**図 1　がん患者の自己負担額と償還・給付額(年間)**
n=6,604(平均年齢 63.3 歳, 粒子線治療患者は除外)

があった患者の割合(該当者の割合)を乗じたものである.

　直接費用として, 入院(入院した患者の割合74.4%)の自己負担額は 51.9 万円, 外来(該当割合 100%)は 18.1 万円, 交通費(同 93.7%)は4.5 万円である. また, 間接費用として, 健康食品・民間療法(該当割合 56.8%)の費用は 21.7万円, 民間保険料(同 85.1%)は 25.3 万円, かつら代などその他の支出(同 42.5%)は 13.8 万円である.

　一方, 年間の償還・給付額は, 平均 62.5 万円である. 内訳をみると, 高額療養費(該当割合52.6%)は 28.3 万円, 医療費還付(同 23.2%)は8.6 万円, 民間保険の給付金(同 44.8%)は 101.8万円である.

**b. 化学療法を受ける患者の経済的負担**

　がんの治療は多種多様であり, 患者の病態に応じた個別性が高いが, 一般に, 化学療法, 造血器腫瘍の治療, 放射線治療などでは, 患者の自己負担が重くなっている可能性がある. そこで, 化学療法を受ける患者(n=1,150, 平均年齢 63.4 歳)について集計すると, 年間の患者自己負担額は, 平均 133.1 万円と, がん患者全体よりも 30 万円程度高額である(図 2, 3). 償還

・給付額も平均 75.2 万円と, がん患者全体よりもやや多くなっている.

　造血器腫瘍の治療(n=399, 平均年齢 58.3歳)では, 年間自己負担額は平均 154.1 万円, 償還・給付額は平均 112.3 万円と, がん患者全体よりも自己負担額は約 1.5 倍, 償還・給付額は約 2 倍多い水準となる.

　また, 放射線治療(n=1,419, 粒子線治療を除く, 平均年齢 62.3 歳)では, 年間自己負担額は平均 129.8 万円, 償還・給付額は平均 77.9 万円である. 更に, 粒子線治療(n=388, 平均年齢 68.0 歳)をみると, 先進医療としての 288 万円の自己負担を含め, 年間の負担額は平均420.4 万円に上る. 調査時点では, 粒子線治療をカバーする民間保険はなく, 償還・給付額は平均 115.9 万円にとどまる.

　自己負担の支払いには貯蓄の取り崩しや民間保険の給付金が充てられている場合が多い(図4). がん保険を扱う民間保険会社を調査[2]したところ(n=17), 外来化学療法では, これを給付の対象としていない民間保険が多いなどの課題がある(図 5). また, 造血器腫瘍患者では, 仕事への影響, 収入の減少など現役世代としての悩みも少なくない. 粒子線治療では, 施設が
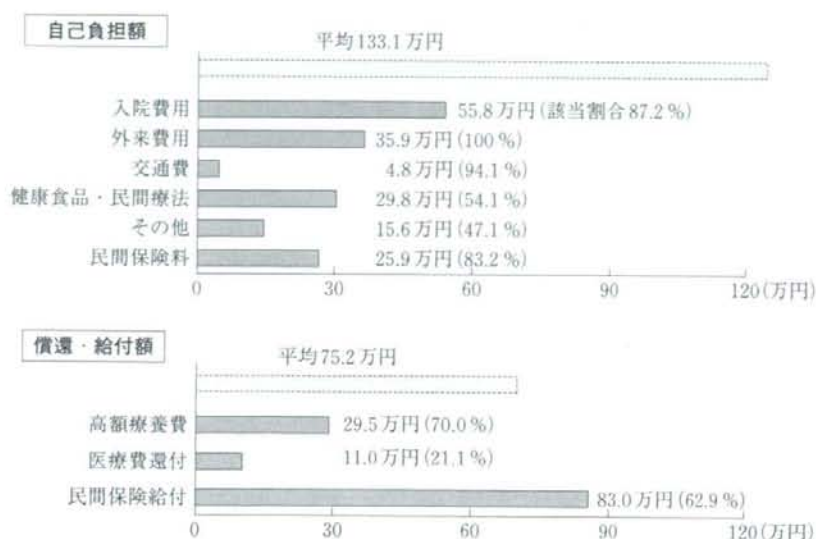
自己負担額

平均133.1万円

| | |
|---|---|
| 入院費用 | 55.8万円(該当割合87.2%) |
| 外来費用 | 35.9万円(100%) |
| 交通費 | 4.8万円(94.1%) |
| 健康食品・民間療法 | 29.8万円(54.1%) |
| その他 | 15.6万円(47.1%) |
| 民間保険料 | 25.9万円(83.2%) |

0    30    60    90    120(万円)

償還・給付額

平均75.2万円

| | |
|---|---|
| 高額療養費 | 29.5万円(70.0%) |
| 医療費還付 | 11.0万円(21.1%) |
| 民間保険給付 | 83.0万円(62.9%) |

0    30    60    90    120(万円)

図2 化学療法を受ける患者の自己負担額と償還・給付額(年間)
n＝1,150(平均年齢63.4歳)

(万円)

平均自己負担額

平均償還・給付額

| | 全体 (粒子線治療を除く) (n=6,604) | 化学療法 (n=1,150) | 造血器腫瘍治療 (n=399) | 放射線治療 (粒子線治療を除く) (n=1,419) | 粒子線治療 (n=388) |
|---|---|---|---|---|---|
| 自己負担額 | 100.7万円 | 133.1 | 154.1 | 129.8 | 420.4 |
| 償還・給付額 | 62.5万円 | 75.2 | 112.3 | 77.9 | 115.9 |

図3 治療法別にみた患者の自己負担額と償還・給付額(年間)

遠いことによる交通費の負担(13.0万円)が大きい，民間保険が十分な役割を果たしえないなどの課題がある.

c. 経済的理由による治療変更

化学療法を受ける患者で，治療に影響したとする回答は6%程度であるが，そのうち4割が治療法を変更または中止したとしている(図6).

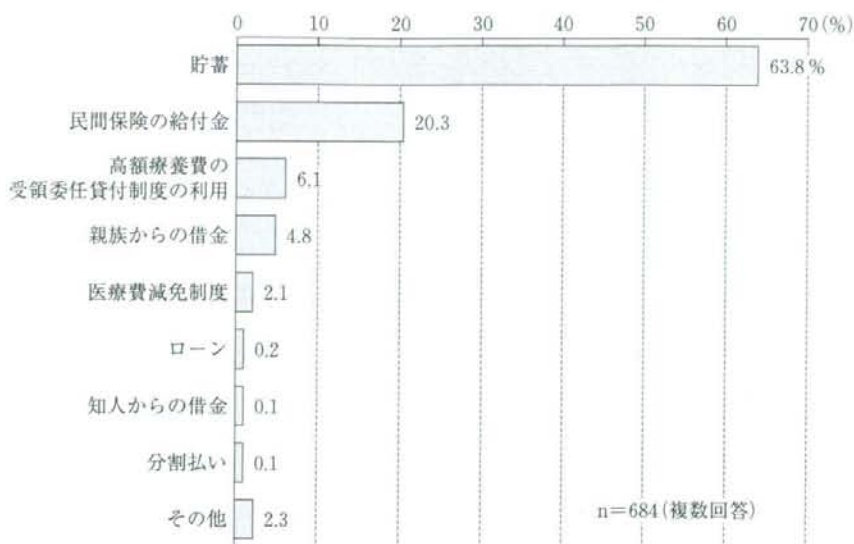一方，がん臨床医(n=691，回答率32.5%)に対する調査では，半年間のがん診療で，経済的理由によって治療を変更した経験を有する医師は81人(11.7%)，その患者数は106人(平均61.0歳)である．事前に説明した医療費は73.8
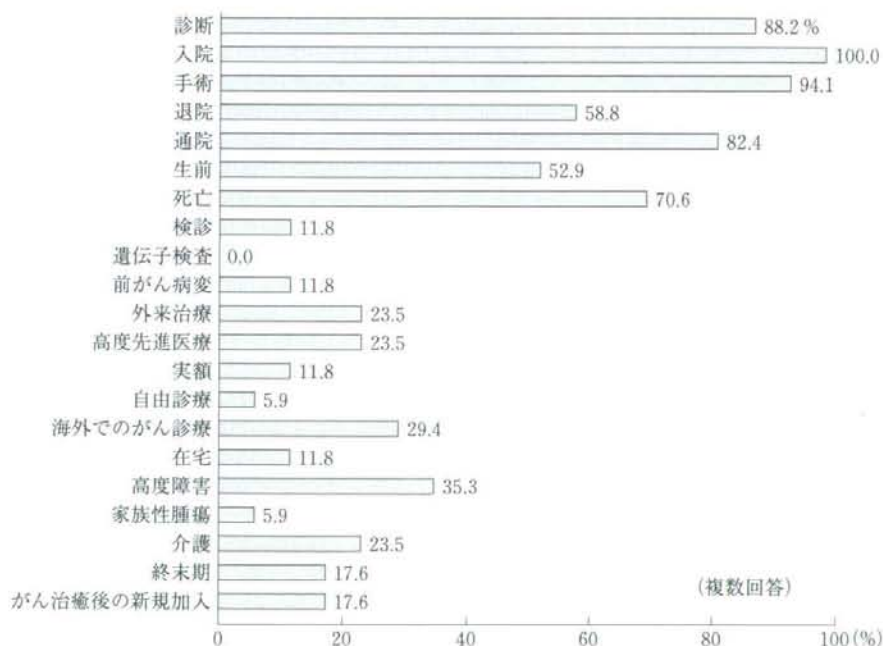
図 4　化学療法を受ける患者の自己負担金支払いの原資



