coronary-artery stenting vs. CABG	Death occurred in 0.9% of PTCA stent patients versus 5.7% in CABG patients,	Requirements for new revascularization procedures were higher in PTCA stent than in CABG patients (16.8% vs. 4.8%, p < 0.002).
17	×	proximal, isolated de novo left anterior descending coronary artery disease	coronary-artery stenting vs. CABG	the incidence of death and myocardial infarction being similar (7% vs 7%, respectively)	At a mean follow-up of 2.4 years, a primary end point had occurred in 19 patients (31%) in the stent group and in 4 (7%) in the CABG group

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(3) 安全性・信頼性

1 件が触れており、stent implantation と CABG は isolated, proximal left anterior descending coronary artery stenosis 治療に安全であるとしている。(MED-17)

(4) 患者QOL

1件 PTCA と CABG のQOL に有意さが無いとしたものがあった。(MED-17)

(6) コストベネフィット

2件が調査しており、stent が CABG より initial procedure で安価としたもの、provisional stenting は最も安価だが、primary stenting は CABG、balloon より高価だとしたもの各1件である。

抄録 No	Stent の CABG に対する評価	コスト
9	○	The costs for the initial procedure were \$4,212 less for patients assigned to stenting than for those assigned to bypass surgery, but this difference was reduced during follow-up because of the increased need for repeated revascularization; after one year, the net difference in favor of stenting was estimated to be \$2,973 per patient.
22	×	Provisional stenting had lower projected costs over a 4-year period than either traditional PTCA (-\$1742, or -3.4%) or contemporary CABG (-\$832, or -1.7%), mostly because of reductions in emergency CABG after PTCA. In contrast, primary stenting had higher projected costs over a 4-year period than either PTCA (+\$333, or +0.7%) or contemporary CABG (+\$1243, or +2.5%), mainly because of the higher initial procedure costs.

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E. PTCA と PTCR (アテローム切除) の比較

PTCA と PTCR (アテローム切除) の比較試験は3件あり、結果の差を認めていないものが多い。

(1) 技術適用疾患

Coronary artery disease と Coronary artery stenosis である。

(2) 診断・治癒能力

PTCA と PTCR (アテローム切除) の比較では成功率に差が無く、net gain 等の細かい比較をしたものが多い。

抄録 No	PTCR の PTCA に対する評価	疾病名称	救命率・生存率
MED	△	Coronary	Procedural success was comparable in the PTCR and in the PTCA group

4		Disease	(80% vs. 76%, P = 0.260). The need for stent implantation due to a residual stenosis >50% or a bail-out situation was significantly higher in the PTCA group (9.7% vs. 2.0%, P = 0.001).
41	△	Coronary Disease	Clinical follow-up to 1 year showed nonsignificant 13% to 17% reductions in the PTCR of the study for mortality rate (0.6% versus 1.6%; P=.14)
51	△	chronic coronary artery occlusion	Despite the advantage of rotablation with significant reduction of early and stable dissections (p < 0.01) only slight difference in restenosis-rate and comparable results for the rest parameters were achieved

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(3) 安全性・信頼性

(4) 患者QOL

(7) コストベネフィット

特に記述がなかった。

#### F. その他

stent と血栓溶解剤の効果比較が2件あり stent が良い結果を得ている。stent 閉塞への血管造影剤の影響を扱い ionic contrast media が優れているとしたもの、stent と balloon 後の血小板と好中球の活性化プロセスを血球解析で観察し stent の方が活性化されるとしたもの、balloon の膨張圧と stent の位置安定性を試験し高圧が良いとしたもの、stent 後の exercise がQOLを向上するとしたもの等が見られた。

ACP-Journal Club-6 の1件は PTCA と CABG の双方を invasive therapy とし、反虚血性薬物等の conservative 治療と比較して効果ありとしている。

