2. 頭蓋内構造物や血管の検出率を向上させる試み

当施設では側頭骨窓不良に対して，頭蓋内構造物や血管の描出を改善するために単結晶探触子の有用性を検討する研究と，前頭骨窓の有用性を検討する研究を行ってきた。

Philips社製iE33と単結晶S5-1MHz探触子もしくは，Philips社製Sonos 5500と従来型S3-1MHz探触子を使用して，異なる時期に入院した脳血管障害症例のカラードプラによる中大脳動脈の検出率を比較し単結晶探触子の有用性を検討した。その結果，中大脳動脈の検出率は単結晶探触子では71％，従来型探触子では59％であった（$p < 0.05$）[14]。次に，同一症例を対象に日立メディコ社制Preirusと単結晶探触子S70もしくは従来型探触子S50Aを使用して，Bモードによる中脳や蝶形骨小翼とカラードプラによる中大脳動脈の検出率を比較検討した。中脳の検出率は単結晶探触子で77％，従来型探触子で63％（$p < 0.01$），蝶形骨小翼は各々73％，65％（$p < 0.01$），中大脳動脈は各々58％，57％（n.s.）であった。2つの検討で中大脳動脈検出に関して異なる結果が出たことは，対象症例や機種の違いによる可能性がある。単結晶探触子の使用によりBモード上の頭蓋内構造物検出率が改善することで検査が容易となることが示唆された。

前頭骨窓からの頭蓋内血管評価の有用性の検討[13]では，側頭骨窓に前頭骨窓からの検査を組み合わせると側頭骨窓単独の検査より前大脳動脈のA1の検出率は46.0％から58.6％（$P = 0.001$），A2の検出率は6.7％から43.6％（$p < 0.001$）まで改善した。前頭骨窓の併用は，特に前大脳動脈を評価に有用と考えられた。

3. 中大脳動脈検出のためのBモード上の指標

わが国における脳血管障害患者での側頭骨窓不良の割合（4割前後）は欧米諸国（1割未満）に比べ高いが，側頭骨窓が不良であるかを判断する指標が今ひとつ判然としなかった。つまり，中大脳動脈水平部が検出できない場合に，側頭骨窓が不良であるのか，中大脳動脈が閉塞しているのかの判断が困難であった。そこで，急性期虚血性脳卒中患者を対象にカラードプラ上の中大脳動脈水平部の検出と最も関連のあるBモード上の構造物が対側側頭骨，同側蝶形骨小翼，中脳のいずれであるかを検討した[9]。構造物とM1の描出状態の関係（Spearman's rank correlation coefficient）は対側側頭骨0.68，中脳0.66，蝶形骨小翼0.80であった。よって，蝶形骨小翼が十分に観察できない場合には側頭骨窓不良のため中大脳動脈水平部を観察できない可能性が高いので，他の画像診断による頭蓋内血管の評価を検討する必要がある。

Ⅳ. 超音波併用血栓溶解療法

基礎研究では，立花（俊）ら[15]が1981年に*in vitro*でウロキナーゼ溶液に血栓を入れ48kHzの超音波を照射することで血栓線溶率が著しく上昇することを報告した。Kudoら[16]は1989年に犬股動脈血栓塞栓モデルで200kHzの超音波を用いて血栓溶解促進作用を確認した。立花（克）ら[17]は1995年に超音波造影剤をウロキナーゼと超音波に併用することで血栓溶解率がさらに改善することを報告した。

臨床研究では，2004年にAlexandrovら[1]が発症3時間以内の虚血性脳卒中例で2MHzのTCDモニターをIV rt-PA療法中に行うと，治療開始2時間以内の中大脳動脈閉塞の完全再開通率が有意に改善することを報告した。この検討では，TCDモニター群の49％に完全再開通もしくは神経学的症候の著明改善を認めたのに対して，非TCDモニター群では19％であった（$p = 0.03$）。しかし，ドイツで行われたTranscranial Low-Frequency Ultra-

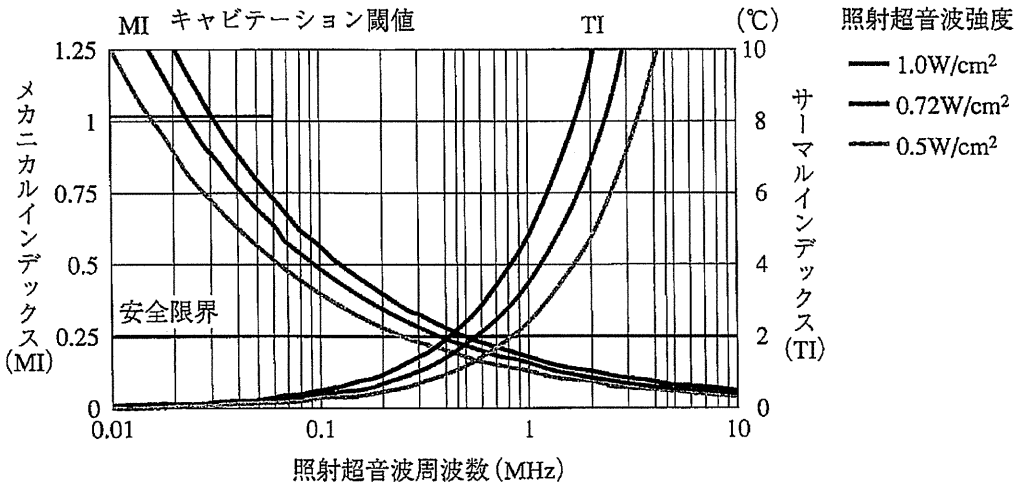

図6. 照射超音波周波数，強度とメカニカルインデックス，サーマルインデックスの関係
（文献22から引用）

sound Mediated Thrombolysis in Brain Ischemia Study (TRUMBI) 研究[18]では，治療群で明らかに頭蓋内出血が増加し研究は中断された。この研究では300kHzという非常に低周波数のバースト波（パルス幅0.5ms）を平均音響強度0.7W/cm²で照射しており，バースト波の特性では頭蓋内に到達する最大音圧は11.2W/cm²程度になっていたと推測されている。さらにダイヤモンド型に配置された4つの超音波照射部位から構成される探触子を用いるために各々の超音波ビームが重なった場合には最大音圧44.8W/cm²，パルス幅2.0ms（各々4倍）にもなり，頭蓋骨内で起こる低周波超音波の多重反射やそれによるキャビテーション発生が頭蓋内出血の一因と考えられた。その後，2006年にスペインからTCDモニターに超音波造影剤（Levovist®）とrt-PA療法を併用すると完全再開通率が有意に改善し，24時間後の神経症候改善の割合が多い傾向にあることが報告された[19]。この検討での完全再開通率は，Levovist®併用群54.5％，rt-PA療法にTCDモニターのみ併用した群39％，rt-PA単独群23.9％（p＝0.038）で，24時間後の神経症候改善は各々55％，41％，31％（p＝0.065）であった。Eggersら[20]は2008年に1.8（～4）MHzセクタ型探触子を使用したTCCSモニターをrt-PA療法中に行うと閉塞血管の再開通率が改善することを報告した。脂質膜で被われた1～2μmの一定したサイズのMRX-801というマイクロバブルを併用した超音波血栓溶解療法の第2相臨床試験であるTranscranial Ultrasound in Clinical Sonothrombolysis (TUCSON)[21]では，4つの用量漸増試験の2番目の用量で症候性頭蓋内出血が27％に発生し，3番目の用量以上の試験は中止された。現在までに第3相試験は行われていない。

