表1 患者と医師にある「医療によってもたらされる害」についての認識

医師側の認識	患者側の認識
害は，自分がもたらしたものか？ それとも別の何か(薬，もしくは運)がもたらしたものか？	医療は私に益をもたらすはずであった．その医療によって，私は傷ついてしまった．何かの間違いが起きたに違いない．
害は，純粋に害なのか？ リスクがもたらした事象ではないのか？	
有害事象は，私の過失によるものか？ 私の行いは正当ではないのか？	
きわめて小さな確率でもたらされる害については，説明することのほうがむしろ有害ではないか？	

ろう．

ここで，医療事故における一般的な定義を確認してみたい．

【医療事故】医療従事者が行う業務上の事故のうち，過失が存在するものと不可抗力(偶然)によるものの両方を含めたもの．

【医療過誤】医療従事者が行う業務上の事故のうち，過失の存在を前提としたもの．

ここで，患者に発生する事故とは，死亡，生命の危険，病状の悪化などの身体的被害，および苦痛，不安などの精神的被害を指し，過失とは，行為の違法性，すなわち客観的注意義務違反をいう．注意義務は結果発生予見義務と結果発生回避注意義務とに分けられる[3,4]．

有害事象が発生し，システムとして何が問題であるかについて考える時，過誤による事故か，過誤によらない事故なのかについて検討することはとても大切なことである．たとえばCase 2において，慎重にプロセスを得たうえで行った鎖骨下静脈穿刺によって患者が気胸を起こしてしまった場合，それは過誤なのだろうか？ 大腿静脈穿刺で中心静脈が留置された後，7日後に患者に発生した肺塞栓は過誤なのか？ これについては医療者のなかでもずいぶん認識が違うのかもしれない．

最後に，害が発生する確率に関して，医療者はあらかじめ知ったうえでさまざまな判断をしている．たとえばCase 1において，カルバマゼピンなどの抗てんかん薬を処方する場合には，有害事象の可能性を医師自身から患者に示唆していたかもしれない．H_2ブロッカーのように，とくにスチーブンス・ジョンソン症候群の発生率が高いわけではない薬に関しては，通常，あえて患者を脅すようなことは控えるべきであるという意見ももっともである．そんなことをいったら，白血球減少など，起こりうるすべての副作用について話さないといけない．もたらしうる害が，重篤であり，なおかつ一定の可能性を超える時，初めて医療者は副作用に関する警告的な発言をするのである．

● 患者の認識

ただ，おそらく上記のすべては，患者にとっては医療者側の都合のよい認識であろう．患者にとって，医療によってもたらされた害は，並大抵のものではない．レストランに行ってまずいものを出されることについては，客は多少のリスクを自覚しているかもしれないし，期待以上であった，期待はずれであったという評価によって，それなりに心の落ち着きどころもあるであろう．しかし医療サービスにおいては，受診する際に，医療が自分に害を与える可能性があることは普通考えない．すなわち，患者にとっては，具合の悪い自分をよい方向に向けてくれるであろうと期待して医療行為を受けたのに，自分にさらなる不幸な転機がもたらされたとすれば，何かの間違いがあったに違いないと感じるのが普通である．行為と有害事象との関連の直接性や，純粋に確率的にもたらされた事故なのか，それともエラーによるものなのかを患者が判断することはまず不可能である．さらに，たとえきわめて少ない確率で患者への有害事象が発生したとしても，その患者にとって，確率は何の問題解決にもならず，ただ

"医療行為によってひどいことになってしまった"という明確な事実が存在するだけである(表1).

正義と悪

患者が医療者を信じることができないことの1つは，医療によって起こる有害事象があるからである．そして，有害事象をゼロにすることは，絶対にできない．有害事象をもたらすのは通常悪人のやることであり，正義の味方のやることではない．医療者は，正義の味方なはずなのに，おかしいではないか？ ここに，医療への不信感が生まれる．では，医療はどうすればいいのか？

患者にとって，「これは絶対に癌に効く！」といって，たとえば，アヒルのクチバシの粉やキノコのエキスをすすめる人と，保険医療で医療行為をしている医師との差は何であろう？ 患者にとって，前者は，医療の限界を突破できるとてもよい人かもしれない．一方で，自分をだまして大枚を稼ごうとしている悪い人かもしれない．詐欺罪でつかまるほどの悪い人ではないかもしれないが，誇大広告をしている可能性はある．ただ，それはある意味，致し方のないことであろう．デパートで，高くて良質な服を買うことと，安くて流行の服を買う次元と大差はない．サービスの消費者は，サービスの提供者が自分に益をもたらすのかどうかについて判断しながらサービスを選択する責任がある．しかし，医療者は患者にとって決してそのような存在であってはならない．医療とは，社会保険によって成り立っているサービスなのであり，医師は常に患者にとって最大の恩恵を与えるべき存在でなければならない．おそらく，医療が社会保険でなかったとしても，その位置関係は変わらない．医療サービスはもともとそのような性格を帯びているものであり，おそらく患者にとっても医師にとってもそれは前提であろう．医療サービスの最も大きな特徴は，サービスのすべてが患者の利益に向かっていると，医療者自身も含め，患者にかかわるすべての人がもつ前提意識にあるといえよう．

医療によってたまたま悪いことが起きてしまった．あってはいけないことが起きてしまった．ここだけみれば，正義であるはずの医療が悪に染まったと考えられても仕方がない．しかし，そこで自らの正当性を弁明することに終始したり，有害な事象を避けるために過剰に消極的になったりすることは，それこそ問題なのではないだろうか？

われわれは，起こしうる傷害について患者に何を伝えるべきか？

サッカーで，たまたまオウンゴール(*J1*)をしてしまった選手に対して，チームメイトが責めることはない．なぜなら，チームメイトはオウンゴールをした文脈を理解できるからである．心ない観客の一部だけが，選手を「裏切り者！」と罵倒するのだ．患者は観客か？ 患者は当事者である．医療者とはチームメイトのはずである．ただ，医療において起こってしまう不幸な転帰について，その細かい部分を，患者と医療者が互いに理解しあうことは非常に難しいであろう．

