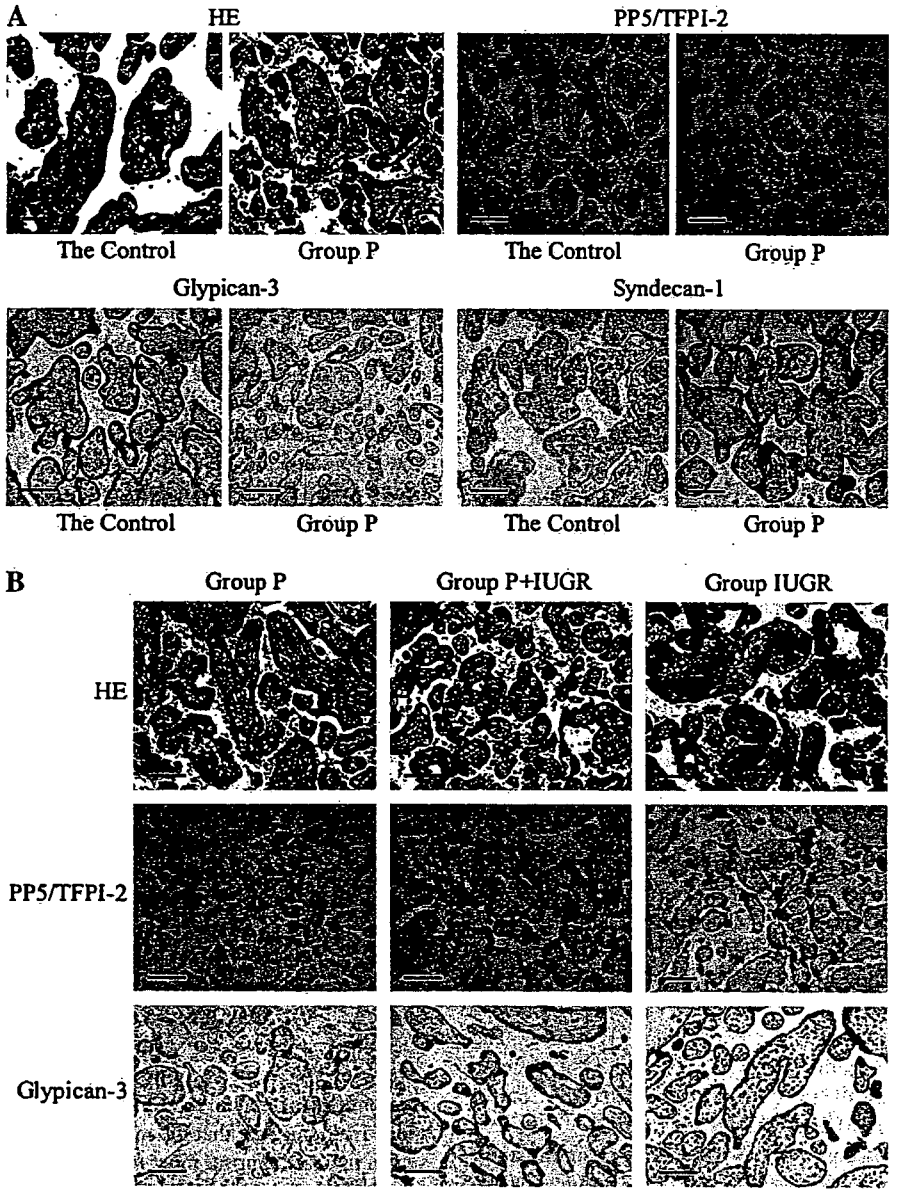
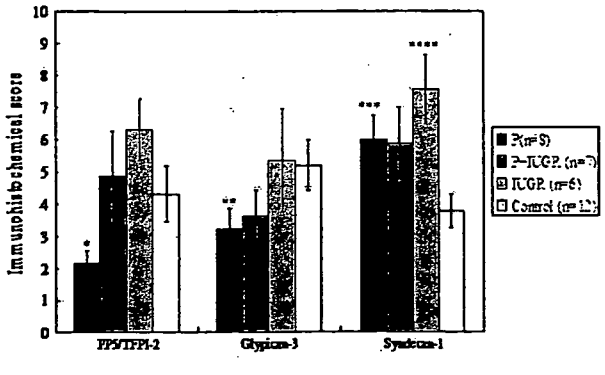


Fig. 2. Examples from the results of immunohistochemical studies. All images original magnification, ×100; scale bar, 100 μm. (A) HE staining, and immunohistochemical staining for PP5/TFPI-2, glypican-3, and syndecan-1 in the placental samples of the Control and Group P. (B) HE staining (the upper lane), and immunohistochemical staining for PP5/TFPI-2 (the middle lane) and glypican-3 (the lower lane) in the placental samples of Group P (the light column), Group P + IUGR (the middle column), and Group IUGR (the right column).

maternal serum, such as the metabolic pathway of the protein. Influences of impaired renal clearance of the glycoproteins, and of antihypertensive drugs in the patients with preeclampsia might not be ignored. As for the influence of renal function, even the clearance of human chorionic gonadotropin, a glycoprotein mainly excreted in urine, is shown to be not different between the patients with preeclampsia and normal Controls [45], which implies minimal influence of renal function. Further studies on the metabolic pathway of PP5/TFPI-2, as well as precise evaluation of the kinetics of PP5/TFPI-2 in preeclampsia, are required.

Third, syndecan-1 was immunohistochemically detected at significantly higher intensities in the placenta in Group P and Group IUGR than in the Control, contrary to another report [46]. This contradiction might be caused mainly by the different methods used for evaluation; for example, we used a semiquantitative scoring system that focused on both the intensity and the quantity of the stained areas, whereas others had scored only for the intensity.

Fourth, we found that preeclampsia and IUGR, often considered to share the same pathological basis in common, presented distinct distributions of PP5/TFPI-2. In Group IUGR



	P(n=8)	P+IUGR (n=7)	IUGR (n=6)	Control (n=12)
PP5/TFPI-2	2.16±0.39*	4.86±1.43	6.31±0.95	4.33±0.85
Glypican-3	3.25±0.62**	3.64±0.79	5.36±1.62	5.22±0.77
Syndecan-1	6±0.74****	5.89±1.12	7.57±1.07*****	3.8±0.53

Fig. 3. Comparison of the immunohistochemical scores for PP5/TFPI-2, glypican-3, and syndecan-1 in the placental samples. Data are expressed as the mean ± SE. Student's t test was used for all comparisons. *$p = 0.035$, compared to the Control, and $p = 0.001$, compared to Group IUGR, **$p = 0.045$, compared to the Control, ***$p = 0.023$, compared to the Control, and ****$p = 0.003$, compared to the Control.