抄録 No	Stent の 評価	疾病 名称	技術	治癒性
7	- (exercise training の効果は ○)	coronary artery disease	PTCA or stent and exercise training	The angiographic restenosis rate was unaffected by ET (T: 29%; C: 33%, P = NS) and was not significantly different after PTCA or CS. However, residual diameter stenosis was lower in trained patients (-29.7%, p = 0.045). During the follow-up (33+/-7 months) trained patients had a significantly lower event rate than controls (11.9 vs. 32.2%, RR: 0.71, 95% confidence interval [CI]: 0.60 to 0.91, p = 0.008) and a lower rate of hospital readmission (18.6 vs. 46%, RR: 0.69, 95% CI: 0.55 to 0.93, p < 0.001).
10	○	acute ST segment elevation myocardial infarction	primary PTCA with stent vs. thrombolysis	In successfully reperfused coronary arteries following acute ST segment elevation myocardial infarction, primary angioplasty with stent implantation reestablished TIMI grade 2 or 3 flow faster and more effectively than thrombolysis did.

12	○ (the ionic Ioxaglate の評価)	acute and subacute stent thrombosis	the ionic Ioxaglate vs. non-ionic contrast media	overall mortality within 12 months was significantly reduced by the use of Ioxaglate (22.9% vs 16.3%, P=0.001).
18	-	angina pectoris	coronary stent vs. balloon	the transcardiac gradient of platelet surface expression of CD62P (p < 0.001) and CD63 (p < 0.01) increased immediately after coronary stenting, but increased less significantly immediately after balloon angioplasty (CD62P, p < 0.01; CD63, p < 0.05).
33	○	myocardial infarction	primary stenting vs. thrombolytic therapy	In patients treated with angioplasty (55) and rt-PA (55) the rate of in-hospital mortality and reinfarction was 3.6% versus 9.1% (p=0.4). At 1 year, the incidence of death, reinfarction or repeat TVR was 11% in PTCA group versus 52.7% in the rt-PA group (log-rank 22.38, p < 0.0001).
47	○ (high-pressure dilatation)	de novo coronary artery stenoses of <math>\leq 15\text{ mm}</math> length	PTCA, Wiktor stents oversizing at normal balloon pressures vs. high-pressure dilatation	Intracoronary ultrasound catheter pull-backs after stent implantation showed incomplete stent attachment with one or two struts protruding into the vessel lumen in 3 of 10 patients in group 1 but in no patient after high-pressure dilatation in group 2 (p<0.01). Recross and high-pressure dilatation of the 3 stents in group 1 achieved complete attachment of all stents.
ACP 5	○	acute myocardial infarction	invasive treatment (PTCA, CABG) vs. conservative treatment	Reinfarction: Invasive 5.6% Conservative 10.5%  Admission for unstable angina: Invasive 17.9% Conservative 29.5%

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### 5-3-2 Angioplasty, Laser

MEDLINE 6件、ACP-Journal Club 1件の文献があった。このうち6件が Angioplasty, Laser と PTCA, Balloon との比較を行ったものである。

#### A. Angioplasty, Laser と PTCA, Balloon との比較

##### (1) 技術適用疾病

MEDLINE の6件は Angioplasty, Laser と PTCA, Balloon との比較を行ったものである。うち1件は、stable angina and a longer coronary lesion (> 10 mm)において心筋灌流シンチグラム造影によって評価される長期的結果が同等と評価しているが、残りの5件はいずれも、balloon に対する利点が無い、または劣る評価であった。それらの疾病名は、stable angina and a coronary lesion of more than 10 mm in length, obstructive coronary artery disease (2件), functional and total coronary occlusions, femoral artery occlusion である。

ACP-Journal Club では該当論文は1件のみであったが、CO<sub>2</sub> レーザを用いた Transmyocardial revascularization が CABG, PTCA の治療が思わしくない患者の難治性アンギナと左心室の free-wall 虚血治療に有効であったという報告である。