つなぎとめるものは何だろうか？ それは，医療行為のプロセスの背景にある，患者ケアを行ううえで理念を共有することであると信じたい．"私は，あなたの健康を高めるために，何かするという役割を担っている．私が行う行為によって，ひょっとしたらあなたを傷つけてしまうかもしれない．どうするべきかについては，あなたとともに考える必要がある．ただ，その行いは，

JIMノート

J1 オウンゴール

自分のチームのゴールに誤ってボールを入れてしまうこと．敵の攻撃を防いだ時に偶然起きてしまうことがある．オウンゴールでも，敵が入れたものと同じように1点となる．

(たとえば金銭的，学問的な私の利益ではなく)あなたの利益に基づいて行われるものである"という理念を共有することが，おそらく医療者から患者に伝えることのできる精一杯のところであり，そして最も大切なところであろう．

あらゆる情報は脅しや防御の手段ではなく，相談内容としておおらかに語られるべきである．そして，患者に不幸なことが起こってしまった場合，医療者は，どんな理由であれ，医療が与えた傷に対して「悪かった，すいません」と言うところから始められないだろうか？ 間接的であろうが直接的であろうが，自分がした行いのために切ないことになっている当事者に対して，「悪かった，すいません」と言えないのであれば，それは世の中のどこかが間違っているのだと思う．昨今の医療事故に関する警察の介入や，医療者の防御的な対応への流れは，医療を受ける側，提供する側，お互いの信頼をより遠いものにする．信頼のないなかで決まったオウンゴールには，罵声しか残らない．

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医療サービスの評価
その構成要素と評価の枠組みについて

尾藤 誠司

Question & Answer

Q：医療の質を構成する要素は？
A：構造(ストラクチャ)，プロセス，アウトカムがあり，これらそれぞれに評価する方法がある．
Keyword：医療評価，医療の質，プロセス，アウトカム

「医療サービス」という言葉に違和感を持っている医療者は少なくないと思う．「サービス」という言葉には，なんだか営利企業が顧客におもねっているようなイメージが付きまとうのだ．実は，私も少し違和感を持っていて，もう少しうまい訳があればよいかな，と時々思う．しかしながら，「サービス」の本質的な意味は，プロフェッショナルが，最大限の誠意とともにその技量を対象者に対して提供する，ということである．その意味においては，心停止患者にACLSを行うことも「医療サービス」の範疇の中にある．接遇的な部分は医療サービスのほんの一部分にすぎない．すなわち，よい医療サービスとは，いかにその受け手——すなわち患者や市民——にとって益の大きな医療提供がなされるか，ということを示すものであり，医療サービスの評価とは，たとえば保険のシステムのようなきわめてマクロなものから，ベッドサイドにおける医療スタッフの細やかな対応まで，提供されるすべての医療に対して，それがどれほど“よいもの”か，査定することを示す．

この数年，医療サービスに関連するような言葉が巷をにぎわしている．「アウトカム評価」「DPC」「インディケーター」「テクノロジー・アセスメント」など，それまでは聞かれなかったような言葉を一般紙でも目にするようになってきた．これは，わが国において，いままで専門家の聖域に安住していた医療が，いよいよ評価される時代になってきたことを明確に示すものであろう．一方では，医療サービスがいったいどのような基準で評価されるのか，ということについて，一定の見解がもたれているとは言いがたい．

本稿では，医療サービスを評価する際の基本的な概念を紹介し，とくに，医療の質の評価について，その構成要素と，評価の方法などに関する一般的なレビューを行う．

医療サービスはどのような概念で構成されているか？

提供された医療サービスは，最大限に効果的なものでなければならない．これは感覚的に誰もが納得するものである．しかしながら，いかに効果的なものであったとしても，そのサービスを一部の人にしか提供できなかったり，そのために多大な費用を費やしてしまっては，一概にそれをよいものであるということはできない．いくつかの視点において統合されたうえで，よい医療である必要がある．その視点は，「3つのE(effectiveness, efficiency, equity)」と呼ばれるものである．

Effectiveness(効果)とは，現実世界の中で医療サービスがどれほどその受給者に寄与しているかを表すものである．患者の余命を明らかに伸ばす

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治療法や，非常に精度の高い検査は“効果の高い”医療サービスであるといえる．Efficiency(効率)は，効果の絶対量ではなく，提供側の支出を勘案したうえでの効果の査定のことを示す．同じくらいの効果をもたらすプログラムであれば，支出は少ないほうがより“効率が高い”，すなわち，よいサービスであるといってよい．たとえば高血圧治療において，利尿薬とACE阻害薬に同じ効果があるのであれば，安価な利尿薬を第一選択とすることが，より効率的な医療の提供である[1]．最後のequity(公正性)とは，医療サービスを必要としている人たちに，必要に応じたサービスが差別なくなされているかどうかを表す．社会保険制度が不完全であり，医療保険の多くを民間保険によってまかなっている米国では，公正性の問題は医療サービス上の大きな問題点となっている(*J1*)．

よい医療サービスを規定する3つの要素

上記の概念を加味したうえで，医療サービスにおいて何が評価されるべきかを簡単にまとめたい．医療サービス評価の対象は，大きく分けて，①アクセス，②コスト，③クオリティ(質)，の3つである[2]．簡単にまとめれば，医療に対するアクセスの評価は，主に公正性の評価，コストの評価は効率の評価(実際には，コストを評価しただけでは効率の評価にはならない)，そして，質の評価は効果(効率も含む)の評価を主に行うことを目的としている．