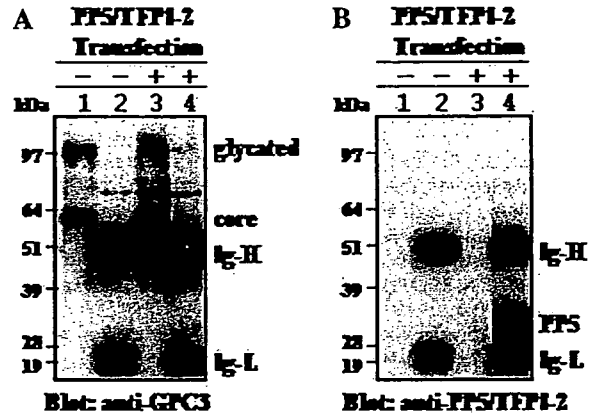


Fig. 5. Interaction of PP5/TFPI-2 and glypican-3 by immunoprecipitation experiments. HepG2 cell lysates from the PP5/TFPI-2 expression vector transfectant or the empty vector one were prepared as described in the text. Ten microliters of each sample before immunoprecipitation was loaded as input. Ten microliters from each 50 μl immunoprecipitant was also loaded. (A) Immunoblotted with anti-glypican-3 antibody and (B) with anti-PP5/TFPI-2. Molecular size from the marker bands was presented on the left side of each panel. Lanes 1 and 3, inputs; Lanes 2 and 4, immunoprecipitants. Ig-H, immunoglobulin heavy chain; Ig-L, immunoglobulin light chain; glycated, the glycated form of glypican-3; and core, the core protein of glypican-3.

and Group P + IUGR, the maternal serum PP5/TFPI-2 levels and placental immunohistochemical intensities of PP5/TFPI-2 were comparable to the Control. Although the patients in Group P and Group P + IUGR had preeclampsia to the same severity, they were not the same in the status of PP5/TFPI-2. The reason of the different status of PP5/TFPI-2 between preeclampsia and IUGR, as well as its relation to the clinical symptoms, is not known. Further studies would provide some available information on the pathogenesis of preeclampsia and IUGR.

Finally, we found that the umbilical serum levels of PP5/TFPI-2 were too low to be measured. The PP5/TFPI-2 levels were decreased in the maternal serum samples obtained 4 days after delivery, in agreement with another report [30].

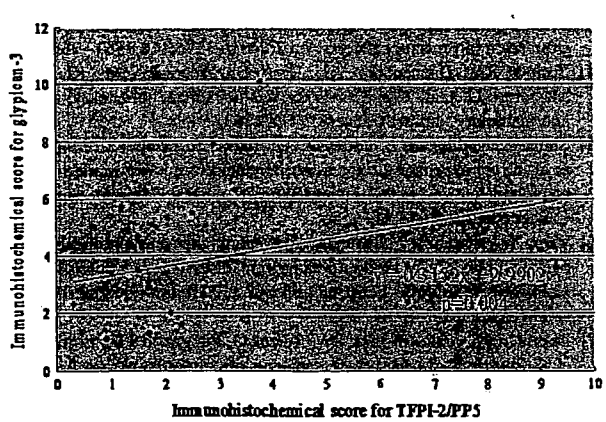


Fig. 4. Correlation between the immunohistochemical scores for PP5/TFPI-2 and those for glypican-3. C.I. = 0.506, $p = 0.004$ (Spearman's correlation test).

The role of PP5/TFPI-2 in pregnancy is not yet fully understood, but it is certain that PP5/TFPI-2 functions within the maternal serum and/or in the placenta, rather than in the fetal side. Our hypothesis has been that PP5/TFPI-2 works as an anticoagulant on the villous surface, which is not verified yet. Another group [47] has shown that the cognate tissue factor initiated coagulation inhibitor TFPI (or TFPI-1) is responsible for inhibiting coagulation in the placenta. Our finding in the present study, demonstrating the loss of PP5/TFPI-2 in the syncytium of the patients with preeclampsia, might imply its anticoagulant feature, because preeclampsia often encounters with elevated coagulation activity. Measuring the parameters of maternal coagulation activation in parallel with the examinations of placental events in situ should be considered as a further step to answer these questions.

In summary, the interaction of PP5/TFPI-2 with glypican-3 has been demonstrated from our studies. In patients with preeclampsia, there was a discrepancy in the PP5/TFPI-2 level in maternal serum, and the immunohistochemical intensity of the protein in the placenta. A decrease in the amount of glypican-3 in the placenta seems to hold the key for the discrepancy, but further studies are necessary to clarify the facts. Preeclampsia and IUGR, often regarded to share the same pathological basis, appeared to be totally distinct in terms of PP5/TFPI-2 distribution.

Acknowledgments

We would like to thank Mr. Yoshiyasu Nakamura (for his assistance in staining procedures) and Mrs. Hiroko Matsubara (for her assistance in Western blotting) at Kanagawa Cancer

Center Research Institute, and all the staffs in Maternity and Neonate Center for their help in collecting samples.

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特集

がん対策・2

がん対策と経済学①
米国における保険者のがん検診サービスの枠組みに関する調査

経営的視点に焦点を当てて

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公　衆　衛　生
第71巻　第2号 別刷
2007年2月15日　発行

医学書院

がん対策と経済学 ①

米国における保険者のがん検診サービスの枠組みに関する調査
経営的視点に焦点を当てて

大重 賢治[1)] 岡本 直幸[2)] 水嶋 春朔[3)]

わが国においては，早期発見・早期治療を行う目的で，公的な保健事業として各種のがん検診が実施されてきた．公的な事業として行われる以上，その支出に見合うだけの効果が得られているかを評価することは重要なことである．

保健事業の経済的評価の手法としては，費用効果分析，費用便益分析などがあり[1~4]，多くの研究にて活用されている．がん検診の場合，「効果」の指標は，がん検診を行うことによって獲得された余命年数(life-year saved)や質調整生存年数(quality-adjusted life years)であり[5~7]，「便益」の指標は，がん検診に対して住民が支払っても良いと考える(willingness-to-pay)金額の総和となる[8~10]．すなわち，がん検診を経済学的に評価するためには，がん検診の「効果」や「便益」を数値で表すことが基本条件となる．しかしながら，これらを定量的に示すことが難しいこともあって，わが国においては，がん検診の経済的評価はまだ十分になされていないのが現状である．

「効果」や「便益」が，がん検診に投じた費用に見合っているかは，経済的に非常に重要な視点であるが，その他，もう1つ重要な視点(もしかしたら，政府や保険者にとっては最も重要な視点？)として，がん検診事業を行うことによって，将来の医療費が抑制されるか否か，がある．

経済的評価の手法としては費用分析の範疇に入り[2)]，検診事業を行う場合の費用と行わない場合の費用をいわば金銭的損得の観点から検討するものである．保険者が営利企業の場合，検診事業を行わない場合の費用が行う場合の費用を上回ると考えられる場合，保険者に検診事業を行う経済的インセンティブが発生する．逆に言うと，補助金などの制度がない限り，赤字になるような事業には取り組みにくいというのが現実であろう．たとえ保険者が，非営利団体であったとしても，恒常的に赤字を生み出すような事業には積極的にはなれないと考えられる．