##### (2) 診断・治療能力

Laser と Balloon の比較試験で治癒率、生存率、再発率、影響性に関して、抄録中に数値が記載されているものを下表に示す。

抄録 No	Laser の評価	疾病名称	技術	治癒率、救命率・生存率	再発率・予防率、影響性
MED 1	△	stable angina and a longer coronary lesion (> 10 mm)	excimer laser angioplasty vs. balloon angioplasty	61% of patients assigned to laser angioplasty were asymptomatic at 6 months follow-up compared to 52% of patients assigned to balloon angioplasty	
2	×	complex coronary lesions	excimer laser angioplasty vs. balloon angioplasty	There were no deaths.	Myocardial infarction, coronary bypass surgery, and repeated angioplasty occurred in 4.6, 10.6, and 21.2%, respectively, of patients treated with laser compared with 5.7, 10.8, and 18.5%, respectively,

					of those treated with balloon.
3	×	obstructive coronary artery disease	YAG laser angioplasty vs. balloon angioplasty	At a mean follow-up time of 11.2 +/- 7.7 months, there were no differences in late or event-free survival in patients assigned to laser treatment versus PTCA alone.	use of the laser, versus PTCA alone, did result in significantly more major and minor procedural complications (18.0% vs. 3.1%, p = 0.0004), myocardial infarctions (4.3% vs. 0%)
4	×	functional and total coronary occlusions	Excimer laser angioplasty vs. balloon angioplasty	No deaths occurred.	There were no significant differences between the laser angioplasty group and the balloon angioplasty group in the incidence of myocardial infarctions (1 patient vs 3, respectively), coronary bypass surgery (4 patients vs 2), repeat angioplasty (10 patients vs 8)
5	×	femoral artery occlusion	balloon angioplasty with laser assistance vs. balloon angioplasty alone	Overall success (+/- S.D.) (Kaplan-Meier) at 1 year was 67% (+/- 5%) and at 2 years 43% (+/- 7%).	There was no significant difference (p > 0.05) in outcome between limbs undergoing laser assisted balloon angioplasty and balloon alone either overall or within the stenosis or occlusion subgroups.
6	×	obstructive coronary artery disease	excimer laser angioplasty vs. balloon angioplasty	The angiographic success rate was 80% in patients treated with laser angioplasty compared with 79% in patients treated with balloon angioplasty. There were no deaths.	Myocardial infarction, coronary bypass surgery, and repeat angioplasty occurred in 4.6%, 10.6%, and 21.2%, respectively, of the patients in the laser angioplasty group compared with 5.7%, 10.8%, and 18.5% of the balloon angioplasty group.
ACP 1	○	angina	transmyocardial revascularization with a carbon dioxide laser vs. medical treatment	TMR (Laser) was better than medical treatment for relieving angina at 3 months (67% vs 20%, P < 0.001) and 6 months (67% vs 27%, P < 0.001).	

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(3) 安全性・信頼性

特に記述がなかった。

(4) 患者QOL

ACP-Journal Club の1件では、数値は無いが、Quality of life and cardiac perfusion were also evaluated in < 80% of surviving patients at 12 months. という記述があった。

(5) コストベネフィット

特に記述がなかった。

5-3-3 Catheter Ablation

MEDLINE で収集された 38 件と CCTR 1 件の論文抄録の要点を記す。

収集した論文を分類すると、カテーテル先端のチップに関するものが合計 13 件と最も多かった。内訳は、電極を塩水等で湿潤 (irrigated) させる形式の試験が 5 件、電極サイズを 8 mm として通常の 4 mm と比較したもの 3 件、温度制御或いは温度モニタリングを行う形式が 5 件で、いずれも対象へのエネルギーの伝達効率を改善し、また、凝固物の付着を防止し、処置時間と透視時間の短縮を狙ったものである。