上記の3つの要素の中で，わが国において改善が急務であるものは何であろうか？ アクセスに関していえば，国民皆保険制度の恩恵のために，無保険であることによって医療サービスの提供が受けられないという状況はほとんどない．さらに，すべての医療機関に対して国民が自由に診療を受けられる環境があり，先進国の中でもアクセスに関する問題は非常に小さいといえる．また，コストに関しても，将来的には医療費の増加が懸念される一方，少なくとも現時点においてはGDPの7%強と，英国を除けばほかの先進諸国に比較してかなり低い支出であり，急務の問題とは考えにくい．米国の現状は，この2点において惨憺たるものであり，解決すべき問題は山積みである(表1)．

表1　日本，英国，米国の医療サービスの比較

	日本	英国	米国
アクセス(公正)	○	△	△
コスト（効率）	○	○	×
質（効果）	△	△	○

（近藤克則：「医療費抑制の時代」を超えて．p30より引用）

しかしながら，そのような環境にあり，さらには“エクセレントな医療の提供”がなされているイメージの強い米国でも，現在，医療の質の改善が大きなプライオリティとなっている．とくに，専門医療より，よりプライマリ・ケア・レベルでの医療の質の評価と改善に焦点が当てられている．

わが国の提供する医療の質は，はたしてどうなのだろうか？ その答えはよくわからない．エビデンスがないからである．しかしながら，とくにプライマリ・ケアにおいて，その質に大きなばらつきがあることが推察される．わが国において，医療サービスの向上を考えるうえでまず取り組むべきは，質の部分であろう．それが正当に評価され，根拠として提示されたうえで，初めて改善への方策を立てることが可能になるのである．

JIMノート

***J1*　日米英の医療保険制度**

日本のように，国民のほぼすべてが社会保険に加入しており，なおかつどの医療施設にも直接かかることができるシステムは少ない．米国では，高齢者を対象とした社会保険であるMedicare，公共福祉プログラムであるMedicaidがあるが，保険の中心は民間保険であり，また，多くの人々は経済的な理由から民間保険にも入ることができていない．また，英国は，医療サービスへの支出は基本的に税金でまかなっている．

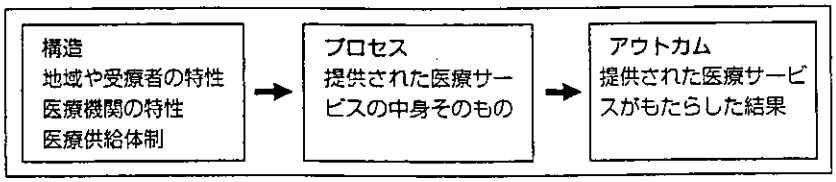

図1 医療の質の概念図

医療の質はどのような枠組みで評価されるのか？

それでは，医療の質というものが，どのように評価されるのかについて説明したい．医療の質は3つのレベル，すなわち，①構造，②プロセス，そして，③アウトカム，のレベルで評価が行われる(図1)[3]．

構造とは，医療サービスを提供するうえであらかじめ備わっている環境を指す．今までわが国において行われてきた病院管理的な視点による医療の質評価の多くは，この構造レベルでの評価である．たとえば，入院患者ケアを評価する際に，その施設に栄養サポートチームや感染対策委員会があるかどうか，日中，1人の入院患者に対して何人の看護師を配置することができるか，などがこれにあたる．構造レベルでの評価は，マクロな視点で把握がしやすいため，評価の中では最も簡便な方法である．一方，構造レベルの評価は，実際の医療サービスが提供される前段階のものであり，間接的な評価の意味合いしか持たないこと，さらに，非常に低いレベルの質の医療に関しては評価が可能であるが，一定レベル以上の質評価には向かないなどの欠点がある．

プロセス評価とは，提供される医療そのものの妥当性について評価することを指す．医療行為の具体的な内容に入っていくために，評価の方法はよりミクロな視点のものとなる．たとえば，心筋梗塞で入院した患者に対してアスピリンの処方がなされているか，というような個別の医療内容をチェックしていく方法である．次稿(東論，p200)でもあるように，一般的に臨床評価指標やインディケーターといわれるものは，主にこの医療プロセスを評価することを中心に構成されていることが多い．医療プロセスの評価は，医療行為そのものを評価する行為であるため，非常に直接的であり，また，改善点に具体性があるため，現在では医療の質を評価する方法としては中心的な役割を担っている．しかしながら，たとえば診療録を一つひとつチェックする煩雑さや，個人情報保護の問題など，方法の困難さに欠点があり，さらには，評価しているプロセスが本当に妥当なものであるかを評価する必要もあるなど，問題点も多い．

アウトカム評価は，提供された医療によって，その受給者，すなわち患者や市民がどのように恩恵や害を受けたか，という査定を行う方法である．特定の手術に対する施設間の死亡率のばらつきや，クリティカル・パス導入前後での平均在院日数の差などは，アウトカム評価の典型的な例である．この方法は，多くの臨床研究で行われている方法と類似しているため，医療者にとっては最もなじみやすい方法であろう．アウトカム評価は，プロセス評価に比較すればずいぶん煩雑さが少ないといえるが，アウトカムの差がはたして本当に医療の質の差であるかどうかについては一概に言えないことが多く，結果の妥当性を吟味する必要が常にある．最近では，死亡率や在院日数など従来から行われていたアウトカムの評価だけではなく，たとえばQOLや患者満足度など，より患者側に立脚した視点でのアウトカム評価も行われるようになってきた[4]．これらの“患者立脚型アウトカム”は，医療者のフィルターをかけることな

く評価することが可能なため，米国などでは，民間保険会社が自社の提供するプログラムの質を示す指標として取り入れている．

3つのレベルでの医療の質の評価には，それぞれ利点と欠点がある．実際には，構造，プロセス，アウトカムのうちどれか1つを評価するよりは，たとえばプロセス，アウトカムの両方について評価し，総合的に医療の質を査定するほうが望ましい．

質の評価の問題点とバリア

医療の質は，継続的に評価され，改善に向けた努力がなされるべきであることは，おそらく疑う余地がない．しかしながら，実際にそれを行うにはいくつかの問題点や，越えなければならない壁が存在する．