われわれは，平成17年度厚生労働科学研究費補助金特別研究「がん検診の経済的効果及び制度の在り方に関する研究(主任研究者：水嶋春朔)」の一環として，医療が市場経済の仕組みの中で動いている米国において，がん検診がどのように提供されているかを調査した．米国の医療制度では，主体が，保険者およびサービス供給者ともに民間であることから，がん検診に対する考え方の中に経営的視点が反映されているのではないかと考えたからである．最も確認したかったのは，米国におけるがん検診が，政府の指導のもとにしぶしぶ行われているのか，それとも事業として積極的に行われているのかという点である．調査結果については，厚生労働科学研究費補助金特別研究報告書にて報告[11)]を行っているが，本稿では，そ

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表　マネージドケア型組織 HMO と PPO の比較(文献[13]より)

	HMO	PPO
名称	Health Maintenance Organization	Preferred Provider Organization
主目的	医療費のコントロール	医療費のコントロール
特徴	医療機関と財政機関の両方を組織内に併せ持つ．組織外で行われた医療サービスには保険は支払われない．	医療保険者が独立した医療機関と契約を結び医療ネットワークを形作る．契約を行った医療機関は通常よりも安い金額で医療サービスを提供する．患者がネットワーク以外の医療機関を受診した場合，給付水準が減額される．
経済的インセンティブ	費用効果的なサービスを行おうとするインセンティブが働く	費用効果的なサービスを行おうとするインセンティブが働く
ゲートキーパーの存在	医療サービスの提供をコントロールする(ゲートキーパーの役割を担う)医師が存在する．ゲートキーパーである医師を介しない医療サービスには保険が支払われない．	ゲートキーパーの役割は存在しない．
医師の関わり方	組織に直接雇用される形態と，雇用ではなく契約を結ぶ形態がある．	組織と医師・医療機関との間で契約が結ばれる
組織の例	Keiser Parmanente 等	Health Net Inc. 等

註) この表は典型的な組織形態の比較であり，実際にはバリエーションが存在する．

の概要について紹介したい．

米国の医療保険者

米国では，高齢者と障害者を対象とした医療制度(メディケア)と貧困者のための医療制度(メディケイド)を除いては，医療は私的なサービスとして提供されている．医療保険は，主に福利厚生の一環として企業によって購入されてきた．

米国の国民医療費の対 GDP 比は，先進国の中でもずば抜けて高く，医療費の上昇は，医療保険の購入者である企業にとっても大きな負担となっていた．そのため 1980 年代頃より，医療費の抑制(企業側からみれば負担する保険料の抑制)に対して効果の期待できるマネージドケア型の医療システムが発達し，現在では，米国における民間医療保険の大部分が，この型のヘルスプランを採用している[12~15]．

マネージドケア型の医療システムの特徴は，保険者が，供給する医療，利用方法，価格などを一定の管理状態に置くところにある．このシステムの具体的な形態として，健康維持組織(Health Maintenance Organization：HMO)がある．HMO の基本的な形は，保険者と医療提供者(病院/医師)が一体となっているものである．

マネージドケア型の医療システムの形態にはバリエーションがある．例えば PPO(Preferred Provider Organization)のように，保険者が特定の医療サービス機関と契約を交わし，保険加入者にそれらのネットワーク内の医療機関を利用するよう奨励するシステムや，Point of Service(POS) Plan のように，HMO と PPO を併せたようなシステムもある(表)[13]．

調査地

2006 年 3 月，米国カリフォルニア州においてヘルスプランを提供しているマネージドケア型の組織を訪れ，がん検診サービスのあり方に関して聞き取り調査を行った．同州は，マネージドケア型の医療システムが最も発達している州の 1 つである[16]．訪問した機関は，HMO 型の Keiser Parmanente[17](以下，Keiser と略)と，PPO ネットワーク型の Health Net Inc.[18](以下，Health Net と略)である．聞き取り調査の相手は，両組織共に医師であり，Keiser の担当者の職位は，Assistant Medical Director for Quality and Clinical Analysis，Health Net の担当者の職位は，Regional Medical Director であった．

調査結果

1. がん検診の実施状況

両組織とも，がん検診は，United States Preventive Task Force[19]と American Cancer Society[20]のガイドラインに沿って実施していた．実施対象のがんも共通しており，積極的な検診の対象としているのが乳がん，子宮頸がん，大腸がんである．前立腺がん検診に関しては，「50歳以上の男性，ハイリスクの場合には45歳以上の男性に対して，PSA(prostate specific antigen)テストを，益と害を理解してもらった上で，希望があれば提供している(Keiser)」，「50歳以上の男性に対して，直腸診検査を毎年受けることを勧めている．PSA検査に関しては，まだ具体的な方針は立っていない．擬陽性が多いため判断保留中である(Health Net)」との回答であった．肺がん検診と胃がん検診は，有効性に関するエビデンス不足ということで，両組織とも実施を勧めていないとのことであった．

1) 乳がん検診の状況

Keiserでは，50～69歳の女性に対して2年に1度のマンモグラフィーによる検診を推奨している(40～49歳に関しては専門家との相談の上で実施)．受診率は最新の結果で84%とのことである(2年に1度の受診で，“受診者”にカウントされるため，対象者の84%が1年間に受診しているというわけではない．以下同様)．

Health Netでは，20～40歳の女性には3年に1度，40歳以上には毎年，医師による診察を受けるよう推奨している．また，40歳以上の女性にはマンモグラフィーによる検査を，1年もしくは2年に1回受けるよう推奨している．超音波検査は，ルーティンの検査としては行われていない．2005年，カリフォルニアにおける検診受診率(2年間で1回でも受診したもの)は，74.9%であった．

2) 大腸がん検診の状況

Keiserでは，50歳以上に対して，年に1度の便潜血テスト，5年に1度のS状結腸内視鏡検査(Flexible Sigmoidoscopy)による検査，10年に1度の大腸内視鏡(Colonoscopy)による検査を推奨している．受診率は最新の結果で45%である．

Health Netにおける大腸がん検診の取り組みも，Keiserと同様である．既往歴，家族歴があるような人には，より頻回の大腸内視鏡検査を勧めているという．2005年，カリフォルニアにおける検診受診率は45.7%であった．

3) 子宮頸がん検診の状況

Keiserでは，30～64歳までの女性に対して，3年に1度のPAPテストとHPV(human papilloma virus)検査を行うことを推奨している．18～29歳にも3年に1度のPAPテストを実施し，陽性者に対してHPV検査を追加して行うことを勧めている．受診率は最新の結果で79%である．

Health Netでは，21～65歳までの女性に対して，PAPテストを少なくとも3年に1回は行うように勧めている．2005年，カリフォルニアにおける検診受診率は，81.9%であった．

2. がん検診の経済的側面

検診受診料に関しては，「契約している医療保険の内容によって異なっており，無料から多少料金のかかる場合もある(Keiser)」，「どのような契約を行っているかによってバリエーションが多く，一概には言えないが，乳がん，大腸がん，子宮頸がん検診の受診者負担は大きくはない．無料の場合もある(Health Net)」との回答であった．