Ⅴ．低侵襲的低周波超音波脳血栓溶解法

わが国では，東京慈恵会医科大学の古幡らが超音波血栓溶解療法のための新規装置を開発中であり，*in vitro*の基礎研究[2,22]や霊長類のカニクイザルを用いた前臨床研究で安全性と有効性を確認してきた。この研究では，500kHz連続波，照射超音波強度0.5W/cm²以下による超音波血栓溶解が，キャビテーショ

ンと発熱を安全限界以下にできる至適条件であることを明らかにしている（図6）[22]。この安全な超音波条件による急性期虚血性脳卒中患者を対象とした臨床治験の準備中である。

筆者らは，古幡らの臨床治験に備えヒストリカルデータとして発症12時間以内の中大脳動脈閉塞による虚血性脳卒中14例でTCCSを用いて閉塞血管のモニターを行った。そのうちrt-PA静注療法を受けた7例（男性5例；平均80歳）の治療前National Institutes of Health Stroke Scaleの中央値は12（四分位値10～15）であった。治療開始時からモニターを開始して2時間のモニター中に4例（57％）で完全もしくは部分再開通を確認した。再開通した4例全例で発症24時間以内にNIHSS 4点以上の改善を認めた。症候性頭蓋内出血は1例（14％）であった。

Ⅵ. おわりに

経頭蓋超音波検査は非侵襲性でベッドサイドで簡便に施行可能であり，急性期虚血性脳卒中の治療効果を判定するために閉塞血管の再開通をリアルタイムに評価可能である。このリアルタイム性は今後登場するであろう様々な治療法の評価手段としても有用であろう。また，経頭蓋超音波の併用により血栓溶解療法の促進作用が示されており，今後は安全性を確保でき，操作が簡便で，多くの虚血性脳卒中症例に対して適応可能な超音波治療装置の登場が期待される。

謝　辞

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Common Carotid Artery Dissection Caused by a Frontal Thrust in Kendo (Japanese Swordsmanship)

Rieko Suzuki, MD; Masato Osaki, MD; Kaoru Endo, MD; Tatsuo Amano, MD; Kazuo Minematsu, MD, PhD; Kazunori Toyoda, MD, PhD

A 66-year-old right-handed man suddenly developed left hemiplegia after an opponent thrust at his neck with a bamboo sword during a practice game of Kendo (Japanese swordsmanship; Figure 1). Fifty minutes later, he visited our emergency service. His blood pressure was 77/55 mm Hg in the left arm but could not be measured in the right arm; his right radial artery was initially pulseless but became palpable 1 hour later. He was somnolent and had left unilateral spatial neglect, left complete hemiplegia, and left-sided sensory disturbance. Enhanced computed tomography (CT) showed an occlusion 15 mm distal to the origin of the right common carotid artery (CCA) without any abnormal findings at the aorta and innominate and right subclavian arteries. On emergent carotid ultrasonography, an intraluminal filling defect occupied the right CCA and swung back and forth with pulsation. He was diagnosed as having ischemic stroke, possibly caused by traumatic CCA dissection, although an infarct was not identified on brain CT.

On the second day, fresh infarcts were identified in the right hemisphere on diffusion-weighted MRI, and the right internal carotid, middle cerebral, and posterior cerebral arteries were poorly demonstrated on magnetic resonance angiography (Figure 2). On the fourth day, the right CCA was recanalized, and the intimal flap was identified on ultrasonography (Figure 3 and Movie I in the online-only Data Supplement). A mobile thrombus was identified within the true lumen, but its shape changed on the follow-up ultrasonography 9 hours later. The false lumen diminished, and the thrombus disappeared with a mild aneurysmal change after day 30. The patient was diagnosed as having a definite dissection of the CCA. These dynamic changes were also identified on CT angiography (Figure 4). The right distal CCA was severely stenotic on the fourth day. The stenosis became milder with aneurysmal change on day 10. The intimal flap and double lumens in the right CCA were detected on axial CT scans. The small false lumen was also identified in the distal

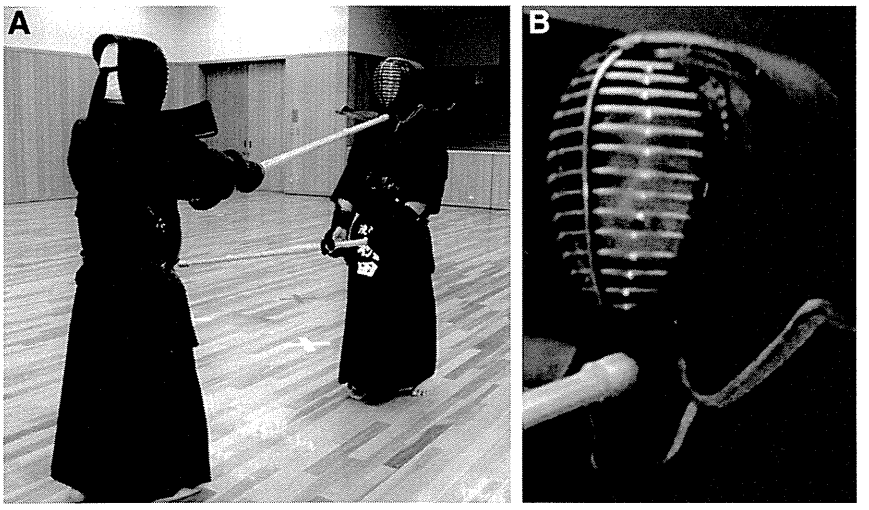

Figure 1. A, A performance of tsuki in Kendo. **B**, A bamboo sword is thrust at the partner's throat armor.

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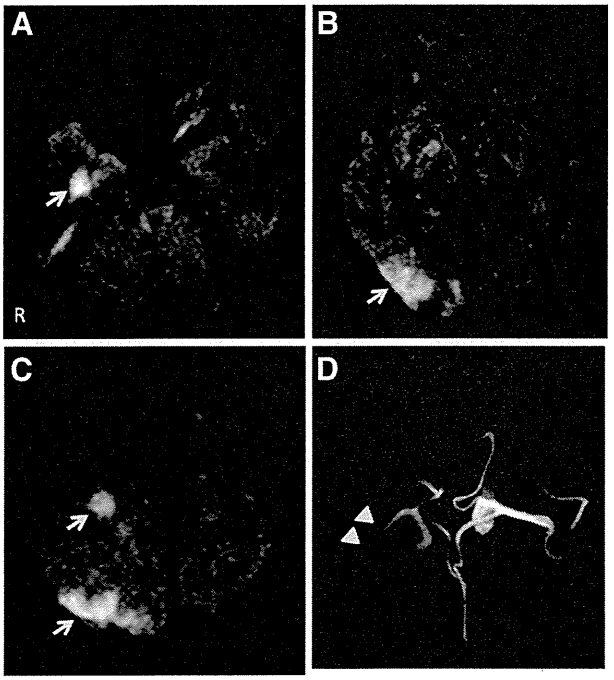

Figure 2. Brain magnetic resonance (MR) images on day 2. **A** through **C**, Diffusion-weighted MR imaging studies demonstrating fresh and scattered infarcts in the right middle and posterior cerebral artery areas (arrows). **D**, MR angiography demonstrating poor visualization of the right internal carotid, middle cerebral (arrowhead), and posterior cerebral arteries.

innominate artery, indicating the existence of the reversible innominate dissection that had caused pulselessness at the time of the initial examination. At hospital discharge on day 49, the patient still had severe hemiplegia. He did not develop recurrent stroke.

A frontal thrust of Kendo can cause cervical artery dissection and stroke,[1] although it has rarely been reported.[2] The strength of this report is that dynamic changes in the morphology of the dissected CCA were clarified through the use of both ultrasonography and CT angiography examinations.

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Disclosures

None.