図 5　民間がん保険で給付対象となる項目 (民間がん保険会社 17 社)

万円，変更後は 15.4 万円である．

　この結果から，経済的理由によって治療を変更する患者の割合は 1 ％以下 (入院 0.83 ％，外来 0.05 ％) と推計されるが，患者・家族と，治療にあたる担当医師などの苦悩は大きいと思われる．

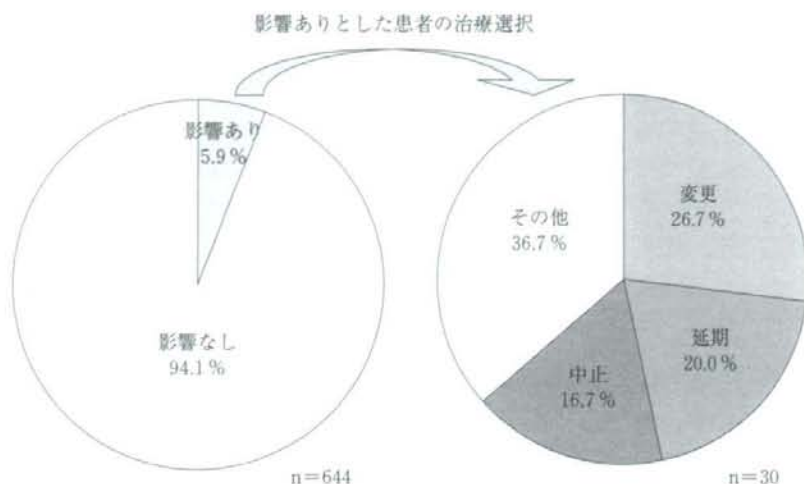　今後，スピードアップする技術進歩によって，がん患者には更なる福音がもたらされる一方，

影響ありとした患者の治療選択



図6　化学療法を受ける患者の経済的負担による治療への影響

今よりも重い経済的負担が要求されることになる恐れがある. 医療の進歩をあまねく患者に届け, 患者中心のがん医療を展開するには, 質, 効率, 安全の確保とともに, 患者負担を最小限とする創意工夫が欠かせない.

患者負担を最小化するには, 臨床現場での配慮, 現行制度の弾力的運用, 制度の抜本的改革の3つのレベルで, 実現可能な方策が検討されなければならない. 臨床現場での配慮としては, 検査や投薬の適正化, ジェネリック医薬品の使用, 入院適応の厳格化, 在院日数の短縮, 経済面に関するインフォームド・コンセントの徹底, 一般患者が経済的問題を気軽に相談できる窓口の設置など, 様々ある.

### d. がん患者の経済的負担感

がん患者が支払う自己負担額と, 意識にのぼる経済的な負担感とは必ずしも一致しないと考えられる. このため, 患者の自己負担額を軽減することとともに, 経済的負担感を軽減することもまた重要である. これには, がん患者の家計・所得水準や, がん医療に対する思い入れの程度などが影響する可能性がある.

前者について, 総務省家計消費状況調査に準じて設定した調査[1]を実施してみると, 世帯年収, 貯蓄額, 世帯借入金・未払い残高とも, 一般国民における分布と大差はなく, 世帯年収は

700万円未満が7割, 個人収入は500万円未満が8割を占める.

患者の経済的負担感(n=1,419)は10段階のVAS(視覚評価法)でみると, 平均は5.3とほぼ中程度であるが, 非常に重い(回答者の12%)から, 負担感は全くない(6%)まで分散が大きい. 収入・資産と, 負担感に有意な関係はみられなかった.

一方, がん患者のQOLをEuroQol(EQ-5D)で把握し, がん患者の経済的負担感を構成する要因に関する階層的重回帰分析を行うと, 窓口での外来費用や交通費によって負担感が増すことがうかがえる. 不安・ふさぎ込みがある, 家族に迷惑をかけていると思う場合においても, 負担感が増すことが判明した. 患者負担を最小化する臨床現場での配慮の一つとして, 患者のQOLを改善することの意味は大きいと思われる.

### e. 経済面の説明と同意

担当医が, 臨床面だけでなく, 経済面についても十分な説明行うことは, インフォームド・コンセントを徹底するという意義に加え, がん患者の経済的負担感を軽減する意義も少なくないと考えられる. がん患者に対する調査[4]では, 医療側から費用に関して'十分な説明を受けた'とする回答は1/4にすぎず, 過半数は'説明が

なかった'としている.

　一方, がん臨床医に対する調査でも, 経済的負担についての説明を, '必ずする'または'たいていする'との回答は1/4であり, 過半数は'説明をあまりしない'としている.

　このように, 経済面の説明は極めて不十分な状況にあることから, 費用に関するデータベースの整備や, 患者説明を支援するツールの開発は喫緊の課題と考えられる. そこで, 患者説明を支援するツールとして, 医師向けの費用ナビゲーション・システムの開発を進めており, 最近, その試作品が完成した.

　これは, 診療支援のパソコン画面に, 患者の性・年齢, 保険の種類, がんの部位, ステージ, 転移の有無, 治療法などを入力(選択)することで, 標準的な治療における平均的な医療費(自己負担額)が表示されるものである. この画面を参考にすれば, 多忙な臨床現場においても, 患者に経済面の必要な説明を行うことが可能になると考えられる.

## 2. がんの医療費

### a. 国民医療費に占めるがん医療費

　平成17年度のがんの医療費は, 2兆5,748億円で, 一般診療医療費の10.3%を占める.

　部位別の医療費は, 厚生労働省の'国民医療費'には公表されていないので, 患者調査, 社会医療診察行為別調査により推計した. 総数では, がん医療費に占める割合が高いのは, 肺癌(12.0%), 胃癌(11.1%), 結腸癌(9.8%), 乳癌(8.8%), 肝癌(7.2%), 直腸癌(5.6%)などの順である.

　男女別にみると, 男性では, 肺癌(14.8%), 胃癌(13.1%), 結腸癌(9.1%), 肝癌(9.0%), 前立腺癌(8.2%)などの順, 女性では, 乳癌(19.3%), 結腸癌(10.6%), 肺癌(8.6%), 胃癌(8.6%), 子宮癌(5.8%)などの順である.

### b. 我が国の cost of cancer

　がん医療の経済的な意味は, cost of cancer でみることができる. cost of cancer は, がんの医療費(直接費用)と, がんの罹患や死亡による逸失利益(間接費用)の合計である[5]. これは, が

ん対策の投資効果と, がん医療の進捗状況を経済面から評価する指標であり, 効果的ながん医療の推進と, これに必要な財源を確保するための基礎資料といえる.

　逸失利益は, がんの罹患(morbidity cost), 死亡(mortality cost)で生じる. 本来得られるはずの生産性(賃金嫁得額)の経済的損失として算定する. がんで生じる痛みや苦悩の代価としての精神的・社会的費用は推計が容易でないため, 間接費用には含めないことが多い. がんの医療費(直接費用)は, 抑制すべき(財政当局)と, 増やすべき(医療提供側)との相反する立場があるが, がんによる逸失利益の削減については異論はないと考えられる.

　我が国の cost of cancer を, 人口動態調査, 国民医療費, 患者調査, 国勢調査, 労働力調査を用いて算定すると, 平成17年の場合, 9兆9,179億円と推計される. 内訳は, 医療費が2兆5,748億円, 入院および外来受診による逸失利益が5,563億円, 早期死亡による逸失利益が6兆7,868億円である.

　部位別にみると, 肺癌は, 医療費が3,101億円, 療養による逸失利益が735億円, 死亡による逸失利益が1兆2,238億円で, 合計1兆6,074億円となり, 最も高額である. 胃癌は, 各2,856億円, 735億円, 1兆300億円で, 合計1兆3,891億円であり, 肺癌に次いで高額である. その他主要な部位の cost of cancer をみると, 肝癌が9,912億円, 結腸癌が7,970億円, 直腸癌が4,984億円, 乳癌が5,597億円, 前立腺癌が2,709億円, 子宮癌が2,108億円などである.