次に多かったのは、アブレーションと抗不整脈薬との効果を比較したもので 7 件であった。うち 5 件はアブレーション後のペースメーカー併用療法を比較している。

その他、アブレーションのためのマッピングに関するものが 4 件、アブレーションサイトに関するものが 4 件、焦点アブレーションと直線アブレーションの比較、再発防止の抗不整脈薬についての各 2 件等が続いた。

疾病名称としては、心房細動(chronic / paroxysmal) atrial fibrillation 15 件、心房粗動 atrial flutter 11 件、房室結節再入性頻脈 atrioventricular nodal reentrant tachycardia 3 件、心室性頻脈 ventricular tachycardia 2 件、不整脈 arrhythmia 1 件、副作用としての血栓 thrombolism 1 件であった。

A. 湿潤チップ (irrigated ,cooled tip)

塩水等で先端電極を湿潤 (洗浄) と冷却をさせると高周波アブレーションの傷が大きいことが知られている。臨床的效果を試験した 5 件の論文が見られ、いずれも効果を認めている。そのうち 2 件は、僧帽弁置換の MAZE 治療に関するものである。

(1) 技術適用疾病

chronic atrial fibrillation undergoing mitral valve replacement 2 件, atrial flutter 2 件, ventricular tachycardia 1 件であった。

(2) 診断・治療能力

湿潤させた電極によるアブレーションは傷が深くなり処置時間、透視暴露時間は短縮できるとしている。No.16 の論文においては、8%の患者に重度の合併症があったと述べているが、一方 No.20 の論文では顕著な side effect は無かったとしている。

抄録 No	Irrigated tip の評価	疾病名称	技術	治癒性
MED	○	chronic atrial	MAZE operation	Thirty-day mortality was 0% in both groups. After 12 months, sinus rhythm was reinstated significantly more often in

3		fibrillation		patients of group A (cumulative rate of sinus rhythm 0.800) compared to patients in group B (0.267) (P<0.01). 66.7% of patients in sinus rhythm of group A had documented biatrial contraction. (MAZE 治療)
4	○	typical atrial flutter	irrigated catheters vs. standard catheter	Both mean duration of the procedure (164.56 versus 70.35 minutes) and fluoroscopic time (40.16 versus 16.8 minutes) was significantly less with irrigated catheters (p < 0.001).
5	○	chronic atrial fibrillation and mitral valve disease	MAZE procedure	Survival after 12 months for group A and B was 73% and 93% (p = 0.131). (MAZE 治療)
16	○	ventricular tachycardia (VT) associated with structural heart disease	Cooled RF Ablation System vs. conventional technic	Catheter ablation was acutely successful, as defined by elimination of all mappable VTs, in 106 patients (75%). In 59 patients (41%), no VT of any type was inducible after ablation. Twelve patients (8%) experienced a major complication. After catheter ablation, 66 patients (46%) developed one or more episodes of a sustained ventricular arrhythmia.
20	○	common flutter	irrigated-tip vs. conventional tip	The number of applications, procedure duration, and x-ray exposure were significantly higher with the conventional than with the irrigated-tip catheter: 13+/-10 versus 5+/-3 pulses, 53+/-41 versus 27+/-16 minutes, and 18+/-14 versus 9+/-6 minutes, respectively. No significant side effects occurred, and the coronary angiograms of the first 30 patients after ablation were unchanged.

○：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

透視時間の減少による安全性に言及している論文が2件見られた。

抄録 No	Irrigated tip の評価	安全性
MED 4	○	mean duration of fluoroscopic time (40.16 versus 16.8 minutes) was significantly less with irrigated catheters (p < 0.001).
20	○	x-ray exposure were significantly higher with the conventional than with the irrigated-tip catheter: 18+/-14 versus 9+/-6 minutes