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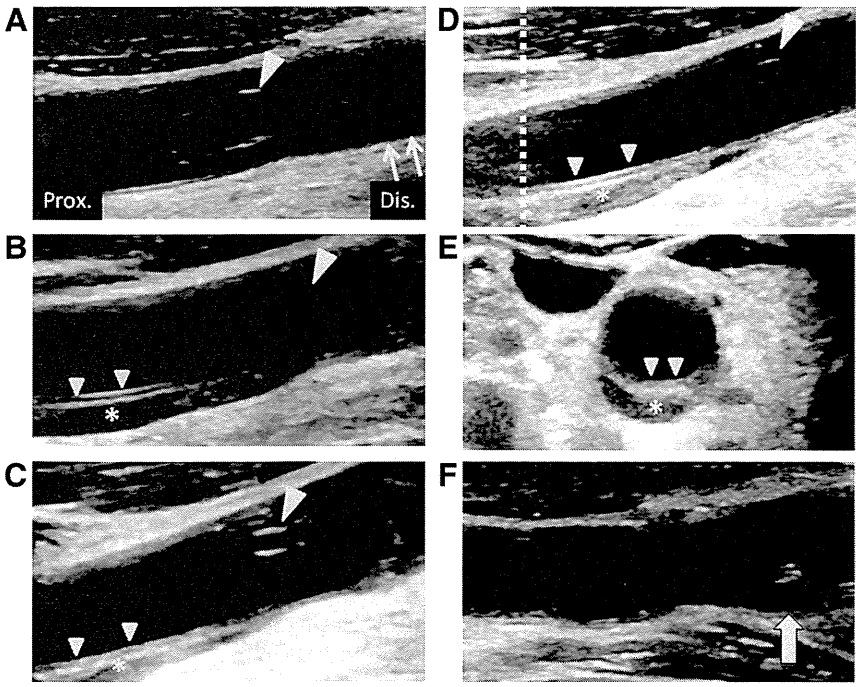

Figure 3. Changes in a B-mode image of the right common carotid artery (CCA). **A**, On day 2, the distal CCA is occluded with a thrombosed false lumen (arrows). A mobile thrombus is identified proximal (Prox.) to the occlusion site (arrowhead). **B** through **E**, Longitudinal (**B–D**) and axial (**E**) B-mode images on day 4 at 10 AM (**B**), 7 PM (**C**), and 9 PM (**D** and **E**). **E**, Axial image of a dotted line on **D**. The distal (Dis.) CCA is recanalized. The mobile thrombus gradually changes in shape (arrowhead). An intimal flap (small arrowhead) and a thrombosed false lumen (asterisk) are seen at the proximal CCA. **F**, On day 48, the mobile thrombus and the thrombosed false lumen disappear completely. Aneurysmal formation is seen (filled arrow).

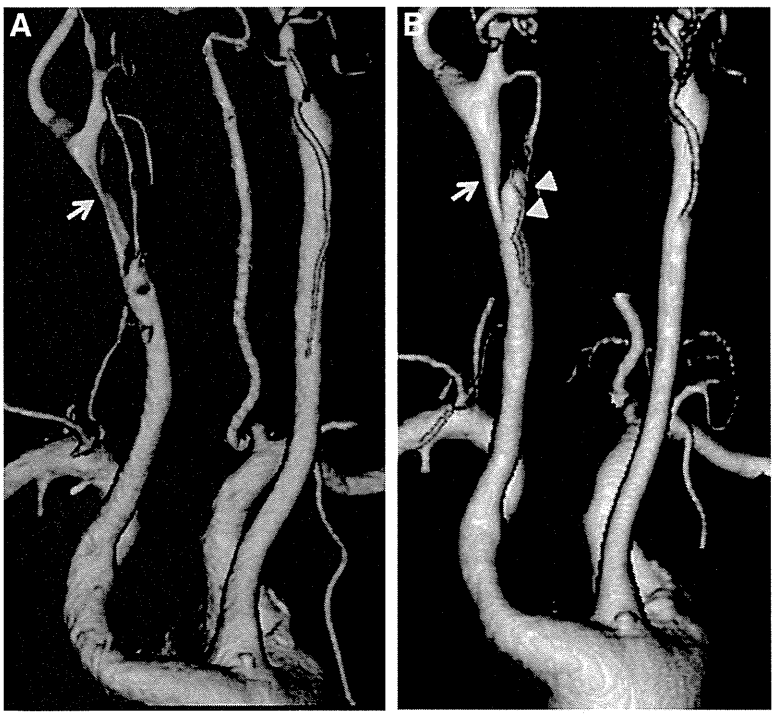

Figure 4. Cervical computed tomography angiography. **A**, On day 4, the right distal common carotid artery (CCA) is stenotic (arrow). **B**, On day 23, the stenotic CCA becomes wider (arrow), and aneurysmal formation is evident (arrowhead).

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Perspectives in Medicine

Evaluation of very early recanalization after tPA administration monitoring by transcranial color-coded sonography

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KEYWORDS
Transcranial ultrasound;
Acute ischemic stroke;
Recanalization;
Tissue plasminogen activator;
Magnetic resonance angiography

Summary
Background/aims: Cerebrovascular ultrasonography was useful clinically for evaluating cerebral hemodynamics rapidly and in real-time for patients with acute ischemic stroke. We analyzed if the patients had early recanalization or not using transcranial color-coded sonography (TCCS) in order to evaluate the usefulness of real-time monitoring in systemic thrombolysis.
Methods: Subjects were patients who had acute ischemic stroke with intravenous tissue plasminogen activator (tPA) within 3 h from onset. We evaluated occlusion of intracranial arteries from transtemporal or suboccipital window by TC-CFI with Thrombolysis in Brain Ischemia (TIBI) flow-grading system and monitored residual flow in real-time every 15 min until 120 min after the t-PA bolus.
Results: We could monitor residual flow in 5 patients who had good echo windows (4 male, mean age; 60.8 ± 6.4 years). Two patients had proxymal occlusion of the middle cerebral artery (MCA), one patient had distal occlusion of MCA, one patient had M2 occlusion and one patient had distal occlusion of unilateral vertebral artery. Four patients had early complete recanalization within 60 min after the t-PA bolus (two patients were 60 min and other two patients were 30 min), however, occlusion persisted during 120 min monitoring in one patient with proximal occlusion of MCA. NIH Stroke Scale of two patients with very early recanalization was 0 at the end of the treatment. There was no symptomatic and asymptomatic intracranial hemorrhage in 4 patients except for the patients without recanalization.
Conclusions: It is anticipated that real-time ultrasound monitoring is useful for evaluating a very early thrombolytic effect of tPA connected with early clinical recovery.

Introduction

The National Institute of Neurological Disorders and Stroke trial of recombinant tissue plasminogen activator (tPA) showed that intravenous thrombolysis with acute ischemic stroke within 3 from onset had favorable clinical recovery compared with placebo-treated patients [1]. However, a thrombolytic effect was not evaluated with monitoring of occlusion artery in this study. Cerebrovascular ultrasonography was useful clinically for evaluating cerebral hemodynamics rapidly and in real-time for the patients with acute ischemic stroke compared with magnetic resonance

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angiography (MRA). The timing and speed of recanalization after (tPA) therapy monitoring by transcranial Doppler (TCD) correlates with clinical recovery [2,3]. These real-time flow informations are useful in developing next therapies and in selection for interventional treatment.

The aim of this study was to analyze if the patients had early recanalization or not using transcranial color-coded sonography (TCCS) in order to evaluate the usefulness of real-time monitoring in systemic thrombolysis.