　がんとともに, 我が国の三大死因である心疾患, 脳血管疾患について同様に試算を行うと, 各3兆4,423億円, 4兆1,028億円となる. 心疾患, 脳血管疾患と比較してみても, がんの逸失利益, とりわけ, 早期死亡による逸失利益は群を抜いて多いことがわかる. 第3次対がん総合戦略で示された, 死亡率の2割削減という目標の達成は, 必要性も緊急性も極めて高いといえる.

　がんの逸失利益を最少化するには, がんの予防, 早期発見と早期治療, 有効な治療法の開発

とともに, 良質で効率的ながん治療の推進が欠かせない. がんによる社会的損失を減少させるためには, 有効ながん対策であれば, 10兆円からの巨額の資源投入を行うことも社会経済的に許容されうることが示唆される.

## 3. がん医療の経済分析

### a. 経済分析の手法

がんの臨床医を対象に, がん医療の経済分析に関する意識調査(n＝1,703, 回答率24.3％)を実施したところ, がん医療を評価する場合, 臨床面, QOL面, 経済面の重要度は, 全体を100％として, 各59.0％, 26.5％, 14.5％(平均値)という結果であった. そして, 将来は, これらは44.6％, 35.5％, 19.9％になることが望ましいと回答していた[6]. 臨床面と, QOLプラス経済面とが, 半々の重要度をもつことになる.

医療の経済評価は, 医療に投じられた資源, すなわち, 人, 物, サービスまたはそれらが換算された費用と結果とのバランスを評価するものであり, 代表的な分析法として, 費用便益分析(cost-benefit analysis: CBA), 費用効果分析(cost-effectiveness analysis: CEA), 費用効用分析(cost-utility analysis: CUA)の3つがある. 医療の経済分析は, 医療費の抑制を目的にしたものではなく, 医療の無駄や判断ミスを防ぎ, より質の高い医療を実現するための意志決定の補助手段である.

### b. 費用便益分析

がん治療への資源投入量と得られる成果とのバランスシートを明らかにするには, 入口と出口をともに貨幣で比較する, 費用便益分析が有用である. そこで, 主要な7種のがんについて, がん検診から確定診断, 各種の治療を経て, 回復または死亡に至る複雑な臨床経過を類型化し, Markovモデルに準じたシステムモデルを開発した[6].

モデルのパラメータには, 罹患数, 死亡数, がん発見時のstage分布, stage別の治療法の選択, 5年生存率, 進行の確率など, 渉猟しうる各種のデータを用いた. そして, がん診療に係る生涯医療費を費用, 生存期間における労働生産性(賃金稼得額)を便益として, 費用便益分析を行った. 一部のデータはばらつきが大きかったが, 有理Bezier曲線による補正を行うことで, より現実的なモデルの構築が可能となった.

モデルからは, がん治療のstage別, 治療法別, 転帰別に, 我が国の患者数, 期待生存年, QALYs(quality-adjusted life years)当たり医療費の増分, 費用便益比などが算出される. また, 近い将来にがんの罹患率や死亡率(5年生存率)が変化(改善)した場合の, 費用便益比の変化, PYLL(potential years of life lost)の変化などのシミュレーションが可能となる.

その結果, 例えば5年生存率が1％改善すると, 男性の胃, 肺, 大腸, 前立腺癌の費用便益比は各1％, 2.5％, 1.6％, －0.6％増加する. 生存率の改善による費用便益比の増加幅は胃, 乳房, 子宮癌よりも肺, 大腸癌で大きくなる. また, 罹患率の変化による費用便益費の将来推計を行うと, 大腸でその減少幅が大きいことがわかる.

## おわりに

がん対策基本法には, 患者に等しく適切ながん医療を提供することが謳われており, 患者の身体的, 精神的な悩みに加え, 経済的な悩みにも十分な対応をしなくてはならない. 技術進歩などに伴う高額な薬剤・機器の導入によって, 患者の経済的な負担は更に大きなものになる恐れがある. がん医療の経済分析は, 患者の経済的負担を最少化しつつ, 優れたがん医療を実践するための意志決定の補助手段としてその重要性が増している.

また, 患者数増加や技術革新などによって, がん医療には今後も多くの医療資源が消費されることが予想される. 社会からは, 莫大な資源投入が正当化されるための根拠(evidence)とそれに相応しい結果(outcome)が求められている. がん医療の長足の進歩に見合う医療資源を引き続き確保するには, がん医療の経済貢献を明らかにするなど, 国民的合意を促すためのわかりやすい説明を丁寧に行っていく必要があると思われる.

■文　　献

1) 濃沼信夫：厚生労働科学研究費補助金　第3次対がん総合戦略研究事業「がんの医療経済的な解析を踏まえた患者負担最小化に関する研究」平成19年度総括・分担研究報告書, 2008.
2) 濃沼信夫：厚生労働科学研究費補助金　第3次対がん総合戦略研究事業「がん医療経済と患者負担最小化に関する研究」平成18年度総括・分担研究報告書, 2007.
3) 濃沼信夫：厚生労働科学研究費補助金　第3次対がん総合戦略研究事業「がん医療経済と患者負担最小化に関する研究」平成17年度総括・分担研究報告書, 2006.
4) 濃沼信夫：がん患者の経済的負担について. 血液・腫瘍科　53(4): 427-435, 2006.
5) Brown ML, Yabroff KR: Economic impact of cancer in the United States. In: Cancer Epidemiology and Prevention, 3rd ed (ed by Schottenfeld D, Fraumeni JF), p 202-214, Oxford University Press, New York, 2006.
6) 濃沼信夫：がん対策の費用対効果. Geriatric Medicine　42(5): 579-586, 2004.

## REVIEW ARTICLE

Naoyuki Okamoto

# A history of the cancer registration system in Japan

**Abstract** In Japan, the first actual survey of morbidity from cancer was conducted by Dr. Mitsuo Segi in Miyagi Prefecture from 1951 to 1953. Population-based cancer registries were started in 1957 in Hiroshima and 1958 in Nagasaki for the follow-up of survivors of the atomic bombings. Public population-based cancer registries, under the cancer control programs of the prefectural governments, were started in Aichi and Osaka prefectures in 1962. After the Law on Health and Medical Services for the Aged was enacted in 1983, population-based cancer registries were initiated promptly in many prefectures. As of 2007, there were population-based cancer registries in 35 of Japan's 47 prefectures and in one city. The Research Group for Population-Based Cancer Registration in Japan was organized by Dr. Isaburo Fujimoto, the chairperson in 1975, with a grant-in-aid from the National Cancer Research Promotion Program. This research group has continued until now and has been making continuous efforts. To promote standardization of the registry process and to improve the quality of registry data, the Japanese Association of Cancer Registries (JACR) was organized in 1992. The Japanese government Third-Term 10-Year Comprehensive Strategy for Cancer Control was launched in 2004, with the slogan "Targeting a drastic reduction in cancer morbidity and mortality." This strategy includes not only promoting cancer research but also promoting cancer prevention, improving the quality of cancer care, promoting social support systems, and promoting effective systems for monitoring cancer incidence and survival.

**Key words** History · Cancer registry · Population-based · System · Japan

N. Okamoto (✉)
Kanagawa Cancer Center, 1-1-2 Nakao, Asahi-ku, Yokohama 241-0815, Japan
Tel. +81-45-391-5761 (ext. 4030); Fax +81-45-366-3157
e-mail: okamoto@gancen.asahi.yokohama.jp

## Introduction

Cancer has been the leading cause of death in Japan since 1981. In spite of the various steps taken by the Ministry of Health and Welfare in Japan to reduce cancer incidence and mortality, the cancer death toll now exceeds 300 000 per, accounting for more than 30% of all deaths in the country. A national registry for monitoring the morbidity and mortality of cancer is an essential support for strategies and policies to control the disease. Five decades ago, several prefectural governments launched population-based cancer registries in cooperation with prefectural medical associations and cancer centers. Though these registries have been of great help, no surveillance systems have been established for the monitoring of high-quality data on cancer incidence at the national level.

Here we review the history of the Japanese cancer registration system in the hope of activating new cancer surveillance systems and standardizing the registration process further.

## Establishment and progress of population-based cancer registries in Japan

Modern-day cancer statistics were first compiled on a large scale in London in 1728. Two centuries later, physicians and administrators in Hamburg conducted a general survey of cancer (in 1900) and established a population-based cancer registry[1] (in 1929).