○：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) 患者QOL

(5) コストベネフィット

特に記載事項は無かった。

B. 温度制御或いは温度モニタリング

高周波パワー制御と比較して、チップの目標温度を制御する方式の効果に関して試験する論文と、目標温度の違いによる結果を比較した論文が計5件見られた。うち、温度制御或いはモニタリングが効果あるとしたもの2件、温度制御がモディフィケーションには効果があったが副行伝導路のアブレーションでは手動調節に対し効果なしとするもの1件、温度制御とインピーダンス制御の両方とも良しとするもの1件、目標温度は60度Cの方が48度Cに比較し成功率が高いとするもの1件であった。

(1) 技術適用疾病

疾病名称を特定したのは atrioventricular nodal reentrant tachycardia 2件, atrial flutter 1件に関するものであった。

(2) 診断・治療能力

No.	温度制御の評価	疾病名称	技術	治癒性
MED 25	○	AV nodal reentrant tachycardia	target temperatures of 48 vs. 60 degrees C	The primary success rates were 76% in the patients assigned to 48 degrees C and 100% in the patients assigned to 60 degrees C (P < 0.01).
27	○	atrioventricular nodal reentrant tachycardia	ablation using temperature monitoring with a target temperature of 60 degrees vs. using fixed power at 32 W	The primary success rate was 72% in the fixed power group and 95% in the temperature monitoring group (p = 0.001). The ablation procedure duration (35 +/- 29 min vs 35 +/- 30 min; p = 0.9), fluoroscopic time (32 +/- 17 vs 35 +/- 19 min; p = 0.4), mean number of applications (10.2 +/- 8.1 vs 8.4 +/- 7.9; p = 0.2), and coagulum formation per application (0.2% vs 0.5%; p = 0.6) were statistically similar in the fixed power and temperature monitoring groups, respectively.
34	○	arrhythmia	temperature controlled radiofrequency catheter ablation vs. manually delivered radiofrequency catheter ablation.	The success rate was 92.5% for accessory pathway ablation and 100% for atrioventricular nodal modification. Mapping duration was significantly reduced only in patients undergoing atrioventricular nodal modification. The number of applications was higher for manually delivered ablation in patients undergoing atrioventricular nodal modification (5.6 +/- 1.1 vs 1.9 +/- 0.4, P = 0.004) as was the cumulative energy delivered (5034 +/- 1008 vs 2054 +/- 517 W, P = 0.013) whereas the mean power per application was higher with temperature control (41.4 +/- 1.8 vs 34.1 +/- 1.1 W, P = 0.002). No significant differences in these parameters were found in patients undergoing accessory pathway ablation.

34	○	atrial flutter	power control of energy output model vs. closedloop temperature control model	As compared with group II, group I patients had a higher incidence of coagulum formation (12% vs 2%, $P < 0.05$ ), temperature shutdown (11% vs 0%, $P < 0.01$ ), and impedance shutdown (16% vs 3%, $P < 0.01$ ), more radiofrequency applications ( $7 \pm 3$ vs $4 \pm 2$ , $P < 0.01$ )
35	○ (両方式とも良い結果)	arrhythmia	impedance monitoring vs. temperature monitoring	the success rate (93% vs 93%; $P = 1.0$ ), ablation procedure duration ( $57 \pm 56$ vs $41 \pm 41$ min), fluoroscopy time ( $48 \pm 29$ vs $41 \pm 23$ min; $P = 0.3$ ), number of applications ( $6.2 \pm 4.7$ vs $5.7 \pm 4.6$ ; $P = 0.8$ ), and the number of applications associated with coagulum formation ( $0.1 \pm 0.3$ vs $0.3 \pm 0.6$ ; $P = 0.1$ ) were similar in the two 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

### (3) 安全性・信頼性

温度制御により凝固物の付着やシャットダウンが減ったとの報告があった。

No.	温度制御の評価	疾病名称	技術	安定性
MED 35	○ (両方式とも良い結果)	arrhythmia	impedance monitoring vs. temperature monitoring	number of applications ( $6.2 \pm 4.7$ vs $5.7 \pm 4.6$ ; $P = 0.8$ ), and the number of applications associated with coagulum formation ( $0.1 \pm 0.3$ vs $0.3 \pm 0.6$ ; $P = 0.1$ ) were similar in the two 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