がん検診の実施に関して国の法律はあるか，という問いに対して，カリフォルニアの州法では「規定がある．また，パブリックリポート(保険契約の際の情報となる．毎年作成し加入者に配布)として出す必要がある(Keiser)」との回答を得た．がん検診の実施にあたっての政府の経済的援助は，「ない．ただし，メディケアの場合は，公的な枠組みの中で行われている(Health Net)」とのことである．がん検診に医療費抑制効果があると思うかという問いには，「ある．進行したがんになった場合，抗がん剤がものすごく高い．乳がんの化学療法の費用は，だいたい25万ドルぐらいかかる．がん検診は，とても費用効果的である

(Keiser)」,「ある．進行がんの場合，抗がん剤治療や集中治療など，医療費は莫大なものとなる．検診のコストのほうがはるかに安い(Health Net)」と，明確な回答が返ってきた．

3. 受診率向上の取り組み

がん検診の受診率を上げるためにはどうしたらよいかという問いに対して，「第一に，検診の重要性を会員ならびに医師に認識してもらうことである．特に現場の医師が検診の有効性に確信を持っていることが重要である．医師の認識を高めるための経済的インセンティブも必要である．第二に，がん検診受診勧奨の宣伝をメディアを利用して積極的に行うことが大切である．特に，有名人のがん罹患や死亡の発表に併せたキャンペーンは効果的である．第三に，がん検診の有効性に関するエビデンスを構築する必要がある．そのためには評価研究が欠かせない(Keiser)」,「教育が最も大事である．新聞，雑誌，TV などを使って，がん検診の大切さについて教育を行っている．医師への教育も重要である．また，医師に対しては，検診受診率を高めるため，経済的なインセンティブが考えられている(Health Net)」との回答を得た．

患者(加入者)に対する経済的なインセンティブは，「グループ購入の場合など(企業による保険購入などを指す)，そのグループの受診率によって，保険料が変更されることもある．これも契約の内容による(Health Net)」とのことであった．検診を受けないことに対する患者側へのペナルティおよび医師側へのペナルティは「ない(Health Net)」ということである．

考察

今回の調査では，非営利組織と営利組織の両方の情報を得ることができた．若干の相違はあるものの，がん検診の取り組みはほぼ同様であった．有効性が明らかであるがん検診(乳がん検診，子宮頸がん検診，大腸がん検診)は強力に推進するが，有効性が十分に明らかにされていない検診の実施に関しては消極的であることも共通していた．

営利・非営利の違いがあるとはいえ，両組織とも民間の組織であり，米国の自由市場的な医療制度の中で，魅力的な保険料(保険購入者にとっては安いほうが魅力的)と魅力的なサービス提供で競争を行っている．がん検診は，医療費を抑え保険料を安くするという意味でも，消費者の満足度を高めるという意味でも，経営戦略的に重要な事業のようである．

まとめ

米国のマネージドケア型の組織を訪問し，がん検診サービスのあり方について聞き取り調査を行った．がん検診のサービスは，US Preventive Task Force 等から出されているガイドラインに基づいて提供されており，乳がん検診，子宮頸がん検診に関しては，高い受診率が達成されていた．訪問した２つの組織の担当者とも，乳がん検診，子宮頸がん検診，大腸がん検診には，医療費抑制効果があるとの認識であった．がん検診の実施は，医師-患者関係の中で決定されており，検診の受診率を高めるための方策として，両組織の担当者とも，教育の重要性を強調していた．また，医師に対する経済的なインセンティブも重視していた．

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Palliative and Supportive Care (2007), 5, 19–30. Printed in the USA.

DOI: 10.1017/S1478951507070046

Factors relating to terminally ill cancer patients' willingness to continue living at home during the early phase of home care after discharge from clinical cancer centers in Japan

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(RECEIVED July 30, 2006; ACCEPTED August 27, 2006)

ABSTRACT

Objective: To assess the willingness of Japanese terminally ill cancer patients to continue living at home during the early phase of home care after discharge from a Clinical Cancer Center (CCC) in Japan, and to identify factors relating to their willingness to continue living at home.

Methods: A cross-sectional questionnaire survey of a convenient sample of both Japanese terminally ill cancer patients and their caregivers (PFCs) was conducted (n = 294, effective response rate 25.0%). Questionnaires were mailed and medical records were accessed for 73 pairs of respondents, comprising one terminally ill cancer patient and one PFC.

Results: At about 10 days after discharge, 64 patients (88%) wished to continue living at home. A hierarchical logistic regression analysis was performed on the data. It was found that the fewer the medical treatments undergone (OR = 0.20, 95% CI: 0.05–0.72), the higher the patients' perception that their condition was consistent with care at home (OR = 2.77, 95% CI: 1.08–8.62) and with their functional well-being (OR = 1.45, 95% CI: 1.08–2.17). In addition, the higher the caregivers' satisfaction with life (OR = 2.37, 95% CI: 1.15–5.77), the more willing patients tended to be to continue living at home.

Significant of results: The willingness of Japanese terminally ill cancer patients to continue living at home appears to be affected by caregiver status. This indicates a need for discharging facilities to monitor the state of home assistance and to investigate the nature of assistance required for continuing home care.

KEYWORDS: End-of-life care, Terminally ill cancer, Willingness to continue living at home, Palliative home care, Clinical Cancer Center

INTRODUCTION

In Japan, cancer is the primary cause of death (about 30%), with about 300,000 people dying from it each year (Ministry of Health, Labour and Welfare Percentage, 2006). Assurance of end-of-life cancer care in Japan was established when "palliative care unit fees" were first incorporated in the treatment fees paid to medical institutions under the medical insurance system (Umeda & Iwasaki, 2001). Guidance and management fees for cancer patients living at home and treatment fees paid to medical institutions for home terminal cancer patients were

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also established under the medical insurance system. An "additional palliative care treatment fee," for treatment in general hospitals by palliative care teams that meet given criteria, was further established in 2002 (Komoto, 2002). As a result, appropriate, ongoing palliative care is now available at all stages of the treatment of cancer patients, and a smooth transition of patients to palliative care units and home palliative care is expected.

The period immediately after discharge, that is, the week or two preceding the first outpatient visit, is fraught with various problems associated with the transition to home care (Okaya, 2000; Sakai, 2002). Providing information about emergency measures suited to the physical state of the patient, coordinating the many home medical care and welfare-related professional services, and assisting with complicated issues that increase the anxiety of patients and primary family caregivers (PFCs) are considered to be important (Okaya, 2000; Hakata et al., 2002). Few patients make the decision to "live at home until the end" during the initial period of home care, but it is reported that many talk it over with their families and make the decision when their living situation has become clear, between the end of the initial period and 1 to 3 weeks prior to death (Okaya, 2000). Thus, the extent to which the patient wishes to live at home and whether assistance that is consistent with the patient's wishes is given are necessary considerations in the home care process. Adequate assessment and support during the initial period of home care is of prime importance.