Material and methods

Consecutive patients who had acute ischemic stroke with intravenous tPA within 3 h from onset between April 2010 and January 2011 were included in this study. tPA was administered in a dose of 0.6 mg/kg (10% bolus, 90% continuous infusion during 1 h) according to Japanese standard protocol [4]. The patients with insufficient acoustic window were excluded.

An experienced neuro-sonographer performed all TCCS studies using a EUB-7500 or 8500 with a 2 MHz sector transducer (S50A, HITACHI Medical Corporation, Japan). We evaluated occlusion of intracranial arteries from transtemporal or suboccipital window by TCCS with Thrombolysis in Brain Ischemia (TIBI) flow-grading system [5] and monitored residual flow in real-time every 15 min until 120 min after the t-PA bolus. An insonation time with TCCS was not longer than 5 min in each examination. No head frame was used during insonation. Complete recanalization was defined as TIBI 0—3 to 5, and partial recanalization was defined as TIBI 0—2 to 3.

National Institutes of Health Stroke Scale (NIHSS) scores were obtained before tPA treatment, every 15 min until 1 h and every 30 min after 1 h by a neurologist. Dramatic clinical recovery was defined as a decrease in the total NIHSS score to <3 at the end of tPA infusion.

All patients had magnetic resonance imaging (MRI) including diffusion-weighted imaging (DWI) and MRA before tPA administration. Follow-up MRA was performed immediately after the end of tPA infusion, if possible.

Results

We could monitor residual flow in 5 patients who had good echo windows (4 male, mean age; 60.8 ± 6.4 years). Two patients had proximal occlusion of the middle cerebral artery (MCA), one patient had distal occlusion of the MCA, one patient had a M2 occlusion and one patient had a distal occlusion of the unilateral vertebral artery. One patient with proximal MCA occlusion had an insufficient acoustic window, but we could monitor residual flow at M2.

Four patients had early complete recanalization within 60 min after the t-PA bolus - two patients at 60 min and other two patients at 30 min. In the patient who could be monitored at M2, one of M2 (M2a) was partial at 30 min, another M2 (M2b) was complete at 30 min. On the other hand, the occlusion persisted during 120 min monitoring in one patient with proximal occlusion of MCA.

NIH Stroke Scale of two patients with very early recanalization (within 30 min) was 0 at the end of the treatment (dramatic clinical recovery).

In three patients a follow-up MRA could be performed after the end of tPA infusion. Follow-up MRA showed early recanalization in two patients and no recanalization in one patient. These findings of MRA were consistent with diagnosis of TCCS. There was no symptomatic and asymptomatic intracranial hemorrhage in 4 patients except for the patients without recanalization. Table 1 shows clinical detail data of 5 patients, and Fig. 1 shows the information of TCCS und MRA in patients with very early recanalization (within 30 min).

Discussion

The present study showed that patients with early recanalization had a favorable outcome after tPA therapy. In these

Table 1 Clinical data of subjects.

Case	Age	Sex	TIBI	MRA	Early recanalization	NIHSS before treatment	NIHSS after treatment[c]	Symptomatic ICH
1	68	M	TIBI 3 at Rt M1	Rt M1 distal occlusion	Complete[a]	10	6	–
2	58	M	TIBI 3 at Rt VA	Rt VA distal occlusion	Complete[a]	4	2	–
3[d]	52	M	TIBI 3 at Lt M1	Lt M2 occlusion	Complete[b]	2	0	–
4[d]	60	F	TIBI 0 at Rt M2	Rt M1 proxymal occlusion	M2a; partial M2b; complete[b]	10	0	–
5	66	M	TIBI 0 at Lt M1	Lt M1 proxymal occlusion	No recanalization	18	19	+

M, male; F, female; Rt, right; Lt, left; VA, vertebral artery; ICH, intracerebral hemorrhage.
Case 4; one branch of M2 had complete recanalization < 30 min, the other branch had partial recanalization at 30 min and complete recanalization at 120 min.
[a] Recanalization < 60 min.
[b] Recanalization < 30 min.
[c] NIHSS at 120.
[d] Two patients with gray shaded values had very early recanalization (within 30 min). Details are shown in Fig. 1.

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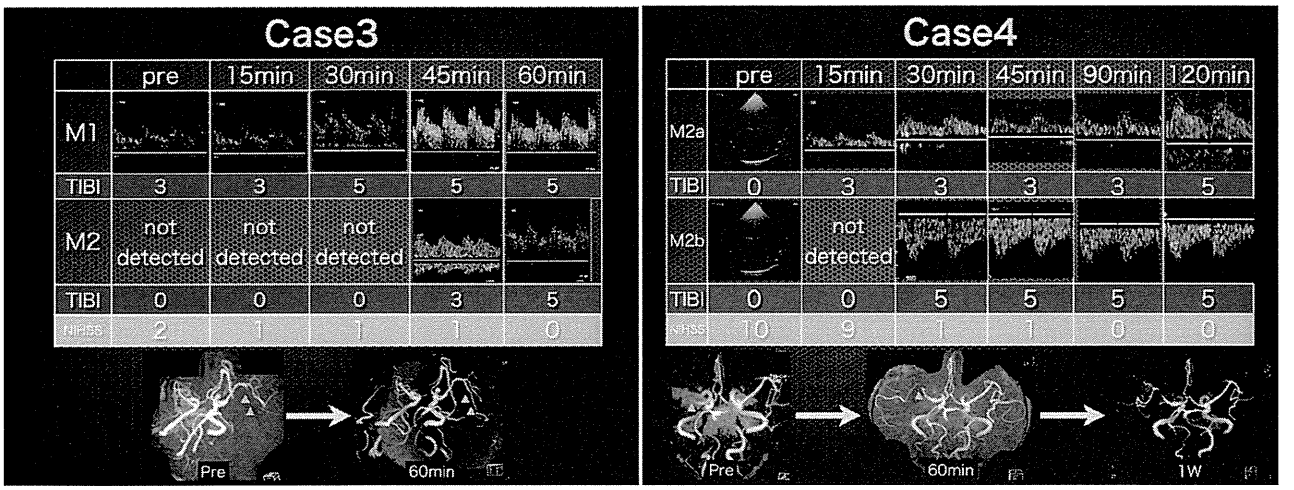

Figure 1 Angiographic information of patients with very early recanalization (see also case 3 and case 4 on table). Upper table is sonogram of residual flow and NIHSS at each examination point. Lower pictures are MRA before and after tPA therapy. Case 3 was M2 occlusion and case 4 with proximal MCA occlusion had insufficient acoustic window, but we could monitor residual flow at M2. Case 3 had very early complete recanalization within 30 min after the t-PA bolus. In case 4, one of M2 (M2a) was partial at 30 min, and another M2 (M2b) was complete at 30 min. MRA findings of these cases were consistent with diagnosis of TCCS.

studies, recanalization after tPA was evaluated by MRA [6,7] or TCD [2,3]. There are different benefits and limitations between MRA and TCD/TCCS in their diagnostic ability and characteristics as a diagnostic device. MRI is the standard device for the detection of vessel occlusion or stenosis, however, it cannot be monitored during tPA infusion because patients who get a MRI have to be transferred to the MRI laboratory. On the other hand, TCD/TCCS is useful for real-time evaluation of intracranial hemodynamics at patient's bedside. Several cases, however, had an insufficient acoustic window especially in Asian elderly female.

In TCD study (2), 25% patients recanalized within the first 30 min, 50% recanalized within 30—60 min, 11% recanalized 61—120 min, and 14% recanalized after first 2 h after tPA bolus administration. The timing of arterial recanalization after stroke onset detected with TCD correlated with early improvement in the NIHSS scores within the next hour after recanalization (S-shaped curve demonstrates correlation between timing of recanalization on TCD and early recovery from ischemic stroke).