### (4) 患者QOL

### (5) コストベネフィット

特に記載事項は無かった。

## C. 電極サイズ

電極のサイズを標準の4mmに対し、8mmのサイズにしてエネルギー注入能力の向上を図った試みが3件あるが、直線アブレーションでは効果ありとしたもの、一方、心臓内部表面との接触が不良で効果なしとするもの、2分割型8mm電極は治癒結果は同じだが印加パルス数と透視時間が減少したとするものが各1件であった。

### (1) 技術適用疾病

3件とも atrial flutter に関するものであった。

### (2) 診断・治療能力

No.	8mm tip の評価	疾病 名称	技術	治癒性
MED 12	○	type I atrial flutter	8-mm split-tip vs. 4 mm-tip	Procedural success was high in both groups (100% vs 93%). However, requirement of a fewer number of radiofrequency pulses and fluoroscopy time suggests superiority of the 8-mm split-tip over the 4-mm tip ablation catheter.
13	△	typical atrial flutter	8-mm tip vs. 4-mm tip	An 8-mm catheter does not appear superior to 4-mm tip electrode for atrial flutter ablation. The potential advantage of allowing higher energy delivery on a larger surface is compensated by the lack of consistent contact with the endocardial surface.
24	○	typical atrial flutter	8-mm tip vs. 4-mm tip	the 8-mm electrode catheter achieved higher complete isthmus block rate (92% versus 67%, P<0.05) with fewer pulses (2+/-1 versus 3+/-1, P<0.05), shorter procedure time (24+/-15 versus 31+/-12 minutes, P<0.05), and shorter fluoroscopic time (14+/-10 versus 23+/-15 minutes, P<0.05).

○：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

特に記載事項は無かった。

#### D. マッピング

アブレーションのためのマッピングに関する論文が4件見られた。従来の fluoroscopic な方法と比較して、electroanatomic 或いは electromagnetic な3次元マッピングが効果ありとするもの3件、簡単な ablation mapping より詳細な activation mapping が有効とするもの1件である。

(1) 技術適用疾病

atrial flutter 3件と, arrhythmia としたものの1件であった。

(2) 診断・治療能力

No.	評価するマッピン グ方式	疾病 名称	技術	治癒性
MED 8	activation mapping	typical atrial flutter	activation mapping technique vs. on-site atrial potential	In successful patients, the mean radiofrequency delivery duration was longer in group II (845+/-776 versus 534+/-363 s; P:=0.03). On-site, clear-cut, widely spaced double atrial

			analysis.	potentials and activation mapping suggesting CBIB were concomitantly observed in only 47 patients (54%), and ambiguous/atypical double potentials were recorded in 31 patients (39%).
11	electroanatomic mapping	atrial flutter	electroanatomic mapping vs. conventional approach	but mean fluoroscopy time was significantly shorter when the CARTO technology was used (group 1: 29.2±9.4 min; group 2: 7.7±2.8 min; P = 0.0001).
14	Electromagnetic mapping	typical atrial flutter	Electromagnetic mapping vs. fluoroscopic mapping	Eight patients from group I (33%) but only 1 patient from group II (4%) were switched. · · The overall fluoroscopy time, including the placement of the diagnostic catheters, was 22.0±6.3 minutes in group I and 3.9±1.5 minutes in group II (P:<0.0001).
19	three-dimensional mapping	Arrhythmia	three-dimensional mapping vs. conventional mapping	Fluoroscopy time was shorter using the CARTO technique: 10±7 versus 27±15 minutes for AVNRT (P < 0.01), 18±17 versus 44±23 minutes for atrial tachycardia and flutter (P < 0.01), 15±12 versus 34±31 minutes for VT (P < 0.05), and 21±14 versus 53±32 minutes for bypass tract tachycardia (P < 0.01).