The first survey of cancer morbidity in Japan was conducted from 1951 to 1953, when Dr. Mitsuo Segi studied a residential population living within a defined area in Miyagi Prefecture. Segi collected data on all of the cancer patients in all of the hospitals in the prefecture, as well as the death certificates for all of the persons in the prefecture who died of cancer (the death certificates were kept at 15 prefectural public health centers). He then compiled lists from these two sources of data, checking the names and addresses of all of the people by hand to eliminate duplications. In 1954,

the results of the first year's survey were published in the *Tohoku Journal of Experimental Medicine*[2] in English (the first such report from Japan ever to be published). Next, a report on the 3-year survey from 1951 to 1953 was published in the *Journal of the National Cancer Institute*,[3] in 1957. Segi adopted a new system that was used in the United States population for reporting and analyzing cancer incidence (so-called age-adjusted incidence) in Japan, and compared the cancer incidences between the two populations. Later, he and colleagues used the world population in 1950 as a base population for an international comparison of incidence and mortality rates.[4] After an actual 3-year survey, the first population-based cancer registry for epidemiological purposes was established to collect data on cancer patients. The new registry was set up in 1959 within the Department of Public Health at the Tohoku University School of Medicine, with the support of a grant from the National Cancer Institute of the United States.[5, 6]

In 1957 and 1958, respectively, the cities of Hiroshima and Nagasaki established population-based cancer registries, in cooperation with local medical associations, to follow-up survivors of the atomic bombings of the two cities. These special-purpose registries have been operated by the Atomic Bomb Casualty Commission (ABCC)–Radiation Effects Research Foundation (RERF) to investigate the long-term effects of atomic bomb radiation on human health.[7]

In 1962, the prefectural governments of Aichi and Osaka, in cooperation with prefectural medical associations, established population-based cancer registries.[8] In ensuing years, this type of population-based cancer registry spread to Kanagawa (1970), Tottori (1971), Kochi (1973), and Chiba (1975) prefectures. Around the time when the Law on Health and Medical Services for the Aged was enacted, in 1983, population-based cancer registries were operating in 14 prefectures throughout Japan and in two cities. The new law recommended that all prefectural governors establish cancer registries as a support for the planning of cancer control programs and the assessment of cancer screenings. Registries were established in 19 prefectures promptly after the law was enacted. As of 2007, there were population-based registries in 35 of Japan's 47 prefectures and one city (see column headed "Prefecture/city" in Table 1).

## Japan's contribution to the establishment of the International Association of Cancer Registries (IACR)

At the sixth International Congress of the International Union against Cancer (UICC), held in Tokyo in October 1966, Dr. Segi and Dr. Takamune Soda invited 47 people from 26 countries to take part in a satellite meeting on cancer registries, including 17 physicians then involved in the registries in Japan. During the meeting, Drs. William Haenszel and Sidney J. Cutler proposed the foundation of an international association for the exchange of information and the promotion of cancer registries worldwide. Not everyone agreed with the proposal or was convinced of the

need for such an association. After clearing many roadblocks and difficulties entailed in the forming of an international association, a subcommittee, set up by Segi and others, concluded that an international association would encourage the development of cancer registries. The objective of the association would not be to compete with or oppose the World Health Organization (WHO), the International Agency for Research on Cancer (IARC), or the UICC, but to support their activities. Shortly afterwards, the International Association of Cancer Registries (IACR) was established. The physicians involved credited the establishment of the association in large measure to the foresight and industry of Dr. Segi.[9]

The first annual meeting of the IACR was held in 1970 in Houston, USA, chaired by Dr. Cutler. The sixth annual meeting was held in 1984 in Fukuoka, Japan, chaired by Dr. Takao Shigematsu.

## History of national cancer control programs in Japan

Japan's first nationwide cancer control surveillances were the three National Cancer Surveys conducted by the Ministry of Health and Welfare in 1958, 1960, and 1962. These were followed by the first national cancer program, in 1966. The surveys and program shared five common goals: to promote cancer education, to promote cancer screening, to establish cancer-oriented medical facilities, to train healthcare providers specialized in cancer treatment, and to promote cancer research. Regrettably, the cancer registration system was not included among these goals. Fourth and fifth National Cancer Surveys were conducted in 1979 and 1989, respectively, but no cancer registry system materialized.

The Japanese government implemented a Comprehensive 10-Year Strategy for Cancer Control (1984–1993) and a New 10-Year Strategy to Overcome Cancer (1994–2003) as nationwide programs to contend with cancer. In 2004, it launched the Third-Term 10-Year Comprehensive Strategy for Cancer Control to promote cancer research and disseminate high-quality cancer medical services. The chief aim was to "drastically reduce cancer morbidity and mortality." This latest strategy includes measures not only to promote cancer research but also measures to prevent cancer, improve the quality of cancer care, promote social support systems, and establish more effective systems for monitoring cancer incidence and survival (see Table 1, column headed "National cancer programs").

## Activities of the Research Group for Population-Based Cancer Registration and the establishment of the Japanese Association of Cancer Registries (JACR)

In 1975, Dr. Isaburo Fujimoto organized the Research Group for Population-Based Cancer Registration (hereafter, the Group) in Japan with funds from a grant-in-aid under the National Cancer Research Promotion Program.

**Table 1.** History of cancer control programs in Japan in terms of cancer registration

| Years cancer registration started | Prefecture/city | Research Group activities | National cancer programs | Laws, guidelines, conferences |
|---|---|---|---|---|
| 1950s | Miyagi (1951–1953 survey) Hiroshima City (1957) Nagasaki City (1958) Miyagi (1959) | | • The First National Cancer Survey (1958) | |
| 1960s | Aichi, Osaka, Hyogo | • Subsidy for cancer research by Ministry of Health and Welfare started | • The Second National Cancer Survey (1960) • The Third National Cancer Survey (1962) • First cancer program implemented (1966) | • International Association of Cancer Registries (IACR) founded (1966) |
| 1970s | Yamagata, Chiba, Kanagawa, Kochi, Tottori, Hokkaido | • Research Group for Population-Based Cancer Registration established (1975–1980; chairperson, Dr. Fujimoto) | • The Fourth National Cancer Survey (1979) | • First annual meeting of IACR, Houston, United States (1970) |
| 1980s | Fukui, Nagasaki Prefecture, Saga, Yamaguchi, Shiga, Toyama, Okinawa, Kyoto, Aomori, Nara | • Research Group for Population-Based Cancer Registration established (1981–1986; chairperson Dr. Fukuma) • Research Group for Population-Based Cancer Registration established (1987–1992; chairperson Dr. Fujimoto) | • Comprehensive 10-Year Strategy for Cancer Control (1984–1993) • The Fifth National Cancer Survey (1989) | • Law on Health and Medical Services for the Aged (1983) • Sixth annual meeting of IACR, Fukuoka, Japan (1984) |
| 1990s | Akita, Okayama, Niigata, Kumamoto, Iwate, Tochigi, Ibaragi, Ishikawa, Gunma, Gifu, Tokushima, Ehime, Kagoshima, Kagawa | • Japanese Association of Cancer Registries (JACR) founded (1992) • Research Group for Population-Based Cancer Registration established. (1993–1995, chairperson, Dr. Hanai) • Research Group for Population-Based Cancer Registration established (1996–2001, chairperson Dr. Oshima) | • New 10-Year Strategy to Overcome Cancer (1994–2003) | • Guidelines for confidentiality in the cancer registration scheme (1996) |
| 2000s | Hiroshima Pref. Yamanashi | • Research Group for Population-Based Cancer Registration established (2002–2007, chairperson Dr. Tsukuma) • The Japan Cancer Surveillance Research Group (2004–2013, chairperson Dr. Sobue) | • Third-Term Comprehensive 10-Year Strategy for Cancer Control (2004–2013) • Action Plan 2005 for Promoting Cancer Control (2005) | • Ethics guidelines for epidemiological studies (2002) • Health Promotion Law (2003) • Private Information Protection Law (2004) • Guidelines for the appropriate handling of personal information by medical and care-related enterprises (2004) • Guidelines on confidentiality in cancer registries (revised, 2005) • Cancer Control Act implemented (2007) |

The meetings of this Group are held annually. This research group has been continuing its work until now, under the direction of five successive chairpersons – Fujimoto himself, followed by Drs. Seigo Fukuma, Aya Hanai, Akira Oshima, and Hideaki Tsukuma. Here we cite five achievements of the Group to promote the standardization of registration procedures.