Our data showed patients with complete early recovery after tPA treatment recanalized within the first 30 min on TCCS monitoring. It is anticipated that early arterial recanalization correlated with early clinical improvement like present studies.

In other TCD study (3), the speed of intracranial arterial recanalization on TCD correlates with short-term improvement after tPA therapy. Short duration (sudden < 1 min and stepwise 1—29 min) of arterial recanalization is associated with better short-term improvement because of faster and more complete clot breakup with low resistance of the distal circulatory bed. Slow (>30 min) flow improvement and dampened flow signal that indicate partial recanalization are less favorable prognostic signs.

However, our study did not use continuous TCCS monitoring, the speed of clot lysis as well as timing of arterial recanalization is useful information for evaluating effect of thrombolytic therapy. This real-time and noninvasive information using TCD/TCCS are the advantage over MRA.

Conclusions

Very early recanalization within 30 min after tPA administration correlated with complete early on TCCS monitoring. It is anticipated that real-time ultrasound monitoring is useful for evaluating very early thrombolytic effect of tPA connected with early clinical recovery.

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Stroke
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A New Support System Using a Mobile Device (Smartphone) for Diagnostic Image Display and Treatment of Stroke

Hiroyuki Takao, Yuichi Murayama, Toshihiro Ishibashi, Kostadin L. Karagiozov and Toshiaki Abe

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A New Support System Using a Mobile Device (Smartphone) for Diagnostic Image Display and Treatment of Stroke

Hiroyuki Takao, MD; Yuichi Murayama, MD; Toshihiro Ishibashi, MD; Kostadin L. Karagiozov, MD; Toshiaki Abe, MD

Background and Purpose—With the increasing demand for rapid diagnosis and treatment of stroke, the telemedicine role of coordinating timely the efforts of the stroke team became important. We developed a system for rapidly exchanging diagnostic images and clinical and management information.

Methods—A system was created on the basis of communicating patient data and images between hospital systems and participating staff members in and out of the hospital through their standard, currently used handheld communication devices. The system is able to transfer clinical data, CT, MR, angiographic, intraoperative images, and expert opinion in real time.

Results—A pilot application of the system in our hospital showed successful information transfer, allowing medical staff to discuss patients' diagnosis and management using a Twitter system.

Conclusions—The system (i-Stroke) may become a useful tool for acute patient management in the field of neurology and neurosurgery. (***Stroke*. 2012;43:236-239.)**

Key Words: acute stroke ■ organized stroke care ■ stroke management ■ telemedicine

Recent clinical results have demonstrated the effectiveness of recombinant tissue-type plasminogen activators in acute stroke within 4.5 hours of onset and every 5 minutes delay in receiving treatment increases by 5% the probability of a poor outcome.[1] Both time and judgment are important when treating patients with acute stroke. However, support by physicians with sufficient experience in cerebrovascular disorders is available in very few hospitals around the clock, 365 days a year. Therefore, the rapid, available at any time consultation between the on-call and the senior specialists is of great importance in deciding optimal treatment.

Recently the use of telemedicine for stroke care has expanded in a range of initiatives through Europe and the United States.[2,3] In 2009, the American Heart Association recommended telestroke systems to be created in hospitals unable to provide treatment within the first 24 hours of stroke onset.[4] Having the same demand in Japan, we established a system that is based on standard portable communication devices and their supporting systems, exchanging high-quality clinical information and imaging for "real-time" support of clinical diagnosis and treatment in these neurological emergencies.

Methods

After current mobile and handheld communication and IT devices progress, we developed the "i-Stroke" system to rapidly access diagnostic images and clinical information, whether in or out of the hospital. This pilot study was conducted in a neurosurgical department. The software was developed by the investigators. It is free software and it is already available at the Apple store. The system comprises a transmitting server and receiving Smartphones (iPhone 4; Apple Inc; Figure 1A) and allows the following functions: (1) stroke call function: informing participating medical staff involved in all aspects of patient management of an expected admission; (2) time-bar function for monitoring patients' management course(Figure 2C); (3) image viewing function (Figure 3A–C; medical images virtually identical to those displayed in the hospital); (4) static and 3-dimensional video images available to off-site users (Figure 3D), tick-box functions for input/displaying data (consciousness level and neurological findings), and automatic calculation of intravenous medication dose (including tissue-type plasminogen activator) from body weight, diagnosis confirmation from clinical history, and findings using checklists; National Institutes of Health Stroke Scale/Glasgow Coma Scale stroke scales, and others) incorporating diagnostic and treatment functions (Figure 2A); (5) real-time video streaming of microsurgical and diagnostic images from diagnostic and operating rooms (Figure 3C); (6) Tweeting to fellow specialists (exchanging opinions on the spot); and (7) interhospital exchange of images and other information, allowing consultations for patients at other hospitals. To protect personal information, all patient information was blindly coded by the VPN system. Therefore, only patient age and gender were provided as identification. After 24 hours of stroke call initiation, all i-Stroke data for the patient are erased automatically.

Results

The i-Stroke project was approved by our Institutional Review Board and 64 "i-Stroke" calls were made between

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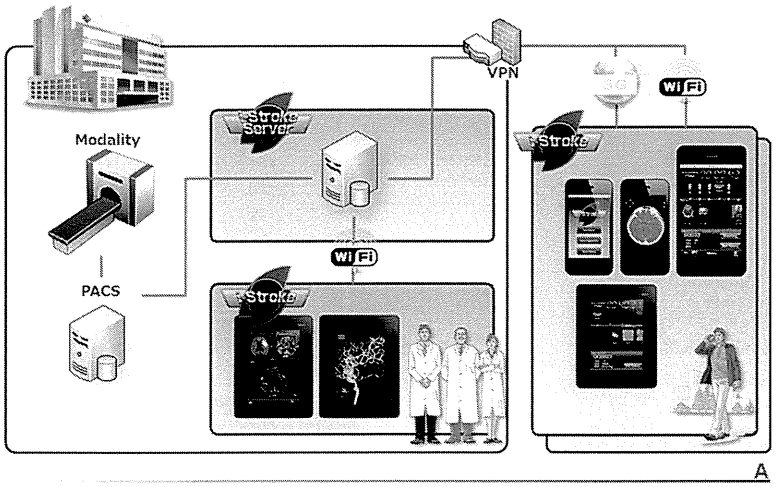

A

		Treatment		Observation	Total
Subarachnoid hemorrhage	Aneurysm	clipping 5	coiling 5	3	13
	AVM	2			2
Intracerebral hemorrhage		4		12	16
Spinal hemorrhage		1			1
Spinal subdural hemorrhage		1			1
Cerebral infarction		1		1	2
Seizure				11	11
Head Injury		16		2	18
Total		**35**		**29**	**64**

B

Figure 1. Components of the system in connection (**A**) and stroke call patients' summary (**B**).

August 2010 and March 2011. Fifty-five patients were admitted by ambulance from the central metropolitan area of Tokyo and 9 patients admitted as walk-ins. The distance of the patient transfer ranged between 1 and 20 km. The patient's diagnosis after completion of the call and clinical management is shown on Figure 1B.

Illustrative Case

A 38-year-old man presented with a severe headache. Three-dimensional CT angiography revealed subarachnoid and intracerebral hemorrhage resulting from a ruptured anterior communicating artery aneurysm. Initiating a stroke call, the images were transferred to the experts on endovascular and open surgical treatment (Figure 3A–B). Monitoring real-time images on the immediately performed angiography, senior neurosurgeons and neurointerventionalists discussed treatment options using the "Twitter option." Surgery was started immediately by the on-call residents, a junior neurosurgeon moved to the hospital monitoring the case on the way, and the senior neurosurgeon advised the team using videostream from an outside location (Figure 3C).