### (3) 安全性・信頼性

透視時間を削減したとする報告が3件見られた。

抄録 No.	評価するマッピング方式	安全性
MED 11	electroanatomic mapping	mean fluoroscopy time was significantly shorter when the CARTO technology was used (group 1: 29.2±9.4 min; group 2: 7.7±2.8 min; P = 0.0001).
14	Electromagnetic mapping	The fluoroscopy time needed for isthmus mapping was 17.7±6.5 minutes in group I and 0.2±0.3 minutes in group II (P:<0.0001).
19	three-dimensional mapping	Fluoroscopy time was shorter using the CARTO technique: 10±7 versus 27±15 minutes for AVNRT (P < 0.01), 18±17 versus 44±23 minutes for atrial tachycardia and flutter (P < 0.01), 15±12 versus 34±31 minutes for VT (P < 0.05), and 21±14 versus 53±32 minutes for bypass tract tachycardia (P < 0.01).

### (4) 患者QOL

### (5) コストベネフィット

特に記載事項は無かった。

E. Site に関する論文

アブレーションまたはモディフィケーションを行う場所について、anterior approach と posterior approach を比較したものが4件あり、どちらかと言えば anterior approach を良しとしたものが3件あった。

(1) 技術適用疾病

atrial fibrillation, atrial flutter, atrioventricular nodal reentrant tachycardia であった。

(2) 診断・治療能力

No.	評価	疾病名称	技術	治癒性
MED 15	A>P	medically refractory paroxysmal (PAF) or chronic atrial fibrillation (AF)	anterior approach vs. posterior approach	The primary success rate (14/18 vs 14/22, P = NS), incidence of transient AV block (3/18 vs 3/22, P = NS), and complete AV block (1/18 vs 1/22, P = NS) were similar between the anterior approach and posterior approach. The major differences between the two groups showed more radiofrequency pulses (10 +/- 4 vs 6 +/- 3 pulses, P < 0.01), longer procedure duration (50 +/- 24 vs 28 +/- 18 minutes, P < 0.01), and longer fluoroscopy exposure time (28 +/- 17 vs 16 +/- 8 minutes, P < 0.01) in the patients who had primary success with the posterior approach.
18	A>P	typical atrial flutter	anterior side of the isthmus vs. posterior side of the isthmus	Among successful patients, number of RF pulses, procedure time, and fluoroscopy time were significantly lower in group A (7.2 +/- 5.4 vs 11.0 +/- 8.1 pulses, p = 0.03; 131 +/- 44 vs 163 +/- 66 minutes, p = 0.03; 31 +/- 19 vs 46 +/- 24 minutes, p = 0.01, respectively). Impairment of atrioventricular (AV) nodal conduction occurred in 5 patients only during ablation at P. AV block was transient in 4 patients and permanent in 1.
30	A>P	chronic atrial fibrillation	anterior approach vs. posterior approach	RF ablation carried out only in the anterior region was safer than a stepwise approach (6% vs 33% incidence of AV block), even though the difference did not reach statistical significance (P = 0.09).

A> P : anteriorの方が posterior より勝る。

(3) 安全性・信頼性

(4) 患者QOL

(5) コストベネフィット

特に記載事項は無かった。

F. リニアアブレーションと焦点アブレーション

アブレーションの形式としてリニアアプローチと焦点アプローチを比較したものが2件あり、いずれもリニアアプローチが優れていると言う結果であった。

(1) 技術適用疾病

atrioventricular nodal reentrant tachycardia と atrial flutter であった。

(2) 診断・治療能力

抄録 No.	リニアアブレーションの評価	疾病名称	技術	治癒性
MED 6	○	common type AVNRT	straight linear approach vs. electrogram mapping focal approach	The success rate did not significantly differ between the two groups. Out of the 22 patients with a successful outcome in the linear group, 17 (77%) attained complete abolition of the slow pathway conduction, whereas this was observed in only eight (32%) patients in the focal group (P < 0.005). The session time was significantly shorter in the linear group.
36	○	common atrial flutter	electrophysiologically guided focal ablation vs. linear ablation	Successful elimination of the flutter circuit was achieved in 28 of 30 patients in Group I and 29 of 30 patients in Group II. However, in Group II, the procedure time (104 +/- 17 vs. 181 +/- 29 min, p<0.01) were significantly shorter than those in Group I.