The levels of pain experienced by terminally ill cancer patients are a source of anguish for the patient's entire family (i.e., the family caring for the patient) (Tsuneto, 1999; Suzuki et al., 2001). It is presumed that the physical and mental state of PFCs is affected by the physical and mental state of the patient (Rossi Ferrario et al., 2003), and also that the desire of PFCs to provide home care, together with their perception of burden or of well-being and satisfaction with life, will affect the quality of life of the patient and the patient's willingness to continue living at home (Sawada et al., 2001). The finding that the stronger the wish of both patient and PFCs to continue home care the more likely it is that the patient will die at home (Schaapveld & Cleton, 1989; Ishigaki, 1998) suggests that taking into account the experience of not only the patient but also the family is vital to continuing home care (Kaye, 1999).

An understanding of the factors affecting terminally ill cancer patients' willingness to continue living at home during the period of transition from Clinical Cancer Centers (CCCs) to home care will permit the development of a concrete strategy for the improvement the home care environment, and this can be expected to raise retention rates. It will thus contribute to the overall improvement of the experience of palliative care for terminally ill cancer patients and their family members.

The objectives of this study were (1) To identify the current rate of willingness of terminally ill cancer patients to continue living at home after discharge from CCCs in Japan and and (2) to identify factors associated with the willingness of the patients to continue living at home.

METHODS

Sample

The subjects were terminally ill cancer patients discharged from CCC institutions and their PFCs. All approved of the study and participated voluntarily, and written consent was obtained. The eligibility criteria were (1) terminally ill cancer patient and the patient's PFCs, (2) aged 18 years or older, (3) free from impaired consciousness and psychiatric disorders, and (4) the physician in charge approved the patient's participation.

CCCs are hospitals and equivalent medical facilities in Japan engaged in research into and prevention, diagnosis, and treatment of cancer and other malignant neoplasms and holding seminars for health care professionals.

Study Samples

A total of 294 pairs of patients and PFCs were selected from 13 of the 27 CCCs that agreed to participate in the study. Then 143 eligible patients (49%) and 121 eligible PFCs (41%) returned their completed questionnaire. Of these, 59 patients and 37 PFCs were not eligible, and 11 patients and 11 PFCs expressed a lack of desire to participate in the study by return postcard. As a result, data from 73 pairs of patients and PFC (25%) were ultimately analyzed. Table 1 shows the characteristics of the patients and PFCs.

Procedure

In September 2001, requests for participation in the study were mailed to all of the Japanese Association of Clinical Cancer Centers asking for their cooperation. The cover letter explained that the survey would be both confidential and anonymous. The CCCs were requested to supply the details of eligible patients. If the CCCs had had eligible patients during the study period, they selected all

Table 1. *Characteristics of the respondents (n = 73)*

A. Characteristics of patients	No. of patients	%	Characteristics of patients		No. of Patients	%
Sex						
Female	30	41	Performance status	0	37	51
Male	43	59		1	21	29
Age				2	10	14
Mean ± *SD*	62.2 ± 10.9			3	4	5
Range	37–84			4	1	1
Education			Total length of hospitalization (days)			
Junior high school	15	21		Mean ± SD	45.7 ± 34.9	
High school	28	38		Median	34	
Technical school/junior college	16	22		Range	3–165	
University/postgraduate	12	16	No. of medical	0	44	60
Unknown	2	3	treatments	1	17	23
Time since discharge (days)				2	8	11
Mean ± SD	9.5 ± 4.4			3	3	4
Median	11			4	1	1
Range	7–28			Mean ± *SD*	0.5 ± 0.9	
Primary site				Median	1	
Digestive system	25	34		Range	0–4	
Lung/pleura	17	23	Type of medical			
Gynecologic	6	8	(Multiple choice)	Pain management	26	36
Hematopoietic system	6	8		IVH	6	8
Mammary gland	7	10		Self-injection	4	5
Other	12	16		Colorectum stoma care	3	4
Metastasis				Indwelling catheter	2	3
Present	50	68		Self-catheterization	2	3
Absent	23	32		Bedsore treatment	1	1
Stage				Other	6	8
III	16	22	Perception of cancer	Present	68	93
IV	51	70	at discharge	Absent	4	5
Unknown	6	8		Unknown	1	1
Therapy			Desire for home care	Present	47	64
Surgery	36	49		Absent	26	46
Chemotherapy	63	86				
Radiotherapy	28	38				
Opioid	20	27				

B. Characteristics of PFCs	*N*	%	Characteristics of PFCs		*N*	%
Sex						
Female	46	63	Primary caregiver			
Male	27	37		Spouse	54	74
Age (years)				Child	11	15
<40	7	10		Parent	3	4
40–49	14	19		Sibling	3	4
50–59	22	30		Friend	1	1
60–69	20	27		Other	1	1
≥70	10	14	Secondary caregiver			
Mean ± *SD*	56.3 ± 12.7			Present	67	92
Median	55.5			Absent	6	8
Range	22–91		Desire for home care			
Education				Present	47	64
Junior high school	11	15		Absent	26	36
High school	35	48				
Technical school/junior college	13	18				
University, postgraduate	11	15				
Unknown	3	4				

eligible patients ready for discharge after the study began.

Ethical Considerations

The study was conducted only after obtaining the approval of the Institutional Review Board of Kanagawa Cancer Center and of each institution. The subjects were informed in writing in the cover letter of the role of participants and of the procedures for ensuring privacy in the handling of data and protecting patient rights. Written consent was obtained prior to the commitment to participate and again at the commencement of participation. All data in the present study were rigorously managed by the researchers so as to ensure privacy.

Questionnaire

The questionnaire was developed based on a systematic literature review (World Health Organization, 1990; Nagae, 1998; Okamoto, 1998; Miyashita et al., 1999; Naylor et al., 1999; Nagae et al., 2000; Naylor, 2000; Ogata et al., 2000) and on pilot study interviews with several terminally ill cancer patients and their PFCs, two directors of home nursing stations providing terminal cancer care, and four oncologists as well as on the experience of the investigators.

The researchers developed the framework of the study (Fig. 1). We proposed two groups of factors associated with the willingness of patients to continue living at home: patient factors and PFC factors. The former were divided into predischarge "patient characteristics," which had been defined at discharge and could not be changed (or were difficult to change) by health care and welfare professionals, and "patient discharge-related information," which was both documented and related to matters that occurred after discharge or could be altered by subsequent events. These data were normally used for postdischarge evaluation, in the wake of discharge assistance. PFC factors were related to the characteristics of PFCs.

The study variables were grouped as follows:

1. Patient sociodemographic variables (sex, age, education level).
2. Patient clinical and functional variables: diagnosis; metastasis; stage; therapy undergone before discharge (surgery, chemotherapy, radiotherapy, etc); perception of cancer at discharge; number of medical treatments; performance status (Eastern Cooperative Oncology Group Performance Status; PS) scale (European Organization for Research and Treatment of Cancer, 1996), whose scores range from 1 to 4 (higher scores represent greater functional dependence); and presence or absence of patient desire for home care at discharge.