Discussion

Compared with existing systems,[5,6] the i-Stroke system represents an advance in the direction of treatment support. Information sent from a fixed workstation can be received wherever there is a mobile signal (i-Phone, Android). In addition to delivering images, when initiated before admission, the i-Stroke system alerts the relevant hospital staff on the patient's arrival condition and time, a key function considering the importance of team stroke treatment. Further on, the display of real-time diagnostic imaging results and other tests permits swift reaction to developments and physicians can objectively identify possible time savings. Clinical evaluation scales (Glasgow Coma Scale, the National Institute of Health Stroke Scale, the modified Rankin Scale) are included in the patient record options.

The real-time viewing of surgical and other procedures by senior experts outside the hospital allows the assessment of treatment progress and provides guidance, contributing to treatment safety and risk management.

The Tweet function permits adding instantly comments about clinical images and other related data. i-Stroke is therefore a novel system that enables simultaneous communication among several members and results in significant time savings on decision-making. Treatment instructions and other orders can be sent with a single touch.

For personal information protection, all mobile devices are identified and password-protected so that only the device owners can see images, and measures such as automatic

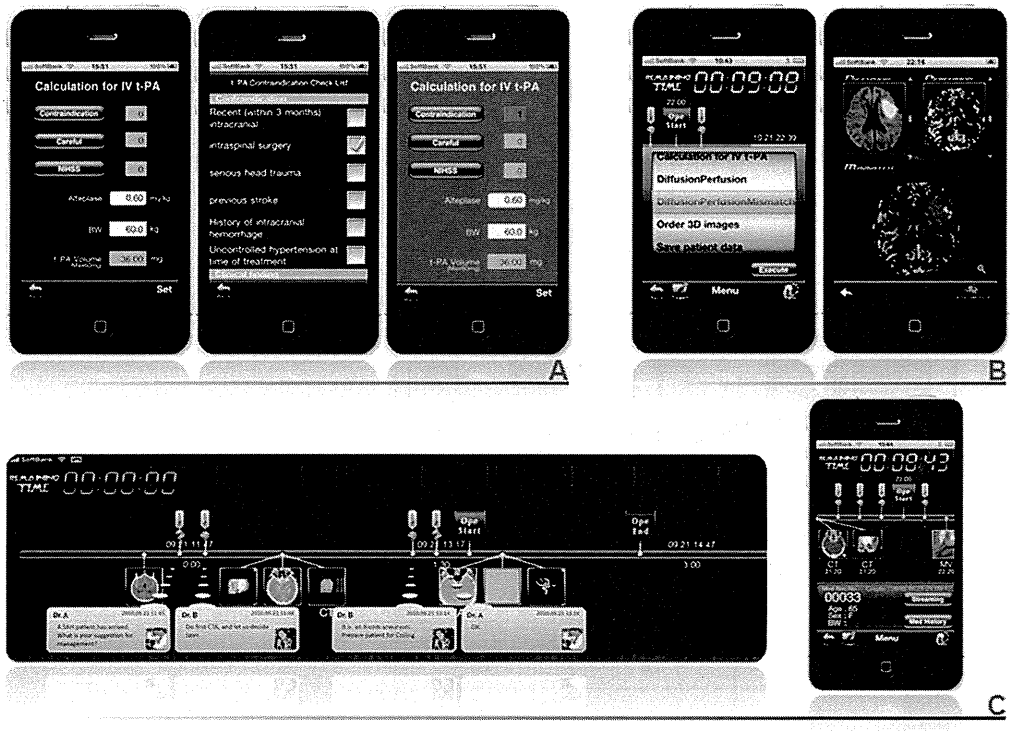

Figure 2. Diagnostic and treatment data display and orders (**A** and **B**), including timeframe display (**C**).

deletion of images within 24 hours of receipt are included. When images are downloaded to the physician's device outside the hospital, to guarantee security, images are automatically rendered anonymous and simultaneously compressed to ensure rapid download, aiming for protection from information leakage.

We hope in this way eventually all emergency patients with stroke nationwide will benefit from this system through

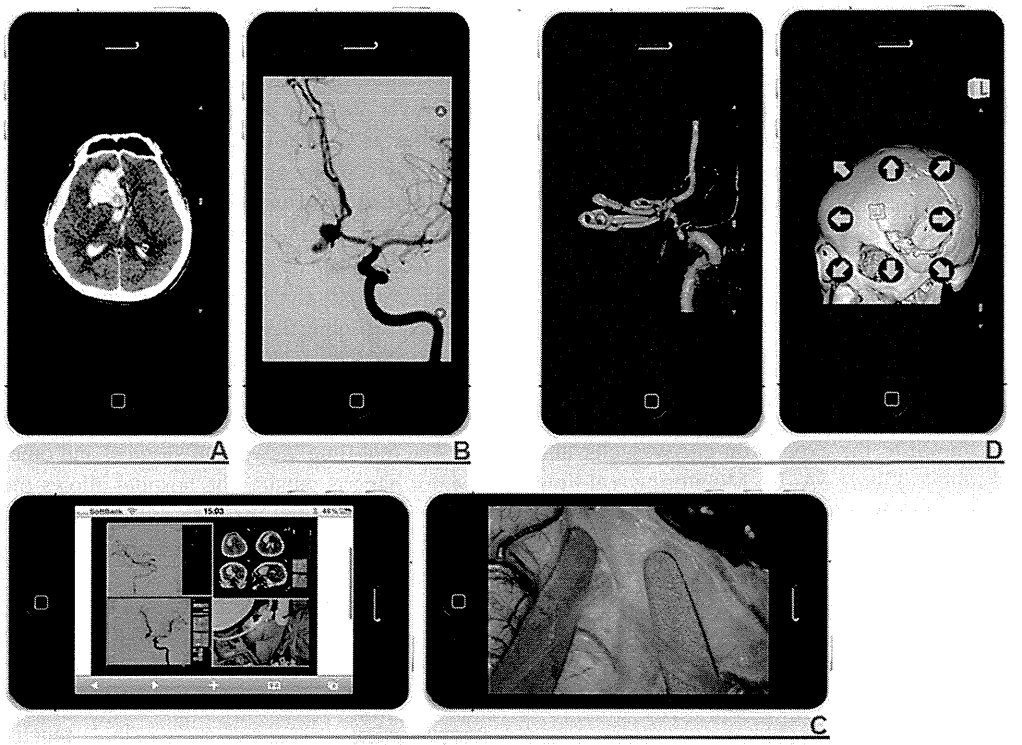

Figure 3. Basic imaging abilities on mobile device. **A**, Admission CT; (**B**) digital subtraction angiography; (**C**) real-time monitoring of the procedure by consulting expert and "real-time" surgical field in display to the expert. Postoperative images: (**D**) digital subtraction angiography and 3-dimensional CT bone reconstruction.

the cooperation of hospitals throughout Japan who wish to participate. Furthermore, similar systems will probably also continue to be adopted worldwide in line with the American Heart Association recommendations.[3,4]

i-Stroke concept and functions can be adapted to other medical fields, and i-Cardiology, i-Obstetrics, and i-Gynecology are under development.

Conclusions

By facilitating the rapid diagnosis and treatment of stroke and other acute neurological and neurosurgical conditions, our system is expected to improve the outcome in many patients. The results indicate its potential to provide benefit for treatment of patients with ischemic stroke, although these series contained only 1 such case. It may also reduce extra working hours, giving physicians the opportunity to be efficient even when being on standby, away from the workplace. Hopefully misdiagnosis and unnecessary transfer of patients will be reduced, ultimately contributing to healthcare cost reduction.