○：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

特に記載事項は無かった。

#### G. 抗不整脈薬との比較

アブレーションと抗不整脈薬の効果を比較したものは7件見られたが、うち5件はアブレーション後にペースメーカーを使用したものである。いずれも抗不整脈薬に対し効果を認めたものである。その中で併用するペースメーカーの比較を行ったものが1件あり、モードスイッチ付 DDDR が VVIR より優れたとしている。中に、抗不整脈の中止は再発を招くと指摘したものが2件みられる。

(1) 技術適用疾病

atrial fibrillation, atrial flutter, ventricular tachycardia であった。

(2) 診断・治療能力

抄録 No.	評価	疾病名称	技術	治癒性
MED 10	○	drug-resistant paroxysmal atrial fibrillation	atrioventricular junctional ablation and DDDR mode-switching pacemaker vs. medical therapy	Ablation and pacemaker treatment were highly effective and superior to drug therapy in controlling symptoms and improving quality of life. However, discontinuation of drug therapy exposed patients to further recurrences of paroxysmal atrial fibrillation and the risk of developing permanent atrial fibrillation.

17	○	atrial flutter	first-line RF ablation vs. antiarrhythmic drug therapy	After a mean follow-up of 21 +/- 11 months, 11 of 30 (36%) patients receiving drugs were in sinus rhythm, versus 25 of 31 (80%) patients who underwent RF ablation (p < 0.01). Of the patients receiving drugs, 63% required one or more rehospitalizations, whereas post-RF ablation, only 22% of patients were rehospitalized (p < 0.01).
23	○	chronic atrial fibrillation	AV node ablation and pacemaker with discontinuation of rate-control medications vs. AV node ablation and pacemaker implantation without discontinuation of antiarrhythmic rate-control drugs vs. pacemaker implantation without 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.
26	○	paroxysmal atrial fibrillation	AV junction ablation and DDDR/MS pacemakers vs. medical therapy vs. ablation and VVIR pacemaker	Ablation and DDDR/MS pacing produced better scores than drug therapy for overall symptoms (-41%, P<0.01), palpitations (-58%, P=0.0001), and dyspnea (-37%, P<0.05).
29	○	heart failure and chronic atrial fibrillation	atrioventricular junction ablation and VVIR pacemaker vs. pharmacological treatment	At the end of the 12 months, the 28 Abl+Pm patients who completed the study showed lower scores in palpitations (-78%; P=0.000) and effort dyspnea (-22%; P=0.05) than the 26 of the drug group.
33	○	symptomatic paroxysmal atrial fibrillation	atrioventricular junction ablation and DDDR mode-switching pacemaker implantation vs. pharmacological treatment	At the end of the 6 months, the 21 patients of the Abl+Pm group who completed the study showed, in comparison with the 18 of the drug group, lower scores in the Living with Heart Failure Questionnaire (-51%, P=.0006), palpitations (-71%, P=.0000), effort dyspnea (-36%, P=.04), exercise intolerance score (-46%, P=.001), and easy fatigue (-51%, P=.02).

○ : Ablation または Ablation + pacemaker が抗不整脈より優れているとする評価、

× : 抗不整脈薬が優れているとする評価

### (3) 安全性・信頼性

特に記載は無かった。

### (4) 患者QOL

QOLに言及したものは以下の3件で、いずれも良い評価を得ている。

抄録	評価	疾病	技術	QOL
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