• First, the Group has been responsible for two major publications (the *Guidelines for population-based cancer registration in Japan*,[10] published in 1975 and the *Standardized methods of population-based cancer registries*,[11] published in 1977) and has translated a third into Japanese (*Cancer registration: principles and methods*, edited by Jensen et al. (translated in 1978). The *Guidelines*

*for population-based cancer registration in Japan* have been revised three times, in 1977, 1986, and 1999.[12]

- Second, the Group has widened the scope and coverage of the various registries open in Japan, bringing them closer to completion.
- Third, the Group has prepared annual cancer statistics on items such as cancer incidence and survival rates by cancer type, with data from all of the member registries.
- Fourth, the Group has published the *Guidelines for confidentiality in the cancer registration scheme* [13] (in 1996).
- Fifth, twice a year, the Group has provided training course schedules and lectures for tumor registrars at the National Cancer Center. It also produces Japanese translations of the SEER program self-instruction manuals for tumor registrars, with permission from the Surveillance, Epidemiology, and End Results (SEER) program.
- Sixth, the Group has promoted the use of registry data for epidemiological research and for the planning and evaluation of the cancer control programs of the national government and municipal governments in Japan.

Population-based cancer registries have been introduced in many prefectures, beginning before the enactment of the Law on Health and Medical Services for the Aged in 1983. Information in these registries is provided on a voluntary basis by doctors and medical institutions, under the jurisdiction of the prefectures. However, the data collected and the systems used to manage the data differ from prefecture to prefecture. The Japanese Association of Cancer Registries (JACR) was organized in 1992 to promote standardization of the registry process and to improve the quality of registry data. The JACR holds annual scientific and procedural meetings to exchange information and provide training for newcomer registrars. Association members introduce their registries and staff on the JACR website (http://www.cancerinfo.jp/jacr/). The association sends its members a JACR monograph once a year and a newsletter every 6 months (see column headed "Research Group activities" in Table 1)

## Changes in registry items and data management systems

Figure 1 shows a typical population-based cancer registry system in Japan. The doctors at hospitals and clinics send cancer reports to the medical association of their prefecture. The medical association, in turn, bundles the reports and sends them to a cancer registry central office each month. Another department in the prefectural government, meanwhile, sends copies of all of the death certificates issued over the past month in the prefecture to the same central office. Personnel in the central office collate all of the cancer reports and death certificates, eliminating duplicate registrations.

In the first cancer survey carried out by Segi,[2] the following information was collected for each patient: name,
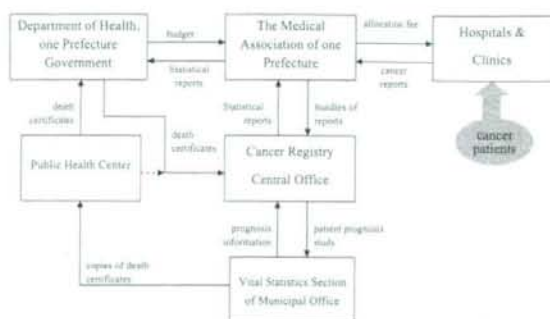


**Fig. 1.** Typical system of a population-based cancer registry in Japan

address, sex, age, date of first symptom, diagnosis, cancer site, and the method used to confirm the cancer diagnosis (microscopic, surgical, by X-ray, other). Once collected, the data were managed by hand using a card system or a hole-sort card system. In the 1960s, a selector machine system using standard cards with 80 columns was introduced. Each piece of information on a cancer case was coded as a number (from 0 to 9) and punched or marked at one point in one column (or at two points in one column to represent alpha-numeric characters in English). As only 80 columns were available per card, the data to be registered in the cancer registries had to be selected very carefully.

In the 1970s, some municipal governments and hospitals began using general computers. The registries at Hiroshima, Nagasaki, and Osaka were computerized forthwith. The conventional media for storing data in those days were paper tape, 80-column cards, open-reel tapes, and 8-inch floppy disks. As time-sharing systems (TSS) had yet to be adopted, all operations of the cancer registry were performed by batch processing. Then, in about 1980, the Osaka Population-Based Cancer Registry developed a semicom-puterized collation method for linking records together using a general computer. This new method has been helpful not only for the routine task of registration but also for linking with files on other populations outside the registry.[14-16]

Now that we have entered the first decade of the twenty-first century, we can cheaply purchase small personal computers (PCs) with the same capabilities as those of the mainframe computers of earlier decades. With advances in computer technology, Chinese characters can now be input directly as data. Many offices operating population-based cancer registries have changed their registration systems to take advantage of this advance.

In 2004, the Japan Cancer Surveillance Research Group (chaired by Dr. Tomotaka Sobue) introduced standard procedures for cancer registries in Japan by selecting a set of 25 standard items for every cancer registry to collect and a standard registry system based on a PC platform[17] (see Table 2)

Table 2. Changes in data items collected at cancer registries in Japan

| Item collected | At beginning of cancer survey | At beginning of cancer registry | Standard items in standard registry |
|---|---|---|---|
| Name of hospital | | O | O |
| Patient's ID no. in hospital | | O | O |
| Patient's name | O | O | O |
| Sex | O | O | O |
| Age | O | | |
| Birth date | | O | O |
| Address of patient | O | O | O |
| Date of first symptom | O | | |
| Diagnosis | O | O | O |
| Date of diagnosis | | O | O |
| Site of cancer | O | O | |
| Laterality | | | O |
| Primary site | | | O |
| Histology | | O | O |
| Extension of disease | | O | O |
| Method of diagnosis | O | O | O |
| Screening or first symptoms | | O | O |
| Surgery of primary site | | O | O |
| Laparo/thoracoscopic surgery | | | O |
| Endoscopic surgery | | | O |
| Result of surgery | | | O |
| Date of surgery | | O | O |
| Radiation therapy | | O | O |
| Chemotherapy | | O | O |
| Immunotherapy | | O | O |
| Endocrine therapy | | | O |
| Other therapies | | O | O |
| Date of death | | O | O |
| Cause of death | | O | |
| Place of death | | O | |

O, collected item

## Protection of personal information and laws related to cancer registries

Notification of cancer cases to the population-based cancer registries in Japan is not compulsory for physicians and medical institutions, but voluntary. The Law on Health and Medical Services for the Aged enacted in 1983 was the first law to recommend that the prefectures establish cancer registries to help them with anti-cancer programs and to evaluate cancer-screening programs. The effects of this recommendation were obscure, however, and the law was withdrawn several years later. Though many provisions of this law were reintroduced in an amended law enacted in 1986, the provisions on cancer registries were dropped. Later, in 2003, population-based cancer registration was officially reintroduced as a voluntary task in the newly enacted Health Promotion Law. This law requires national and municipal governments to take steps to ascertain details of the onset of lifestyle-related diseases such as cancer and cardiovascular disease. The Cancer Control Act, approved in 2006, recognizes cancer registries as one of the most important axes of cancer control activities.

JACR and the Research Group for Cancer Registration published *Guidelines for confidentiality in the cancer registration scheme* in 1996[13] and have promoted the protection of personal information since then. The guidelines drew upon the IACR *Guidelines on confidentiality in cancer registries*. The Japanese version of these guidelines was revised in 2005. The guidelines recommend that the staff of population-based cancer registries carry out the registration tasks strictly, so as to avoid infringing upon individual rights or interests due to the loss, leakage, or other mishandling of personal information (see column headed "Laws, guidelines, conferences" in Table 1)
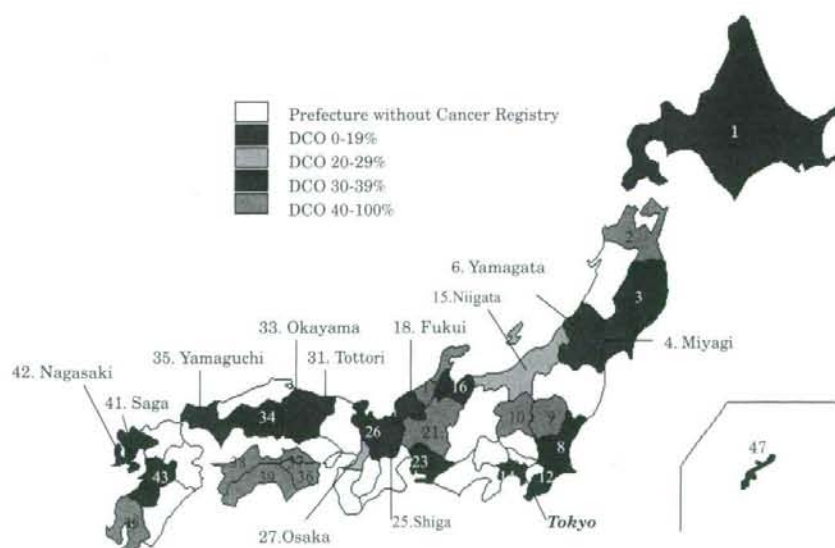
## Current and future status of cancer registries in Japan

Though most registries in Japan are conducted by prefectural governments in cooperation with prefectural medical associations and cancer centers, central offices for cancer registration management have also been established by prefectural medical associations, cancer societies, cancer detection centers, centers for health promotion, medical universities, and prefectural governmental offices. The registration systems they use have not been constructed uniformly. According to the second questionnaire survey on the status of cancer registries, conducted in 2006, the proportion of death-certificate-only (DCO) cases averaged 35.4% and ranged from 0% to 100% (see Table 3 and Fig. 2).