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❶ 超音波診断装置の安全性の確保

古幡　博

人間が作り出した超音波のもつ音圧や粒子速度は，体内に超音波発生源を生物学的にもたない人間の組織に対し，分子の振動や膜などの構造物に振動的圧力を加えるものである。生体組織内では分子の並進運動に超音波エネルギーが変換され，それによって発熱する。この超音波吸収現象によって，伝播経路内で減衰する。同時に細胞膜は疎密波圧力によって引き裂かれるような伸展と圧縮の力が加えられることになる。超音波エネルギーを増加させれば組織の温熱効果，さらには熱焼による壊死・凝固を招来するしきい値もある。
また，強力な超音波の圧力は細胞を引き裂いたり，体液内にキャビテーションを惹起する。よって，生体への有害・無害の機械的な損傷に関するしきい値もある。ここでは，その具体的な考え方について述べる。

安全性の考え方

患者に対する安全性は，装置自体の安全性（product liability；PL）と，装置を使用する医師・検査者のもつべき知識や技能に支えられる安全性（users liability；US）とによって，はじめて確保されるものである。

長い年月にわたる基礎的研究の成果を踏まえ，今日診断装置には米国AIUM，および世界超音波連合WFUMBが提案し，米国FDAが採用している診断用超音波の安全限界値が設けられている。これは生体組織における超音波吸収特性（すなわち，分子レベルの振動発生による超音波減衰）に基づき決められている（**表1，2**）。**表1**には生体組織による吸収特性の差を示した。水に比べ骨における吸収の多いことは注目に値する。このような生体組織特性を考慮して，FDAは**表2**上段（track Ⅰ）の限界値を設定した（安全基準）。

しかし，超音波技術の発展と臨床要求を満足させるため，装置としては，その最大値が最大安全

表1　さまざまな生体組織における超音波吸収係数の違い

rank	tissue
1	water
2	biological fluids
3	soft tissue
4	skin and cartilage
5	fetal bone
6	adult bone

表2　FDAにより超音波診断装置に要求される超音波出力の限界値

SPTA		
track Ⅰ	Ispta.3 [mW/cm²]	Isppa.3 [W/cm²]
peripheral vessel	720	190
cardiac	430	190
fetal & other	94	190
ophthalmic	17	28
track Ⅲ	Ispta.3 [mW/cm²]	Isppa.3 [W/cm²]
peripheral vessel	720	190
real time display	thermal index(TI) mechanical index(MI)	

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限界720mW/cm² (SPTA)，190 W/cm² (SPPI)を超えなければよいとした（trackⅢ）。ただし，生体内におけるTI値(thermal index)とMI値(mechanical index)をreal timeで表示しなければならないことを製造側に追加要求している。すなわち，装置としてはTI値，MI値を表示するので，実際の臨床現場では，検査者がそのTI値，MI値から測定対象部位の安全限界値以下となるよう使用することを，期待している。つまりtrackⅠに示された臓器別の安全限界以下であるかどうかをTI値，MI値から使用者が判断し，後述するALARAの原則に従って，検査することを定めている。逆説的にいえば，装置の最大限界値は超音波企業が担保するが(PL)，装置を患者に適用するときの責任は検査者の責任で(UL)，超音波の生体内の状態を示すTI値，MI値をみながら検査を実施することを求めるものとなっている。臨床側の使用者責任(UL)で超音波検査は行われねばならず，そのとき少なくともALARAの原則(As Low As Reasonably Achievable；診断可能な最低出力で短時間で行うことを原則)に則ることを要求している。

MIの基準

超音波は縦波で疎密波として伝播するが，その圧力変化が組織の静圧よりも著しく低くなるとキャビテーション(空泡)を生じる。このようなキャビテーションの発生条件は1気圧の静圧の水中では1W/cm²程度で生じるとされている。組織圧を考慮すれば1W/cm²以上の音圧でも，組織内ではキャビテーションは発生しにくいと考えられる。しかし，患者個々人の組織状態は不明であるので注意する必要がある。

診断用超音波として用いられる，シングルパルス波による生体組織への機械的な作用は，超音波の音圧と周波数で決定され，その指標である*MI*は次式のように定義される。

$$MI=\frac{P_r}{\sqrt{f}}$$

P_r：生体組織における引き裂き張力(rare factional pressure) [Pa/cm²]

f：超音波周波数 [MHz]

水中ではMI≧1でキャビテーションが発生し，生体組織内ではMI=1.9を安全限界としている。

このMI値は周波数依存があり，低周波数になるほど投与音圧が一定でも引き裂き圧力(rare factional pressure)は増高する(**図1**)。

TIの基準

超音波の吸収によって生じる生体内組織の温度上昇は，次に示す式のように定義される。

$$TI=\frac{W'}{W_{deg}}$$

W_{deg}：生体組織の温度を1℃上昇させるのに必要な超音波パワー[W]

W'：生体組織に照射された超音波パワー[W]