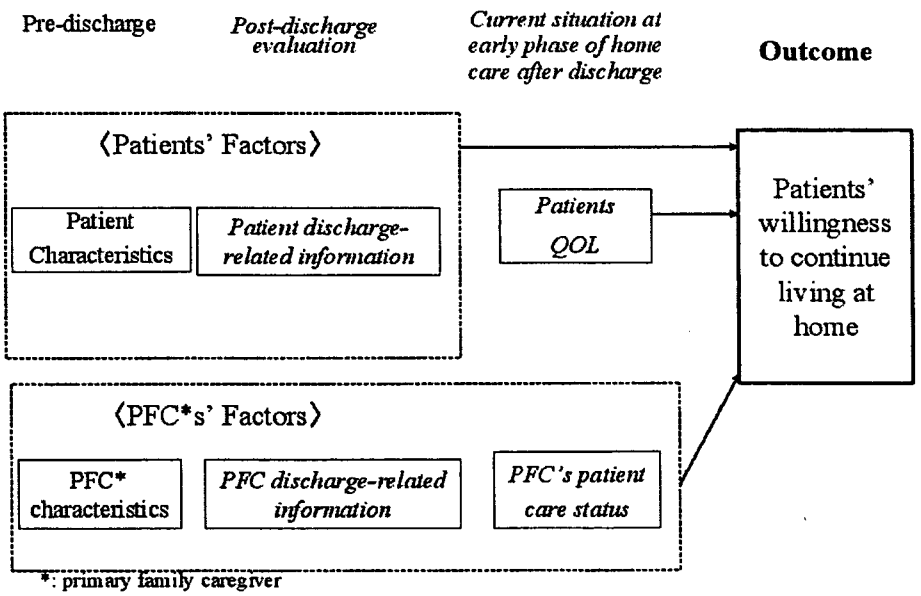

Fig. 1. Research framework of terminally ill cancer patients' and their primary family caregivers' willingness to continue living at home during the early phase of home care after discharge.

3. Patient discharge-related information: patient relationship with PFCs; extent of gap between home care envisioned at discharge and reality; patient satisfaction with discharge care (eight items; five-point scale from "very unsatisfactory" (0) to "very satisfactory" (4): The total score of eight items was used as a single subscale in the subsequent analyses, due to good internal consistency (Cronbach's alpha coefficient = .91), a higher score indicating higher satisfaction with discharge care, within a possible range of 0–32); and stability of correspondence of reality to their image of living at home before discharge.
4. Patient's quality of life: assessed using the subscales of the 27-item Japanese version of FACT-G (QOL). QOL consists of four domains: physical well-being (PWB, 7 items; range 0–28), social well-being (SWB, 8 items; range 0–32), emotional well-being (EWB, 5 items; range 0–20), and functional well-being (FWB, 7 items; range 0–28). Each response was calibrated using a five-point scale. Higher scores indicate higher levels of well-being (Cella, 1997).
5. PFC variables: sociodemographic variables (sex, age, education level); relationship with patient; extent of gap between home care as envisioned at discharge and reality; presence or absence of other family caregivers; and satisfaction with discharge care. The same items as for patients were employed (Cronbach's alpha coefficient = .89).
6. Characteristics of caregiver's support at the time the questionnaire was filled out (after discharge): eight items relating to the PFCs' perception of burden in their situation, such as arrangements for and information held relating to support available when there are changes in medical treatment, or whether respite care is utilized. Respondents chose one of five responses from "inapplicable" to "very applicable."
7. The patient's and the PFC's willingness, or not, to continue with living at home arrangements in the future.

Statistical Analysis

To determine the potential determinants of patients' willingness to continue living at home from the data, preliminary univariate analyses were conducted, as appropriate, using the unpaired t test, the chi-square test (Fisher's exact methods), and the trend test (Cochran–Armitage's trend test) for contingency tables with ordinal data.

The next objective was to simultaneously explore the relationship to patients' willingness to continue living at home to the groups of items covering "patient characteristics," "patient discharge-related information," "patient QOL," and "PFCs' status"

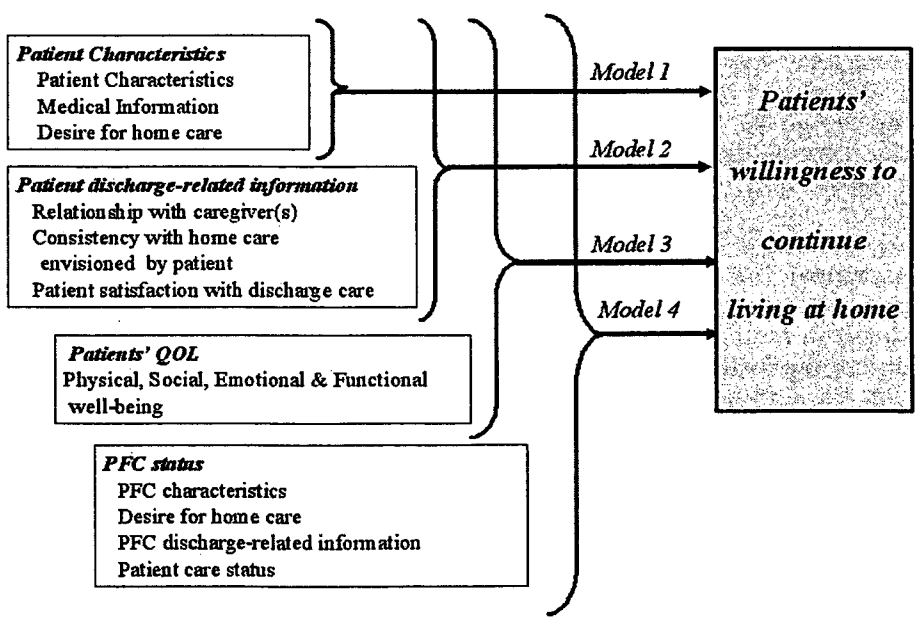

Fig. 2. Analysis model of factors related to patients' willingness to continue living at home during the early phase of home care after discharge.

(Fig. 2). After the univariate analysis, a hierarchical logistic regression analysis (backward elimination; $p > .2$), in four steps, was performed to extract the higher determinants of the patients' willingness to continue living at home: Model 1 consisted of "patient characteristics" alone; Model 2 consisted of Model 1 with "patient discharge-related information" added; Model 3 consisted of Model 2 with "patient QOL" added; and Model 4 consisted of Model 3 with "caregiver status" added. Data analyses were conducted using the SAS ver.8.2 statistical software package (SAS Institute, Cary, NC, USA). All p values were two-tailed and statistical significance was set at the $p < .05$ level.

RESULTS

Patients' Willingness to Continue Living At Home and Related Factors

At about 10 days after discharge, 64 patients (88%) wished to continue living at home. The significance levels of the correlations between patients' willingness to continue living at home and patients' and PFCs' sociodemographic variables are shown in Table 2.

The willingness to continue living at home was significantly lower in patients who underwent a larger number of medical treatments than in patients who underwent fewer treatments ($p = .05$). Patients who had desired home care at discharge also showed a significantly greater willingness to continue living at home ($p = .05$). The more consistent patients felt that their home care after discharge was as they envisioned it before discharge, the more willing they were to continue ($p = .01$). And finally, the higher the score for emotional well-being and the higher the score for functional well-being, the more willing patients were to continue living at home ($p = .01$ and $p = .03$, respectively).