The Third-Term 10-Year Comprehensive Strategy for Cancer Control program was commenced in 2004. Improved

**Table 3.** Current status of population-based cancer registries in Japan

| Prefecture number | Prefecture name | Population[a] | Cancer incidence (number) | Cancer mortality (number) | DCN (%) | DCO (%) | IM ratio |
|---|---|---|---|---|---|---|---|
| 1 | Hokkaido | 5 683 062 | 20 265 | 14 634 | 36.8 | 36.8 | 1.38 |
| 2 | Aomori | 1 475 728 | 6 734 | 3 968 | 45.9 | 45.9 | 1.70 |
| 3 | Iwate | 1 416 180 | 5 878 | 3 819 | 35.7 | 35.7 | 1.54 |
| 4 | Miyagi | 2 365 320 | 11 832 | 5 360 | 14.0 | 14.0 | 2.21 |
| 6 | Yamagata | 1 239 133 | 6 817 | 3 580 | 21.9 | 12.4 | 1.90 |
| 8 | Ibaragi | 2 985 676 | 10 419 | 6 942 | 37.9 | 34.3 | 1.50 |
| 9 | Tochigi | 2 004 817 | 7 316 | 4 633 | 41.3 | 41.3 | 1.58 |
| 10 | Gunma | 2 024 852 | 6 145 | 4 755 | 61.5 | 61.5 | 1.29 |
| 12 | Chiba | 5 926 349 | 19 406 | 12 503 | 36.6 | 31.8 | 1.55 |
| 14 | Kanagawa | 8 489 932 | 27 598 | 17 570 | 33.1 | 33.1 | 1.57 |
| 15 | Niigata | 2 475 733 | 12 339 | 6 757 | 20.5 | 20.5 | 1.83 |
| 16 | Toyama | 1 120 851 | 7 191 | 3 035 | 37.6 | 37.6 | 2.37 |
| 17 | Ishikawa[b] | 1 180 977 | 3 232 | 2 983 | 47.5 | 47.5 | - |
| 18 | Fukui | 828 944 | 3 723 | 2 130 | 9.5 | 0.0 | 1.75 |
| 21 | Gifu | 2 107 700 | 6 229 | 4 918 | 45.2 | 45.2 | 1.27 |
| 23 | Aichi | 7 043 300 | 24 600 | 14 620 | 32.5 | 32.5 | 1.68 |
| 25 | Shiga | 1 342 832 | 5 430 | 2 836 | 26.7 | 15.8 | 1.91 |
| 26 | Kyoto | 2 644 391 | 7 105 | 6 602 | 30.6 | 30.6 | 1.08 |
| 27 | Osaka | 8 805 081 | 32 007 | 21 325 | 37.3 | 26.0 | 1.50 |
| 31 | Tottori | 613 289 | 3 286 | 1 751 | 26.1 | 15.3 | 1.88 |
| 33 | Okayama | 1 937 571 | 10 338 | 4 912 | 16.3 | 7.6 | 2.10 |
| 34 | Hiroshima | 2 878 915 | 19 015 | 7 272 | 37.5 | 37.5 | 2.61 |
| 35 | Yamaguchi | 1 527 964 | 5 977 | 4 420 | 35.2 | 18.4 | 1.35 |
| 36 | Tokushima | 824 108 | 2 579 | 2 260 | 80.8 | 80.8 | 1.14 |
| 37 | Kagawa | 1 029 073 | 1 734 | 2 723 | 100.0 | 100.0 | 0.64 |
| 38 | Ehime | 1 493 092 | 5 694 | 3 912 | 53.7 | 53.7 | 1.46 |
| 39 | Kouchi | 813 946 | 2 401 | 2 286 | 60.3 | 47.8 | 1.05 |
| 41 | Saga | 876 654 | 4 172 | 2 449 | 34.5 | 10.5 | 1.70 |
| 42 | Nagasaki | 1 516 523 | 8 926 | 4 264 | 10.8 | 10.8 | 2.09 |
| 43 | Kumamoto | 1 854 055 | 7 790 | 4 855 | 37.7 | 37.7 | 1.60 |
| 46 | Kagoshima | 1 786 194 | 6 739 | 4 914 | 73.1 | 73.1 | 1.37 |
| 47 | Okinawa | 1 318 220 | 3 838 | 2 411 | 37.6 | 37.6 | 1.59 |
| - | Average | 2 488 452 | 9 586 | 5 981 | 39.2 | 35.4 | 1.62 |

[a] Population in 2005 census
[b] Limited sites only

**Fig. 2.** Prefectures without cancer registries and percentages of death-certificate-only (DCO) cases by prefecture



Prefecture without Cancer Registry
DCO 0-19%
DCO 20-29%
DCO 30-39%
DCO 40-100%

6. Yamagata
15. Niigata
33. Okayama   18. Fukui
35. Yamaguchi   31. Tottori
42. Nagasaki
41. Saga
4. Miyagi
47
25. Shiga
Tokyo
27. Osaka

data for cancer registries are essential for the assessment of cancer incidence, as cited by the program. To improve the quality of the data, the Japan Cancer Surveillance Research Group is now taking steps to standardize the procedures for population-based cancer registries. Though the standardization of population-based cancer registries has dramatically improved through the activities of this Research Group, there are still problems with cancer registries that must be solved soon. Because legal support is necessary, the JACR has issued a declaration requesting a legal basis for reporting to cancer registries through the enactment of a Cancer Registry Law (tentative name). There are hopes that this new law, if enacted, will markedly improve the proportions of DCN and DCO cases, and the incidence/mortality (IM) data in cancer registries in Japan.

## References

1. Wager G (1991) History of cancer registration. In: Jensen OM, Parkin DM, Maclennan R, Muir CS, Skeet RG (eds) Cancer registration principles and methods. IARC Scientific Publication no. 95. IARC, Lyon, pp 3–6
2. Segi M, Fukushima I, Mikami Y, et al. (1954) Cancer illness; among residents of Miyagi Prefecture, Japan, 1951. Tohoku J Exp Med 59:213–224
3. Segi M, Fukushima I, Fujisaki S, et al. (1957) Cancer morbidity in Miyagi Prefecture, Japan and a comparison with morbidity in the United States. J Natl Cancer Inst 18:373–383
4. Segi M, Fuzisaki S, Kurihara M (eds) (1960) Cancer in Japan and the world; epidemiology, statistics and geographical pathology of cancer. Shindan To Chiryo Sha, Tokyo
5. Segi M (1966) Japan, Miyagi Prefecture. In: Doll R, Payne P, Waterhouse J (eds) Cancer incidence in five continents, a technical report. Springer, Berlin Heidelberg Tokyo New York, pp 118–119
6. Aoki K, Kurihara M (1994) The history of cancer registration in Japan: contribution of Dr Mitsuo Segi. Cancer Surv 19:563–570
7. Monzen T, Wakabayashi T (1986) Tumor and tissue registries in Hiroshima and Nagasaki. Gann Monograph on Cancer Res, no. 32:29–40
8. Hanai A, Fujimoto I, Tsukuma H, Oshima A (1999) Cancer registration and cancer trends in Japan. In: Sato S, Miller MW, et al. (eds) Proceedings of the International Symposium "Cancer Epidemiology and Control in the Asia-Pacific Region." International Center for Medical Research, Kobe, pp 80–88
9. Haenszel W (1987) Segi M 1908–1982, Changing cancer pattern and topics in cancer epidemiology, in memory of Professor Mitsuo Segi. Japanese Cancer Association/Japan Scientific Societies, Tokyo; Plenum, New York
10. Fujimoto I (ed) (1975) Guidelines for population-based cancer registration in Japan (in Japanese). The Research Group for Population-Based Cancer Registration in Japan, Osaka
11. Shigematsu T, Yamasaki M, Hanai A, Sakagami F (eds) (1977) Standardized methods of population-based cancer registry (in Japanese). The Research Group for Population-Based Cancer Registration in Japan, Osaka
12. Hanai A, Oshima A (eds) (1999) Guidelines for population-based cancer registration in Japan (fourth revision; in Japanese). The Research Group for Population-Based Cancer Registration in Japan, Osaka
13. Tanaka H, et al. (eds) (1996) Guidelines for confidentiality in the cancer registration scheme (in Japanese). The Research Group for Population-Based Cancer Registration in Japan, Osaka
14. Hanai A, Fujimoto I (1993) Cancer registration in Osaka. Cancer incidence and mortality in Osaka, 1963–1989. Shinohara-Shuppan, Tokyo, pp 226–235
15. Oshima A, Sakagami F, Hanai A, Fujimoto I (1979) A method of record linkage. Environ Health Perspect 32:221–230
16. Fujimoto I, Hanai A, Oshima A (1984) Record linkage in the Osaka Cancer Registry and its application in cancer epidemiology. In: Blot WJ, Hirayama T, Hoel DG (eds) Statistical methods in cancer research. Gann (Suppl), Tokyo, pp 129–141
17. Sobue T, Tsukuma H, Okamoto N, Ajiki W (2007) Handbook on population-based cancer registration in Japan (fifth revision; in Japanese). The Japan Cancer Surveillance Research Group, Tokyo