すなわち，TI＝1ならば生体組織の温度が1℃上昇する。

TIの定義から主要な組織のTIについては**表3**のように，TIS，TIB，およびTICが示される。

胎児において，超音波吸収における骨の発熱や，成人頭蓋骨の超音波吸収での発熱には十分留意すべきである。少なくとも生体内で2℃以上の温度

図1　超音波音圧による細胞引き裂きと超音波周波数の関係

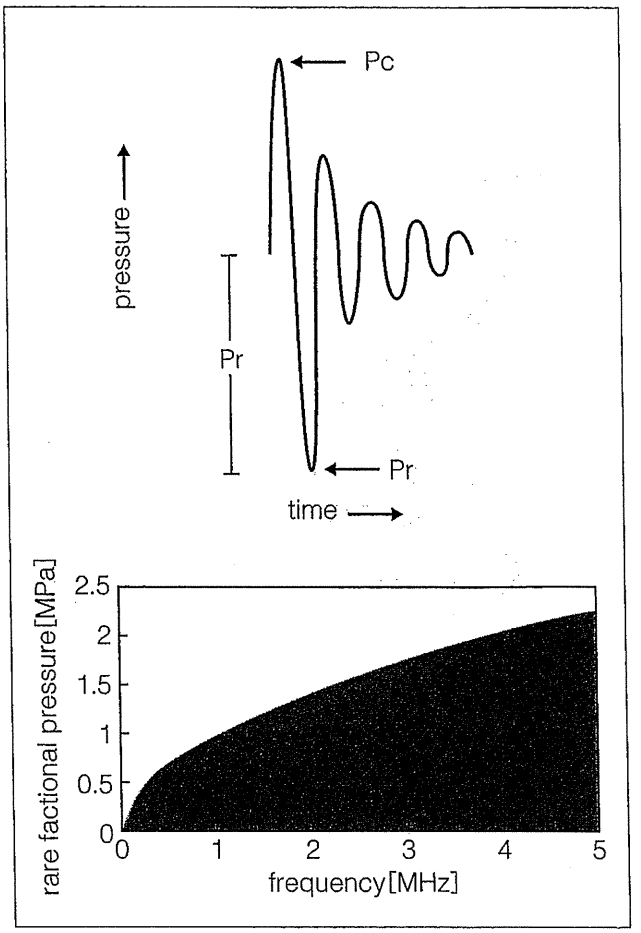


表3　主要な生体組織におけるTI

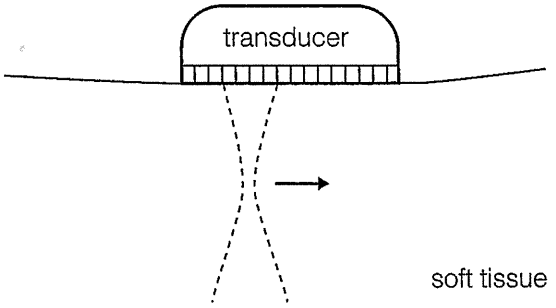
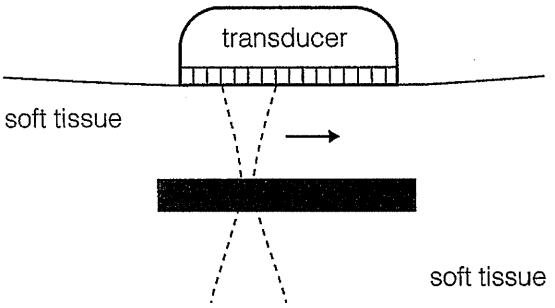
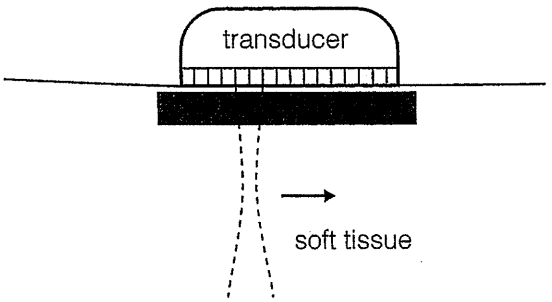
TIS	軟組織(soft tissue)におけるTI 骨以外の部位に適用する。 W_{deg}は次式のようになる。 $W_{deg}=\frac{210}{f}\times10^{-3}$ f：超音波周波数[MHz]	
TIB	体表から深い部位の骨におけるTI 骨は超音波吸収率が高いため別に定義する。 胎児のように，超音波プローブのある体表から深い部位の骨(bone)に適用する。	
TIC	体表に近い骨におけるTI 頭蓋骨(cranium)など体表から近い骨に適用する。	

図2　超音波照射時間と軟部組織内の温度上昇の関係

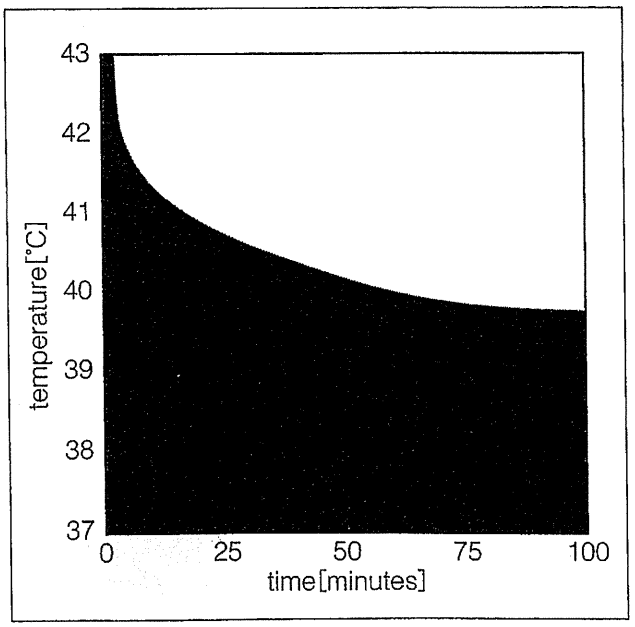


図3　超音波パルスと音響強度IsppaとIsptaの関係

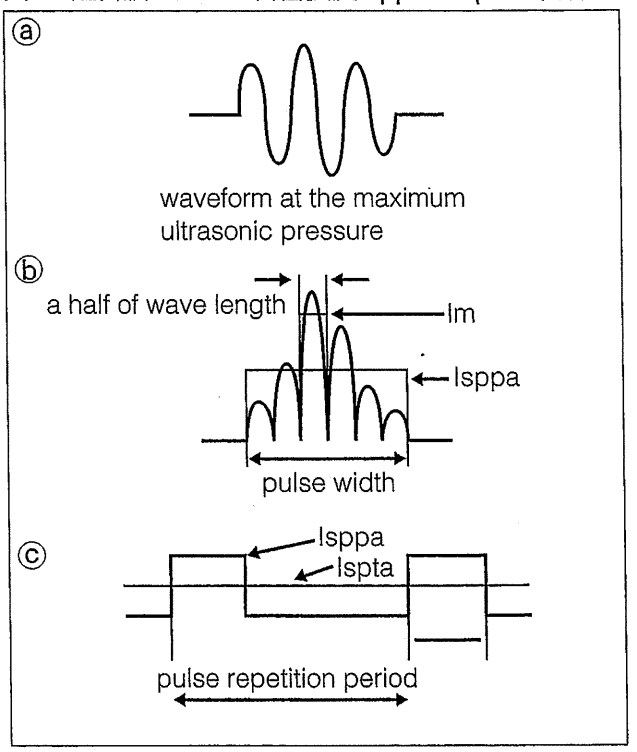
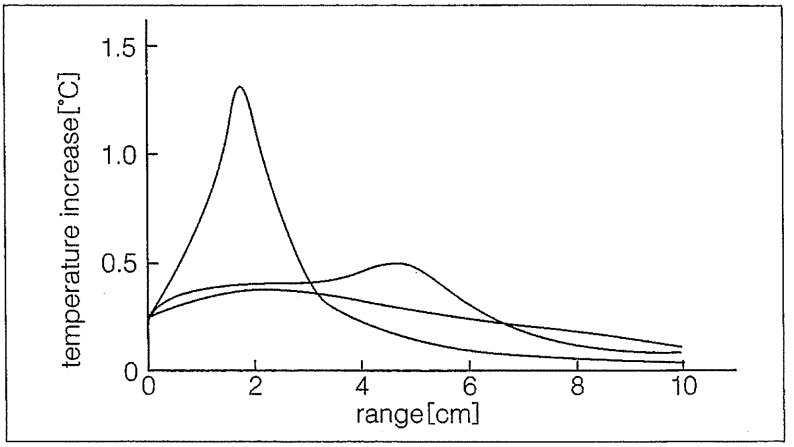


図4　超音波ビーム内の空間的温度上昇の例
（焦点距離2cm，6cm，10cmの場合）



上昇(TI＝2)を限界と考えるべきである。温度上昇と照射時間限界については生体軟部組織で**図2**の関係のあることを踏まえ，限界時間内で検査すべきである。照射時間と温度上昇(TI値)の関係式は次式でも表せる。

$$tc = 4^{(43-TI)}$$

超音波ビームと音響強度

表2のように超音波ビームの空間的時間的平均強度(spatial peak temporal average；SPTA)と空間的ピークパルス強度(spatial peak pulse intensity；SPPI)をもって超音波の生体への安全限界を示すこととしている。その具体的意味を述べておきたい。超音波ビームは電子走査などによって集束点があり，またその集束点を1点でなく，長くとることによって画像空間分解能を高いものとしている。このことは空間的に音響強度の異なる部位が存在することを意味し，その空間内の1つのパルス振幅としての最大値(ピーク値)(SPPI)で限界を定義している(**図3，4**)。超音波機器メーカーは超音波プローブごとの音場分布を調べ，その空間分布から生体内の状態を推定し，TI値，MI値をシミュレーションして表している。

安全な使用には，この点を踏まえた診断装置の扱いが求められる。

おわりに

超音波診断装置は，その最大出力レベルをFDA，ISO，IEC，GIS(いずれも同一基準値を採用)の基準により定められ，機器メーカーはそれを満たす装置を提供している。使用者は対象疾患の病態を考慮し，ALARAの原則に則って検査を行う必要がある。そのようにして得られた画像やソノグラムをもとに患者データを得るには装置の精度を考慮した検査を行われなければならない。正しい生体情報は適切な装置操作と検査法によってはじめて得られるものであることを改めて付言しておきたい。

このような安全責任を担ったデータでなければ，患者の真のデータの発見にはならないと考える。