Turning our attention to PFC variables, the fewer PFCs who expressed the need for further care-related support, the more patients responded that they were willing to continue living at home ($p = .002$). In addition, the higher the caregivers' satisfaction with life, the more willing patients tended to be to continue living at home ($p = .19$).

For variables that exhibited a significant correlation in the univariate analysis, a hierarchical logistic regression analysis was performed using age, sex, and four domains of QOL as independent variables (Table 3).

In Model 1, the number of medical procedures undergone (OR = 0.49, 95% CI: 0.23–0.97, $p < .05$) was significant. In Model 2, the number of medical procedures (OR = 0.44, 95% CI: 0.19–0.90, $p < .05$) and the perception of consistency between care at home as envisioned by the patient and the reality (OR = 2.70, 95% CI: 1.34–6.41, $p < .05$) were both significant. In Model 3, the number of medical procedures undergone (OR = 0.39, 95% CI: 0.13–0.94, $p < .05$) and level of functional well-being (OR = 1.36, 95% CI: 1.06–1.94, $p < .05$), as a domain of patient QOL, were significant. The perception of consistency of care at home as envisioned by the patient and the reality (OR = 2.39, 95% CI: 0.95–7.19, $p < 0.2$) was no longer statistically significant in Model 3.

In Model 4, the significance of number of medical procedures (OR = 0.20, 95% CI: 0.05–0.72, $p < .05$) was low, the significance of perception of consistency of care at home as envisioned by the patient and the reality (OR = 2.77, 95% CI: 1.08–8.62, $p < .05$) was high, the significance of functional well-being (OR = 1.45, 95% CI: 1.08–2.17, $p < .05$) was high, and the higher the caregivers' satisfaction with life (OR = 2.37, 95% CI: 1.15–5.77, $p < .05$), the more willing the patient tended to be to continue living at home.

The model contribution ratios were 17%, 30%, 39%, and 50% for Models 1, 2, 3, and 4, respectively, increasing in order from Models 1 to 4.

DISCUSSION

In the present study, we investigated factors relating to the willingness of patients, early in the period of transition from CCC to home care, to continue living at home, in order to identify possible concrete support strategies for terminally ill cancer patients in this period of home care.

The Association between Characteristics of the Early Phase of Home Care and the Willingness of Terminally Ill Cancer Patients to Continue Living at Home

This study revealed that the physical and psychological burden caused by a large number of medical treatments and inconsistency between home care as envisioned and its reality were factors that made it difficult to accept the continuance of home care (Kaye, 1999). Another important finding is that care provided after discharge should be, as far as possible, consistent with that envisioned by patient before discharge.

Discharge services should address this aspect (Naylor et al., 1999, 2000; Naylor, 2000). Furthermore, the factor where the greater the patient's perception of functional well-being, the more likely are the functions of daily living to proceed smoothly

Table 2. *Result of univariate analysis on patients' willingness to continue living at home (n = 73)*

Patient characteristics	Patients' willingness to continue living at home: Present (*n* = 64) No. of patients (%)	Absent (*n* = 9) No. of patients (%)	*p* value
A. Patient Characteristics			
Age (years)			
<40	1 (50)	1 (50)	0.42[1]
40–49	8 (80)	2 (20)	
50–59	25 (93)	2 (7)	
60–69	14 (88)	2 (13)	
≥70	16 (89)	2 (11)	
Sex			
Female	24 (80)	6 (20)	0.76[2]
Male	40 (93)	3 (7)	
Education			
Junior high school	15 (100)	0 (0)	0.21[2]
High school	24 (86)	4 (14)	
Technical school/junior college	12 (75)	4 (25)	
University, postgraduate	11 (92)	1 (8)	
B. Medical Information			
Primary site			
Digestive system	23 (88)	2 (12)	0.38[2]
Lung/pleura	15 (92)	2 (8)	
Gynecological	6 (100)	0 (0)	
Hematopoietic system	6 (100)	0 (0)	
Mammary gland	5 (71)	2 (29)	
Other	9 (75)	3 (25)	
Metastasis			
Present	43 (86)	7 (14)	0.74[2]
Absent	21 (91)	2 (9)	
Stage			
III	15 (94)	1 (6)	1.00[2]
IV	45 (88)	6 (12)	
Total length of hospitalization (days)			
<30	27 (84)	5 (16)	0.62[1]
30–59	15 (88)	2 (12)	
60–89	15 (94)	1 (6)	
>≠90	7 (88)	1 (13)	
Performance status			
0	34 (92)	3 (8)	0.37[1]
1	17 (81)	4 (19)	
2	10 (100)	0 (0)	
3	2 (50)	2 (50)	
4	1 (100)	0 (0)	
Surgery			
Yes	31 (86)	5 (14)	0.74[2]
No	33 (89)	4 (11)	
Chemotherapy			
Yes	55 (87)	8 (13)	1.00[2]
No	9 (90)	1 (10)	
Radiotherapy			
Yes	25 (89)	3 (11)	1.00[2]
No	39 (87)	6 (13)	
No. of medical treatments			
0	40 (91)	4 (9)	0.05*[1]
1	16 (94)	1 (6)	
2	5 (63)	3 (38)	
3	3 (100)	0 (0)	
4	0 (0)	1 (100)	

(*continued*)

Table 2. *Continued*

Patient characteristics	Patients' willingness to continue living at home: Present (n = 64) No. of patients (%)	Patients' willingness to continue living at home: Absent (n = 9) No. of patients (%)	p value
C. Desire for home care			
Present	43 (91)	4 (9)	0.05*[2]
Absent	21 (81)	5 (19)	
Patient discharge-related information			
Relationship with caregiver(s)			
Not at all good	0 (0)	0 (0)	0.30[1]
Marginally good	0 (0)	0 (0)	
Somewhat good	3 (100)	0 (0)	
Quite good	9 (69)	4 (31)	
Extremely good	52 (91)	5 (9)	
Consistency with home care envisioned by patient			
Completely different	0 (0)	0 (0)	0.01**[1]
Quite different	0 (0)	1 (100)	
Somewhat different	10 (71)	4 (29)	
Marginally different	4 (100)	0 (0)	
Identical	50 (93)	4 (7)	
Patient satisfaction with discharge care (score)[3] (range 0–32)	(73)		
<21 points	11 (73)	4 (27)	0.29[1]
21–25 points	19 (91)	2 (10)	
26–27 points	11 (100)	0 (0)	
>≠28 points	23 (89)	3 (12)	
Patient QOL(FACT-G)			
Physical well-being[3] (range 0–28)			
<12 points	14 (78)	4 (22)	0.26[1]
12–19 points	20 (95)	1 (5)	
20–23 points	14 (78)	4 (22)	
>≠24 points	16 (100)	0 (0)	
Social Well-being[3] (range 0–32)			
<21 points	6 (100)	0 (0)	0.46[1]
21–23 points	2 (80)	0 (20)	
24–27 points	5 (91)	1 (9)	
>≠28 points	51 (85)	8 (15)	
Emotional well-being[3] (range 0–20)			
<10 points	13 (72)	5 (28)	0.01**[1]
10–12 points	19 (86)	3 (14)	
13–16 points	14 (93)	1 (7)	
>≠17 points	18 (100)	0 (0)	
Functional well-being[3] (range 0–28)			
<12 points	25 (78)	7 (22)	0.03*[1]
12–17 points	27 (93)	2 (7)	
18–21 points	11 (100)	0 (0)	
>≠22 points	1 (100)	0 (0)	
PFC status			
D. PFC characteristics			
Age (years)			
<40	7 (100)	0 (0)	0.30[1]
40–49	11 (79)	3 (21)	
50–59	21 (95)	1 (5)	
60–69	18 (90)	2 (10)	
>≠ 70	7 (70)	3 (30)	
Sex			
Female	39 (85)	7 (15)	0.53[2]
Male	25 (93)	2 (7)	
Education			
Junior high school	9 (82)	2 (18)	0.84[2]
High school	31 (89)	4 (11)	
Technical school/junior college	11 (85)	2 (15)	
University/postgraduate	10 (91)	1 (9)	