第一には，妥当な目的を持って妥当な評価基準が設定されているかの吟味が，質評価には必要である．たとえば，1つの施設における医療の質を評価する際にも，目的によって評価の方法は変わってくるであろう．その医療施設に対し，全国的にどのくらいのレベルにあるかを伝えるための評価，もしくは，優良施設かどうかを判別するための評価と，現在の診療レベルの問題点を指摘し，改善を促すための評価とでは，評価の基準や評価方法も異なっているべきである．どのような評価基準を設定するかについては，注意深い考察が必要であろう．第二には，設定された評価基準が，はたして評価尺度としての精度を保っているかどうかを検討する必要がある．ここ数年，わが国で開発されはじめている「エビデンスに基づいた診療ガイドライン」が，一部の専門家から反発を受けている現状もあるが，評価の基準はコンセンサスが得られるようなものである必要がある．さらには，医療者自身に，評価されることに対する警戒心が少なからずあるという点を考慮する必要がある．管理者や評価機関がトップダウンで行う医療の評価は，実行可能性が高い一方，評価される側にストレスを与える．また，評価そのものが目的化してしまい，実際のケアの向上よりも評価でよい点を取ることのみに医療提供者のインセンティブが働くという懸念もある．

おわりに

医療サービスを科学的な方法で評価する試みは，最近本格的に始まったばかりである．質を評価するにあたっては，自分たちの提供する医療の質には現時点で問題があるという認識が必要であり，それを受け入れることは少なからず痛みを伴うものであろう．市場原理を用いた差別化のための評価ではなく，国民の健康を司るプロフェッショナルとして，より自分たちのサービスを研鑽し続けるための自己評価，他者評価を続けていきたいものである．

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Physicians' Attitudes Toward Anticoagulant Therapy in Patients with Chronic Atrial Fibrillation

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Abstract

Introduction **Although many clinical trials have demonstrated that anticoagulant therapy substantially reduces the risk of ischemic stroke in patients with atrial fibrillation (AF), some physicians are reluctant to use anticoagulants. We investigated attitudes of physicians in Japan toward anticoagulant therapy in chronic AF patients.**

Methods **We conducted a survey at the annual meeting of the Japanese Society of General Medicine. We presented subject physicians with 8 vignettes of chronic AF patients and requested that they indicate their most favored choice of therapy from among 6 strategies including warfarin and aspirin.**

Results **We distributed 209 questionnaires and received 139 replies (67% response rate). For all 8 vignettes presented, only 26% of the respondents preferred to use anticoagulant therapy in AF patients. Longer clinical experiences and responsibility at a teaching hospital were associated with negative attitude toward anticoagulant therapy, while experience of preventive therapy in patients with thromboembolism due to AF and strong influence of clinical trials of anticoagulant prophylaxis on their practice were associated with positive attitude toward the therapy. Among patient characteristics in the vignettes, a risk of thromboembolism was positively associated with preference for anticoagulant therapy, but an advanced age and a risk of bleeding complications were negatively associated with the preference for the therapy.**

Conclusions **The physicians in Japan in this survey, especially those with longer clinical experiences or responsibility at a teaching hospital, have a negative attitude toward anticoagulant therapy in chronic AF patients. An advanced age and a risk of bleeding complications of patients are deterrent factors to the use of anticoagulant therapy.**

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Key words: atrial fibrillation, warfarin, physician practice patterns, questionnaires, Japan

Introduction

Chronic atrial fibrillation (AF) is a common arrhythmia and increases in prevalence from approximately 2% in the population aged 60 to 69 years to 7% in 70 to 79 years (1). AF is an important risk factor for ischemic stroke and has been reported to increase its risk about 5-fold (1, 2). Several randomized clinical trials (RCTs) have shown that anticoagulant therapy decreases the incidence of thromboembolism by about 70% in patients with chronic AF (3–8). Consequently, most evidence-based guidelines recommend anticoagulant therapy for chronic AF patients requesting at the same time to be individualized according to each patient's risk for thromboembolism (9–11).

However, anticoagulant therapy trends to be underutilized in chronic AF patients. In fact, only 21 to 60% of chronic AF patients were reportedly given anticoagulants in Western countries (12). Physicians' perceived risk of anticoagulant therapy, i.e., increased frequency of haemorrhagic complications and cumbersome monitoring of prothrombin time among others, seems to be responsible for the reluctance of physicians to undergo the therapy. Several cross-sectional

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surveys on the management of chronic AF patients showed that physicians' perception of risk-benefit balance of anticoagulation affected their decision to anticoagulate chronic AF patients (12). Patients'characteristics, such as age or comorbidity, and physicians' specialty also affected the decision making process.

In Japan, compared to western countries, anticoagulant therapy is far less likely to be given to chronic AF patients. The proportion of patients on anticoagulants has been reported only from 14 to 17% (13, 14). The high incidence of hemorrhagic stroke (15–17) and low incidence of thromboembolic diseases (18) in the Japanese population might explain some of the low proportions of chronic AF patients on anticoagulants. Furthermore, a knowledge gap among primary care physicians regarding results of recent clinical trials, a lack of time to manage in an ideal way every patient at overcrowded outpatient clinics might be the reasons for such low anticoagulation rates in Japan.

The purpose of this study was to examine Japanese physicians' attitude toward anticoagulant therapy in chronic AF patients and to explore the reasons behind a low anticoagulation rate, if revealed, in Japan. We specifically examined what factors of physicians and patients would influence physicians' decision making in this regard.

For editorial comment, see p 529.

Methods

Subjects and Methods

Self-administrated questionnaire was developed and distributed to participants of the 9th annual meeting of the Japanese Society of General Medicine in Tokyo in February 2001. Members of the Society were mostly primary care physicians, internists with subspecialties, and general internists who work at academic settings or teaching hospitals.