# Anxiety and prevalence of psychiatric disorders among patients awaiting surgery for suspected ovarian cancer

Akiko Sukegawa[1], Etsuko Miyagi[1], Mikiko Asai-Sato[1], Haruya Saji[1], Ken Sugiura[1], Takehiko Matsumura[2], Atsushi Kamijyo[2], Yoshio Hirayasu[2], Naoyuki Okamoto[3] and Fumiki Hirahara[1]

*Departments of [1]Obstetrics and Gynecology and [2]Psychiatry, Yokohama City University School of Medicine, [3]Division of Cancer Prevention and Cancer Control, Kanagawa Cancer Center Research Institute, Yokohama, Japan*

## Abstract

*Aim:* The goal of the current study was to determine the anxiety level and prevalence of psychiatric disorders among patients awaiting surgery for ovarian tumors. Also analyzed were the predictive factors for psychiatric disorders and changes after surgical diagnosis.

*Methods:* Patients who underwent surgery for ovarian tumors were examined before and after surgery with the MINI International Neuropsychiatric Interview, the Spielberger State-Trait Anxiety Inventory (STAI) and the Mausley Personality Inventory (MPI). Participants diagnosed with cancer were examined a third time after being given an explanation about whether or not adjuvant chemotherapy was required.

*Results:* Twenty-seven participants completed the study and were analyzed. Nine (33.3%) of these 27 participants were diagnosed as having adjustment disorder. There were no differences in the demographic data, STAI trait anxiety score and MPI score between the participants with or without adjustment disorder. At the pre-surgical interview, the STAI state anxiety score of the participants was high (49.5 ± 10.30). After pathological examination of the tumors, it was found that 12 patients had cancer (malignant group) and 15 patients had a benign tumor (benign group). At pre-surgery, the prevalence of adjustment disorder and the level of anxiety in the benign group were similar to those in the malignant group. There was a second surge of anxiety in patients who needed chemotherapy.

*Conclusion:* The above findings demonstrate that patients with suspected ovarian cancer experience a high level of anxiety. Physicians should be aware of the risk of adjustment disorder in these patients. Additionally, ovarian cancer patients need psychological assessment during the course of treatment.

**Key words:** adjustment disorder, anxiety, ovarian tumor, pre-surgery, psychiatric disorder.

## Introduction

The incidence of psychiatric complications has been reported to be as high as 47% among patients with malignant tumors; 32% of these are adjustment disorders and 6% are depression.[1] Visser *et al.*[2] reported that the quality of life of newly diagnosed cancer patients waiting for surgery is seriously impaired compared with the general population. Patients with suspected malignant breast tumor who were subsequently diagnosed as having a benign tumor showed the same high pre-surgical potential for anxiety as patients who were subsequently diagnosed with breast cancer.[3] Onishi *et al.*[4] reported a case of post-traumatic stress disorder (PTSD) induced by the suspicion of lung cancer.

Across studies focusing on psychiatric distress in ovarian cancer patients, between 30 and 70% of ovarian cancer patients reported moderate to severe levels of

543

anxiety,[5-9] and one-fifth of patients reported symptoms suggestive of clinical depression.[10] A specific feature of ovarian tumors is the uncertainty of the pre-operative diagnosis. Ovarian tumors cannot be definitively differentiated as benign or malignant using a combination of ultrasonography, magnetic resonance imaging (MRI) and tumor markers for pre-surgical diagnosis. On the basis of intraoperative findings, surgical treatment becomes radical for ovarian cancer, but consists of only salpingo-oophorectomy for benign ovarian tumors. Thus, most ovarian tumor patients receive an indistinct explanation about their diagnosis and operation before their surgical procedure. In our experience, many ovarian tumor patients express anxiety or fear about the possibility of ovarian cancer in the interval before surgery. However, little research has focused on pre-surgical psychiatric complications and anxiety in patients with ovarian tumor.

Our objectives were to determine the level of anxiety and the prevalence of psychiatric disorders caused by the diagnosis of ovarian tumor in patients awaiting surgery. Additionally, the predictive factors for psychiatric disorders and post-surgical change when the patients received their diagnosis of cancer or benign tumor were statistically analyzed.

## Methods

The present study was conducted prospectively in the Department of Obstetrics and Gynecology at Yokohama City University Hospital. Patients awaiting surgery for ovarian tumor were recruited to participate in this study. Inclusion criteria were surgery for ovarian tumor as the first treatment in which it was not known whether the tumor was benign or malignant, age from 20 to 80 years, ability to speak and read Japanese, and willingness to participate in the study after informed consent. We excluded the following patients: those with psychiatric complications, those diagnosed with ovarian cancer with positive cytological findings upon examination of the ascites, those scheduled for laparoscopic surgery or emergency surgery, those with poor Eastern Cooperative Oncology Group performance status[11] (ECOG PS 2 or higher), and those with confirmed pregnancy. Approval of this study was given by the Research Ethics Committee of Yokohama City University.

The patients received information about the study by way of an explanatory leaflet when they were scheduled for surgery at the outpatient clinic. Participants who gave written consent were interviewed one day before the surgery after they were hospitalized (Time 1 [T1]). Seven to 14 days after the first interview, depending on the patient's post-surgical condition, the patient was assessed again (Time 2 [T2]) after she received her preliminary diagnosis from her physician based on the intraoperative findings. Patients who were diagnosed as having cancer were interviewed a third time after an explanation of their final diagnosis, prognosis, and necessity of adjuvant chemotherapy or not (Time 3 [T3]) (Fig. 1).
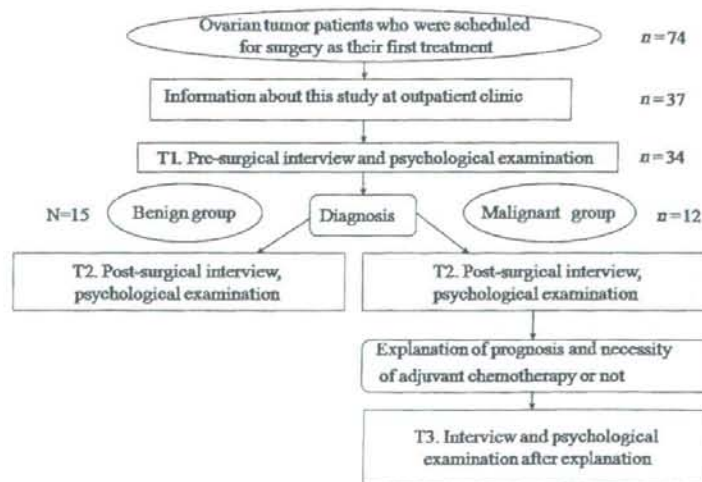


Figure 1 Flowchart of the present study. T1, first interview (pre-surgery); T2, second interview (post-surgery after confirmation of the preliminary diagnosis); T3, third interview (after the explanation about the prognosis and necessity of adjuvant chemotherapy or not).

All interviews were conducted in a private room by one researcher (A. S., a Japanese female gynecologist with psychiatric training). The first (T1) interview consisted of a semi-structured questionnaire, a structured interview to confirm whether the patient had any psychiatric disorders, and psychological examinations. The semi-structured questionnaire in the T1 interview focused on demographic data, such as past history, medical complications, marital status, perinatal history, familial history, education level, and employment status, in addition to data about the present condition, such as primary symptoms and emotional state at the time of the interviews. The second (T2) and third (T3) interviews focused on the same points as the T1 interview, except that they did not include demographic questions. Physiological data concerning the illness were collected from patients' medical records.