(*continued*)

Table 2. *Continued*

Patient characteristics	Patients' willingness to continue living at home: Present (n = 64) No. of patients (%)	Absent (n = 9) No. of patients (%)	p value
E. Desire for home care			
Present	42 (89)	5 (11)	0.34[2]
Absent	22 (85)	4 (15)	
F. PFC discharge-related information			
Relationship with patient			
Spouse	49 (91)	5 (9)	0.33[1]
Child	8 (73)	3 (27)	
Parent	3 (100)	0 (0)	
Sibling	2 (67)	1 (33)	
Friend	1 (100)	0 (0)	
Other	1 (100)	0 (0)	
Secondary caregiver(s)			
Present	58 (87)	9 (13)	0.49[2]
Absent	6 (100)	0 (0)	
PFC satisfaction with discharge care[3] (range 0–32)			
<21 points	11 (92)	1 (8)	0.43[1]
21–25 points	21 (91)	2 (9)	
26–27 points	10 (83)	2 (17)	
>≠28 points	22 (85)	4 (15)	
G. Patient care status			
Support and information are available when there are changes in care status			
Not true	15 (100)	0 (0)	0.28[1]
Marginally true	11 (79)	3 (21)	
Somewhat true	12 (92)	1 (8)	
Quite true	12 (86)	2 (14)	
Very true	14 (82)	3 (18)	
You feel healthy			
Not true	5 (71)	2 (29)	0.79[1]
Marginally true	11 (92)	1 8)	
Somewhat true	17 (100)	0 (0)	
Quite true	15 (88)	2 (12)	
Very true	16 (80)	4 (20)	
Respite from care			
Not true	2 (100)	0 (0)	1.00[1]
Marginally true	2 (67)	1 (33)	
Somewhat true	17 (85)	3 (15)	
Quite true	24 (96)	1 (4)	
Very true	19 (83)	4 (17)	
Additional support etc			
Not true	31 (97)	1 (3)	0.01**[1]
Marginally true	11 (85)	2 (15)	
Somewhat true	14 (93)	1 (7)	
Quite true	5 (83)	1 (17)	
Very true	3 (43)	4 (57)	
Satisfied with life (satisfied with present QOL)			
Not true	4 (100)	0 (0)	0.19††[1]
Marginally true	7 (100)	0 (0)	
Somewhat true	10 (83)	2 (17)	
Quite true	18 (95)	1 (5)	
Very true	2 (25)	6 (75)	

[1]Cochran-Armitage's trend test, [2]Fisher's exact test, [3]Percentile point
††$P < 0.2$, †$P < 0.1$,*$P < 0.05$, **$P < 0.01$

Table 3. *Result of hierarchical regression analysis on patients' willingness to continue living at home (n = 73)*

	Model 1		Model 2		Model 3		Model 4	
	OR[a]	(95% CI[b])	OR[a]	(95% CI[b])	OR[a]	(95% CI[b])	OR[a]	(95% CI[b])
Patient characteristics								
Age (years)		—		—		—		—
Sex (1. Male/0. Female)		—		—		—		—
Performance Status (0–4)		—		—		—		—
No. of medical treatments (0–4)	0.49*	(0.23–0.97)	0.44*	(0.19–0.90)	0.39*	(0.13–0.94)	0.20*	(0.05–0.72)
Desire for home care (1. Present/0. Absent)	3.32	(0.74–17.34)	3.26	(0.64–20.71)		—		—
Patient discharge-related information								
Consistency with care envisioned by patient			2.70*	(1.34–6.41)	2.39	(0.95–7.19)	2.77*	(1.08–8.62)
Patient QOL								
Physical well-being					0.86	(0.67–1.01)	0.83	(0.61–1.02)
Social well-being						—		—
Emotional well-being						—		—
Functional well-being					1.36*	(1.06–1.94)	1.45*	(1.08–2.17)
PFC status								
Age (years)								—
Gender (1. Male/0. Female)								—
Additional support								—
Satisfied with life (satisfied with current QOL)							2.37*	(1.15–5.77)
R^{2c}	0.09		0.16		0.		0.26	
MR^{2d}	0.17		0.30		0.39		0.50	

*$p < .05$
— denotes item was not selected by backward elimination ($p > .2$)
[a]Adjusted odds ratio
[b]95% confidence interval
[c]Coefficient of determination
[d]Max-rescaled coefficient of determination

was found to be associated with the desire to maintain the current home care.

The support of the caregiver is an essential part of home care, and it seems that patients are sensitive to the situation of the caregivers close to them and worry about their caregivers' well-being since it relates to their giving care at home. The caregivers' satisfaction with life appears to bolster the willingness of patients to continue home care.

In the present study, the model contribution ratios were increased by adding the variables of caregiver status to those of patient characteristics, indicating that the attitudes and well-being of caregivers are important factors in the willingness of patients to continue home care and should be taken into account.

Assistance during the Early Phase of Home Care of Terminally Ill Cancer Patients to Promote Its Continuance

Taking account of the caregiver's status is essential if appropriate assistance is to be given during the early phase of home care. Our results indicate that efforts to promote consistency between the care envisioned by the patient and its reality are important, as are measures to reduce patients' fears of difficulties resulting from medical treatments. Thus, there is a substantial need to improve discharge assistance and continuing care, for example, via outpatient counseling for both patients and caregivers (Naylor et al., 1999, 2000; Naylor, 2000).

The importance of the role of caregivers, who are in closest contact with patients, was confirmed by the finding that the level of satisfaction with life of caregivers is associated with the willingness of patients to continue home care. Therefore assessment over time and finding a place to discuss such matters as the feelings about their current lives, not only of patients but also of caregivers, is desirable.

Our results suggest that the following aspects of care should be considered in the development of high quality transitional care from CCCs to the patient's own home in Japan: tailoring a support system for cancer pain relief and other physical suffering, coordinating care with other medical fa-