Measurements

In the questionnaire, we first asked about respondent's background characteristics: age, gender, number of years since graduation from medical school, specialization, and setting of their primary responsibility. Secondly, we asked questions on the following: their experiences of managing an acute thromboembolism in AF patients or bleeding complications due to anticoagulant therapy, and providing preventive therapy for thromboembolism due to AF; their accessibility to a cardiologist and/or a neurologist for consultation. Thirdly, we asked about their belief regarding degree of impact of clinical trial results on their own daily practice and their knowledge of and experience in evidence-based medicine (EBM).

Finally, we presented 8 vignettes of hypothetical patients with chronic nonvalvular AF (NVAF) (see Appendix). Each vignette included different sets of clinical characteristics of a hypothetical patient regarding age, presence or absence of risks for thromboembolism (a history of a transient ischemic attack 6 months ago) and bleeding complications (a history of a bleeding gastric ulcer 3 years ago). We asked the respondents to indicate which management they would choose for these hypothetical patients from among 6 options: "warfarin and aspirin", "warfarin", "aspirin", "warfarin or aspirin", "others" or "none of the above".

Statistical analysis

Based on the answers, we classified respondents into two groups: the one group who had a positive attitude and the other, a negative attitude toward anticoagulant therapy. The former group consisted of the respondents who chose "warfarin" or "warfarin and aspirin" for at least one of the 4 vignettes of hypothetical patients with no particular risk for bleeding complications. The rest of the respondents were considered as having a "negative attitude." Patients with no known risks for bleeding complications, as strongly recommended by authoritative practice guidelines (9–11), should be on anticoagulant therapy regardless of other characteristics of patients.

We examined any association between respondents' attitudes toward or against anticoagulant therapy and responde nts' background characteristics by calculating ratios of proportion of respondents with a positive attitude toward anticoagulant therapy for each category of the characteristics.

We then examined an association between respondents' attitudes toward or against anticoagulant therapy and patient characteristics in the vignettes by building a logistic regression model adjusting all the characteristics of respondents. No variable in the model was eliminated from the analysis. We used the generalized estimation equations approach (19, 20) to adjust for the influence of lack of independency of individual answers; as each respondent might answer the questions in the 8 vignettes consistently toward a specific choice, independence of individual answers was not guaranteed. Microsoft EXCEL2000 (Microsoft Corp.), and SAS System for Windows version 6.12 (SAS Institute Inc., Cary) were used in the analyses.

Results

We distributed the questionnaire to 209 physicians among 253 participants at the meeting, and obtained 139 responses (response rate of 67%). Thirteen responses were excluded because of incomplete answers and the remaining 126 responses were analyzed.

Most of the respondents were middle-aged male physicians (median age: 38 years old, the mean years since graduation from medical school: 14 years) (Table 1). Twelve percent of them were cardiologists. The majority (72%) had their primary responsibility at teaching hospitals and about half (47%) at an academic setting.

For all the 8 vignettes presented, 26% of the respondents chose "warfarin" or "warfarin and aspirin" and 33% "aspirin" (Table 2). Only 34% chose "warfarin" or "warfarin

Table 1. Physicians Characteristics Included in the Survey

Characteristic	No. of Physicians (%)
Gender	
Female	13 (10)
Male	113 (90)
Years since graduation from medical school	
11–	76 (60)
1–10	50 (40)
Specialization (multiple answers)	
Cardiology	15 (12)
General internal medicine/general medicine	73 (58)
Other speciality	38 (30)
Major place of work	
University hospital	59 (47)
Accredited teaching hospital	32 (25)
Non-teaching hospital	24 (19)
Clinic	9 (7)
Research institute	2 (2)
Experience of managing acute thromboembolism in patients with AF	
Yes	120 (96)
No	5 (4)
Experience managing hospitalized patients with bleeding complications due to anticoagulant therapy or antiplatelet therapy	
Yes	83 (67)
No	41 (33)
Experience with preventive therapy for thromboembolism due to AF	
Enough experience	20 (16)
Moderate experience	59 (47)
Poor experience	42 (34)
No experience	4 (3)
Accessibility to a cardiologist and/or a neurologist	
Possible	91 (73)
Impossible	24 (19)
A specialist myself	10 (8)
Impact of clinical trials on your practice of anticoagulant prophylaxis	
Very strong	32 (26)
Strong	73 (58)
Weak	9 (7)
Very weak	5 (4)
Don't know these trials	6 (5)
Knowledge and experience of evidence-based medicine	
Very good	16 (13)
Good	86 (69)
Poor	18 (14)
Very poor	5 (4)

and aspirin" in one of the 4 vignettes of hypothetical patients without a risk for bleeding complication, showing positive attitude toward anticoagulant therapy in our current definition. For the vignettes of hypothetical patients with a risk for bleeding complication, more than 80% of respondents showed a negative attitude. Longer clinical experience and responsibility at a teaching hospital were negatively associated with the physicians' attitudes toward anticoagulant therapy, while experiences of preventive therapy for thromboembolism and a strong influence of clinical trials were positively associated with the therapy (Table 3).

After adjusting all the physicians' background characteristics, respondents were shown to be about 70% less likely to prefer anticoagulant therapy when the patient was an octogenarian or when the patient had a risk for bleeding complication, although twice more likely to prefer the therapy when the patient had a risk for thromboembolism (Table 4).

Discussion

The respondents in this survey showed a very conservative attitude toward anticoagulant therapy in chronic AF pa-

Table 2. Physicians' Treatment Preference in 8 Vignette of Patients with Nonvalvular Atrial Fibrillation

Age	Factors in vignette		Treatment preference by physicians, no. (%)							Attitude to AC, no. (%)		Total
	Risk factor		Positive attitude to AC		Negative attitude to AC							
	Thromboembolism	Bleeding	WA and ASA	WA	WA or ASA	ASA	Others	None	Not sure	Positive	Negative	
68	−	−	1 (1)	39 (31)	8 (6)	63 (50)	0 (0)	13 (10)	2 (2)	40 (32)	86 (68)	126
68	+	−	12 (10)	59 (47)	8 (6)	43 (34)	3 (2)	0 (0)	0 (0)	71 (57)	54 (43)	125
68	−	+	1 (1)	22 (18)	4 (3)	26 (21)	17 (14)	43 (34)	12 (10)	23 (18)	102 (82)	125
68	+	+	4 (3)	36 (29)	6 (5)	35 (28)	19 (15)	11 (9)	12 (10)	40 (33)	83 (67)	123
82	−	−	1 (1)	23 (18)	8 (6)	47 (37)	1 (1)	42 (33)	4 (3)	24 (19)	102 (81)	126
82	+	−	4 (3)	31 (25)	7 (6)	65 (52)	5 (4)	11 (9)	3 (2)	35 (28)	91 (72)	126
82	−	+	0 (0)	8 (6)	3 (2)	20 (16)	13 (10)	72 (57)	10 (8)	8 (6)	118 (94)	126
82	+	+	0 (0)	17 (14)	6 (5)	33 (26)	23 (18)	31 (25)	15 (12)	17 (14)	108 (86)	125
Total			23 (2)	235 (23)	50 (5)	332 (33)	81 (8)	223 (22)	58 (6)	258 (26)	744 (74)	1002

WA: warfarin, ASA: aspirin, AC: anticoagulant therapy.

Table 3. Univariate Analysis of the Influence of Physician Characteristics on Physician's Preference for Anticoagulant Therapy

Physician characteristic	Proportion of physicians who prefer anticoagulant therapy (%)	Ratio of proportion (95% Confidence interval)
Gender		
Female	85	1.4 (1.1–1.9)
Male	60	Reference
Years since graduation from medical school		
11–	54	0.71 (0.55–0.92)
1–10	76	Reference
Specialization		
Cardiology	67	1.0 (0.66–1.6)
General internal medicine/general medicine	60	0.92 (0.68–1.2)
Other speciality	66	Reference
Major place of work		
University hospital/research institute	53	0.73 (0.55–0.98)
Other than the above*	72	Reference
Experience with managing acute thromboembolism in patients with AF		
Yes	63	0.78 (0.49–1.2)
No	80	Reference
Experience managing hospitalized patients with bleeding complications due to anticoagulant therapy or antiplatelet therapy		
Yes	65	1.1 (0.82–1.5)
No	60	Reference
Experience with preventive therapy for thromboembolism due to AF		
Enough/moderate experience	72	1.5 (1.1–2.1)
Poor/no experience	49	Reference
Accessibility to a cardiologist and/or a neurologist		
Possible/a specialist myself	60	0.81 (0.61–1.1)
Impossible	78	Reference
Impact of clinical trials on your practice of anticoagulant prophylaxis		
Very strong	84	1.5 (1.2–1.9)
Other than the above†	57	Reference
Knowledge and experience of evidence-based medicine		
Very good	50	0.77 (0.46–1.3)
Other than the above‡	65	Reference

*Clinical training appointed hospital, non-training hospital, clinic. †Strong, weak, very weak, don't know these trials. ‡Good, poor, very poor.

Table 4. Multivariate Analysis of the Influence of Characteristics of Cases in the 8 Scenarios and Physician Characteristics on Choice of Anticoagulant Therapy

Characteristic	Odds ratio (95% Confidence interval)
Vignette characteristic	
Risk factor for bleeding complication	
Positive	0.35 (0.23–0.52)
Negative	Reference
Age	
82 years old	0.31 (0.22–0.44)
68 years old	Reference
Risk factor for thromboembolism	
Positive	2.4 (1.8–3.2)
Negative	Reference
Physician characteristic	
Gender	
Female	1.0 (0.35–3.0)
Male	Reference
Years since graduation from medical school	
11–	0.43 (0.23–0.81)
1–10	Reference
Specialization	
Cardiology	1.8 (0.72–4.4)
General internal medicine/general medicine	0.73 (0.40–1.3)
Other speciality	Reference
Major place of work	
University hospital/research institute	0.53 (0.30–0.92)
Other than the above*	Reference
Experience managing acute thromboembolism in patients with AF	
Yes	0.20 (0.064–0.60)
No	Reference
Experience managing hospitalized patients with bleeding complications due to anti-coagulant therapy or antiplatelet therapy	
Yes	1.1 (0.60–2.2)
No	Reference
Experience with preventive therapy for thromboembolism due to AF	
Enough/moderate experience	1.4 (0.70–2.8)
Poor/no experience	Reference
Accessibility to a cardiologist and/or a neurologist	
Possible/a specialist myself	0.82 (0.41–1.6)
Impossible	Reference
Impact of clinical trials on your practice of anticoagulant prophylaxis	
Very strong	2.7 (1.4–5.4)
Other than the above†	Reference
Knowledge and experience of evidence-based medicine	
Very good	0.63 (0.26–1.5)
Other than the above‡	Reference

*Clinical training appointed hospital, non-training hospital, clinic. †Strong, weak, very weak, don't know these trials. ‡Good, poor, very poor.

tients even when they had high-risk profiles for thromboembolism. Specifically, for hypothetical patients without bleeding risks who should be on an anticoagulant according to evidence-based recommendations (9–11, 21), only one-third (34%) of the respondents preferred anticoagulant therapy. This figure was much lower than that (61%) reported by Beyth et al who conducted a similar questionnaire survey using vignettes of hypothetical AF patients (22). We would think that this negative attitude toward anticoagulant therapy can have detrimental effects in some AF patients in clinical

practice.

This negative attitude toward anticoagulant therapy may be just a reflection of the preference for antiplatelet therapy. For 8 hypothetical patients, more respondents preferred antiplatelet therapy (i.e., "aspirin": 33%) than anticoagulant therapy (i.e., "warfarin and aspirin" or "warfarin": 25%). Previous surveys conducted in Japan already showed physicians' preference for antiplatelet therapy over anticoagulant therapy [the prescription rates in AF patients; warfarin: 14–17%, aspirin: 18–26%, ticlopidine: 8–26% (13, 14)]. This could be due to the following reasons. First, antiplatelet therapy was also proved to decrease the incidence of thromboembolism (23). Secondly, respondent physicians might have thought that antiplatelet therapy has a favorable risk-benefit ratio because of its low risk of major bleeding complications (24).

Bungard et al proposed three factors to influence physicians in making a decision to prescribe anticoagulant therapy: physician-related factors, patient-related factors, and health care system-related factors (12). Our survey revealed that several physician-related factors (years since graduation from medical school, major place of work, experiences of preventive therapy for thromboembolism due to AF, impact of clinical trials on own practice of anticoagulant prophylaxis) and patient-related factors (age, risks for thromboembolism and bleeding complication) were associated with respondent's preference of anticoagulant therapy. Of particular note is the finding that physicians with longer clinical experience or responsibility at teaching or academic settings were less likely to choose anticoagulant therapy. Since most of them were either generalists or subspecialists in the fields other than cardiology, they may not have the confidence to have updated knowledge about standard management of chronic AF. The number of such patients they see in their clinical fields may be too small to make them feel confident in the management of chronic AF.

The responders' negative attitude toward anticoagulant therapy in an octogenarian patient was very similar to the results reported by Beyth et al (22). Surveys conducted in Western countries (25–32) reported that elderly patients were less likely than middle-aged patients to be anticoagulated, in spite of the fact that aging is one of the most important risk factors for thromboembolisms in chronic AF patients (9–11). Several explanations are possible for such hesitancy. First, respondent physicians might have a belief that elderly patients would have no significant gain of life in any case (33). Second, they might have been afraid of a high bleeding complication rate in elderly patients as previously reported (34, 35).

There are several limitations to this study. First, answers to the questions may not reflect actual practice. Since the questionnaire was self-administered, respondents might have given more idealistic answers than the reality. The questionnaire used in this survey might not have provided respondents with enough information to make the best decision, thus requiring some abstract judgements. Second, there might have been a sampling bias. The respondents in this survey were participants in the annual meeting of the Japanese Society of General Medicine, which consists of physicians who are knowledgeable about the standard practice in Western countries. The current results are thus likely to reflect a more positive attitude of physicians in Western countries. Therefore, the negative attitude shown here of Japanese physicians in this survey toward anticoagulant therapy is rather underestimated and should be a robust finding.

Conclusion

The Japanese physicians in this survey, especially those with longer clinical experiences or responsibility at a teaching hospital, have a negative attitude toward anticoagulant therapy in chronic AF patients. An advanced age and a risk of bleeding complications of patients are deterrent factors to the use of anticoagulant therapy.

Acknowledgement: We conducted this questionnaire survey through the Japanese General Medicine Research Network which is available to members of the Japanese Society of General Medicine.

Appendix (Questionnaire)

Q1 Do you have experience in managing acute thromboembolism in patients with atrial fibrillation (AF)?
1. Yes, 2. No

Q2 Do you have experience in managing hospitalized patients with bleeding complications due to anticoagulant therapy or antiplatelet therapy?
1. Yes, 2. No

Q3 How do you feel about your experience with preventive therapy for thromboembolism due to nonvalvular AF?
1. Enough experience, 2. Moderate experience,
3. Poor experience, 4. No experience

Q4 Do you have access to a specialist consultant regarding preventive therapy for thromboembolism due to AF?
1. Yes, 2. No, 3. I'm a specialist

Q5 How has your practice been influenced by the results of clinical trials on anticoagulant prophylaxis?
1. Very strong, 2. Strong, 3. Weak, 4. Very weak,
5. Unknown / I do not know those trials

Q6 How do you feel about your knowledge and experience of Evidence-Based Medicine?
1. Very good, 2. Good, 3. Poor, 4. Very poor

Q7 If you do not need to consider any limitations related to practice setting, which strategy would you recommend to your patients with chronic nonvalvular atrial fibrillation (NVAF) to prevent thromboembolism in the following scenarios? Please choose one strategy for each scenario.

Strategy List
1. Aspirin, 2. Warfarin, 3. Warfarin and aspirin, 4.Warfarin or aspirin, 5. Other medication(s), 6. No anticoagulation therapy and no antiplatelet therapy, 7. Unanswerable or I have no idea

Scenarios

Scenario 1. 68 y.o. female with NVAF
Scenario 2. 68 y.o. female with NVAF, with a history of a transient ischemic attack 6 months previously
Scenario 3. 68 y.o. female with NVAF, with a history of a bleeding gastric ulcer 3 years previously
Scenario 4. 68 y.o. female with NVAF, with histories of a bleeding gastric ulcer 3 years ago and a transient ischemic attack 6 months previously
Scenario 5. 82 y.o. female with NVAF
Scenario 6. 82 y.o. female with NVAF, with a history of a transient ischemic attack 6 months previously
Scenario 7. 82 y.o. female with NVAF, with a history of a bleeding gastric ulcer 3 years previously
Scenario 8. 82 y.o. female with NVAF, with histories of a bleeding gastric ulcer 3 years ago and a transient ischemic attack 6 months previously

Note

Except for the described factors in each scenario, there are no other relevant factors which could affect your recommendation. For example, you can assume that blood pressure is normal and the patients are on no medication.

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FOCUS GROUP INTERVIEWS EXAMINING ATTITUDES TOWARDS MEDICAL RESEARCH AMONG THE JAPANESE: A QUALITATIVE STUDY

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ABSTRACT

Objectives: the purpose of this study is to explore laypersons' attitudes towards and experiences of medical research, and to compare them with those of physicians in Japan.

Designs and Participants: fourteen Japanese adults from the general public and seven physicians participated in one of three focus interviews.

Setting: Osaka, Japan.

Results: trust and distrust in the physician by whom the participants were invited to participate in research played a considerable role in their decisions about participation. That the participants felt an obligation to participate was also expressed. The lay participants perceived medical research as something entirely outside of their world. A greater willingness to volunteer for research was expressed if there were direct benefits to themselves or their families. Research methods such as use of placebos, double blinds, and randomisations seemed to cause negative attitudes to medical research. All physicians were convinced of the need for medical research, including double-blinded randomised control trials, and its significant role in medical progress. Most physicians thought that the greater awareness of the need for medical research in the community and a better understanding of the psychology of potential research participants were necessary and urgent.

Conclusions: there is a good possibility that the lay public and medical professionals have sharply different beliefs about and attitudes towards every aspect of medical research. Building up a better and equal patient-

doctor relationship based on trust is a key issue in medical research, and it is mandatory to fill the gap in perception regarding medical research between them through fully informed debates.

INTRODUCTION

Research is a systematic attempt to acquire generalisable information about a particular subject area, and the basic goal of medical research is to benefit future patients.[1] It is claimed, from the medical point of view, that medical research on human subjects is a prerequisite to biomedical advances, and the Declaration of Helsinki in 2000 clearly states that medical progress is based on research that ultimately must rest, in part, on experimentation involving human subjects.[2] It might not be untrue to say that no development or improvement in medical care would be achieved without well-intended and well-designed research activities involving human beings. As long as it is conducted ethically and safely, medical research can benefit both suffering patients and society at large.

On the other hand, the history of medical research is, in a way, the history of the unethical conduct of medical researchers.[3] Even in the 1990s history continued to repeat itself.[4] No matter how well-intended researchers might initially be, some consequences of medical research were clearly disastrous due to inadvertence, lack of consideration, failure to conduct a systematic review regarding harms involved, or the researchers' biased risk-benefit

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calculation.[5] Unfortunately, some researchers do not necessarily seem to be motivated to carry out their research on behalf of suffering people or society as a whole. In Japan, for example, a physician who had been engaged in medical research at a university hospital wrote that some researchers have been conducting their scientific investigations purely out of self-interest (e.g. to make their curriculum vitae look better in order to survive in their academic career) and that others are doing medical research merely for the sake of publishing as many research papers as possible in academic journals.[6]

In addition, a shocking case came to light in the year 2000 in Japan. It was reported that one research group conducted an analysis of several genes taken from biological samples that had been previously obtained during the course of other kinds of medical treatment; the genetic analysis of some samples was done without informed consent, and the principal investigator of the team allegedly deceived a local research ethics committee by presenting a false report documenting that all samples were used after written informed consent was obtained. Allegedly, the researchers tried to deceive the research committee in order to avoid a delay in the research project.[7] Such unacceptable behaviour coupled with the aftermath of historically brutal, human experimentation has caused the public to have a negative attitude toward medical research.[8] Although no study has ever been done to demonstrate what ethically problematic research was conducted after the Second World War, and no data has collected the frequency of unethical research in Japan, it is possible that people have suffered from the insensitive and inconsiderate behaviour of medical researchers in their experiences. Recent national public opinion polls showed that only 20% of respondents answered that they trust their physicians a great deal; the main reason of not doing so was a lack of sufficient disclosure about medical information.[9]

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Under these circumstances it has been alleged that, because of the limited willingness of potential research subjects to participate, many large-scale clinical trials have failed to achieve the target number of cases in Japan.[10] For instance, an investigation conducted in 1994 in Japan revealed that 65% of trial-eligible patients (2903 patients) chose to participate in an offered trial regarding treatments for hyperlipidemia, which compared an arm including an experimental drug as well as diet therapy and that using diet therapy alone. The reasons expressed for refusal to participate in the study included: 'I do not want to be a guinea-pig', 'The term for the research is too long', 'My family objected', 'The possible side effects of the new drugs.'[11] Another study which investigated patients' response to an invitation to participate in an equivalent study in Japan revealed that major motivations to take part in the trial were to contribute to the good of society, to co-operate with one's physician in charge, and to trust the physician with everything concerned with medical care.[12]

Similar situations also seem to be the case in other countries. Surveys conducted by Martin et al. and Hunter et al. in the mid-1980s among the general community, oncology and cardiology patients, found that 70–80% of respondents believed that patients should be asked to participate in medical research, while the proportion of eligible patients accepting an invitation to participate in a clinical trial may be as low as 30%.[13] Siminoff et al. reported that only 45% of trial-eligible patients with breast cancer chose to participate in offered trials for adjuvant therapy.[14] Several studies suggest that patients agree to participate in clinical

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trials in the hope of receiving personal benefits, such as a better treatment, because their doctor has asked them, or for altruistic reasons such as contributing to medical science for the good of society. On the other hand, patients who would not join medical research commonly expressed concern about the possibility of additional/unknown side effects or the uncertainty of treatment allocation on a trial.[15]

Awareness of the importance of evidence-based medicine has recently been raised in Japan. In 1998, the Japanese Ministry of Health and Welfare set a new guideline for GCP (Good Clinical Practice) based on ICH 'International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use' in 1996. Under the new law, the participants in pharmaceutical experiments must be fully informed, including side effects and risks, and all experiments have to be examined and approved by an institutional review board (IRB). It seems that some medical researchers have come to understand the importance of informed consent and trust with patients in conducting medical research in Japan.

In our opinion, in order to provide quality healthcare and help suffering people who rely on reliable scientific findings, medical research involving human participants is necessary. At the same time, however, medical research cannot be conducted successfully without people's support and their strong trust in the medical profession, medical science, and the healthcare system in general. This is because medical research relies mainly on the willingness of volunteers or patients to participate.[16] Naturally, no one would participate in research activities unless they feel safe and are treated with dignity. If a significant perceptional gap existed between laymen and professionals regarding the meaning, benefits and risks of medical research, many medical investigations, especially clinical research involving existing patients, would end in failure. Without the patient's assistance and understanding, medical investigators cannot conduct any research. In this sense, mutual understanding and trust between the general public and medical researchers are essential.

There has been little research, however, to reveal similarities and differences between the lay public and the medical profes-

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