The structured interview in the T1, T2 and T3 interviews consisted of the MINI International Neuropsychiatric Interview, Japanese version 5.0.0 2003 (M.I.N.I.), to detect psychiatric disorders based on DSM-IV. To detect for adjustment disorder, we added four questions to the M.I.N.I. that were reported by Passik et al.[12] The abovementioned authors verified the validity of the M.I.N.I. with modifications for adjustment disorder as a way for medical staff other than psychiatrists to detect for psychiatric disorders including adjustment disorder.[12]

The psychological examination consisted of two self-reported questionnaires to assess the participants' psychological status. One of them was the Spielberger State-Trait Anxiety Inventory (STAI),[13] Japanese version,[14] which is a well-known 40-item instrument measuring both transient and enduring levels of anxiety. The cut-off score for state anxiety on the STAI of 42 was adopted based on the study that examined the validity of the STAI in Japanese women.[14] Also used was the Mausley Personality Inventory (MPI),[15] Japanese version.[16] The MPI is a personality inventory with 80 items developed by Eysenck,[15] and the reliability and validity of the Japanese version have been confirmed in Japanese people.[16] The MPI consists of 24 items measuring extroversion tendency (E scale), 24 items measuring neurotic tendency (N scale), 20 items measuring social desirability (lie; L scale), and 12 other items. The participants filled out these two questionnaires by themselves after the interviews in the same private room.

To clarify the relationship between the participants' anxiety and pre-surgical explanation, the participants' attending physicians were asked if they had explained to the patient before the surgery whether the probability of cancer was high, moderate or low. In our department, the physicians' explanation to ovarian tumor patients is generally based on a protocol for ovarian tumors where it is not known whether the tumor is benign or malignant. They explain that ovarian tumors cannot be definitively differentiated as benign or malignant before surgery. In addition, they tell the patient whether the probability of cancer is high, moderate or low based on the clinical examination.

We analyzed the data from two viewpoints. First, we analyzed whether the prevalence of psychiatric disorders depended on the ovarian tumor diagnosis and the level of anxiety in the preoperative interview (T1). We also analyzed the predictive factors for psychiatric disorders, including age, marital status, hope to preserve fertility, complications, history of surgery, educational level, employment status, familial history of cancer, primary symptoms of this illness, performance status at T1, serum tumor marker levels, and diameter of the tumor. Second, the participants were divided into the following two groups: the malignant group which consisted of patients who were subsequently diagnosed as having ovarian cancer, and the benign group, which consisted of patients who were subsequently diagnosed as having a benign tumor. We compared the rates of pre- and post-operative psychiatric disorder and anxiety level. Additionally, the malignant group was divided into the group of patients who were recommended to undergo chemotherapy and the group of patients who were recommended to undergo follow-up without chemotherapy, and we compared the anxiety level at T3.

Student's $t$-test was used to assess group differences in continuous variables; in cases of abnormal distribution, the Wilcoxon rank sum test was used. $\chi^2$ test was used to assess group differences in categorical variables; in the case of small sample sizes, Fisher's exact test was used. All analyses were performed using SPSS version 11.0 for Windows (Chicago, IL, USA).

## Results

### Participants

Among the 151 patients who underwent surgery as the primary treatment for ovarian tumor between June 2005 and February 2007, 77 were excluded because of the exclusion criteria described in the Methods section above. Thirty-seven of the remaining 74 cases were informed of this study, and all except one patient consented to participate. However, two patients did not undergo the first interview because of emergency

Table 1 Prevalence of psychiatric disorder and State-Trait Anxiety Inventory state anxiety scores at pre-surgery

| Prevalence of psychiatric disorder ($n = 27$) | |
| --- | --- |
| Adjustment disorder | 33.3% (9 cases) |
| Non-adjustment disorder† | 66.7% (18 cases) |
| STAI state anxiety score | $49.5 \pm 10.30$ |
| (mean $\pm$ SD) ($n = 27$) | |
| Over cut-off point ($\geq 42$) | 77.8% (21 cases) |
| Under cut-off point ($42<$) | 22.2% (6 cases) |

†Diagnosed as having no psychiatric disorder.

surgery or worsening of general condition (ECOG PS 2). Seven other patients did not complete the interviews for the following reasons: being diagnosed as having no gynecological cancer (four cases), not filling out the psychological questionnaires (one case), and being diagnosed previously with panic disorder (two cases). Therefore, 27 patients were processed and analyzed.

## Prevalence of psychiatric disorders and anxiety among pre-surgical ovarian tumor patients

Nine (33.3%) of these 27 participants were diagnosed as having adjustment disorder by the M.I.N.I. with modifications. There was no other diagnosis of psychiatric disorders among the participants in this study (Table 1). The mean STAI state anxiety score of the 27 patients was higher than the average score among Japanese women in the general population ($49.5 \pm 10.30$ *vs* $36.6 \pm 9.06$), with 21 participants (77.8%) having a score over the cut-off point (Table 1). Twenty-two participants (81.5%) reported feeling anxiety prior to the surgery because of the following reasons: possibility of cancer (20 cases); possible complications of surgery (11 cases); change in the patient's life after surgery (eight cases); concern for her family (three cases); preoperative physical symptoms such as pain due to the ovarian tumor (two cases); and concern for their job (two cases). The demographic data and physical symptoms in the adjustment disorder group ($n = 9$) were compared with those in the non-adjustment disorder group ($n = 18$) (Table 2). There were no significant differences in the demographic and medical characteristics between the two groups. Neither the STAI trait anxiety score nor the MPI score was related to the presence of psychiatric disorder. The STAI state anxiety score was significantly higher in the adjustment disorder group than in the non-adjustment disorder group ($56.9 \pm 7.72$ *vs* $45.9 \pm 9.55$; $P = 0.006$) (Table 3). The proportions of

patients to whom the physicians stated that the patient had a low, moderate or high probability of having ovarian cancer did not significantly differ between the two groups.

## Post-surgical alteration in the malignant and benign groups

Among the 27 participants, 12 participants were diagnosed with gynecological cancer (including one participant with endometrial cancer with ovarian metastasis) and 15 participants were diagnosed with benign ovarian or para-ovarian cysts. The demographic data of the malignant and benign groups were similar (data not shown). The majority of participants (11/12 cases) in the malignant group had primary symptoms of ovarian tumor, in contrast to seven of the 15 patients in the benign group ($P = 0.047$). As to the explanation before surgery, the physician described the probability of cancer as moderate or high to all participants in the malignant group; in contrast, the physician described the risk of cancer as low to six of the 15 patients in the benign group (Table 4). In the malignant group and benign group, the prevalence of adjustment disorder at T1 was 50.0% (6/12) and 20.0% (3/15), respectively ($P = 0.199$; Fig. 2). Post-operatively (T2), the prevalence of adjustment disorder changed to 41.7 and 6.7%, respectively ($P = 0.083$). One notable finding was that four of the six participants who had been diagnosed with adjustment disorder in the malignant group before surgery recovered from the adjustment disorder when they received their diagnosis (T2). Three patients in the malignant group were newly diagnosed as having adjustment disorder post-surgery (T2). The malignant group was more prone than the benign group to suffer from adjustment disorder both before and after surgery, although no significant difference was detected between the two groups.

The STAI trait anxiety score and the scores on the three scales of MPI were analyzed as a percentage of the respective score at T1. The STAI trait anxiety score of the malignant group did not change from T1 to T3; however, in the benign group the score decreased significantly ($P = 0.003$) at T2 (Fig. 3a). The scores on the three scales of the MPI did not significantly change during the study in each group (Fig. 3b). The STAI state anxiety score at T1 was $50.1 \pm 10.72$ and $49.1 \pm 10.31$ in the malignant and benign groups, respectively (Fig. 4). However, the mean score of the benign group at T1 was unexpectedly high and was above the cut-off point. The mean STAI state anxiety score of the malignant group

Table 2 Demographic and medical characteristics of the adjustment disorder and non-adjustment disorder groups

| | Adjustment disorder group ($n = 9$) | Non-adjustment disorder group ($n = 18$) |
|---|---|---|
| Age (mean ± SD, years) | 50.1 ± 15.7 | 51.0 ± 15.3 |
| Living with husband | 7 (77.8%) | 13 (72.2%) |
| Hope for fertility | 2 (22.2%) | 4 (22.2%) |
| Complications | 5 (55.6%) | 9 (50.0%) |
| Past history of surgery | 4 (44.4%) | 7 (38.9%) |
| Education beyond high school | 4 (44.4%) | 10 (55.5%) |
| Employment | 6 (66.6%) | 13 (72.2%) |
| Familial history of cancer | 6 (66.7%) | 10 (55.5%) |
| Physical symptoms at first visit | 6 (66.7%) | 11 (61.1%) |
| Performance status 0 | 7 (77.8%) | 15 (83.3%) |
| Performance status 1 | 2 (22.2%) | 3 (16.7%) |
| Mean diameter of ovarian tumor | 8.5 ± 3.9 cm | 9.1 ± 3.5 cm |
| Rising levels of tumor markers | 4 (44.4%) | 13 (72.2%) |

There were no significant differences in any of the characteristics between the adjustment disorder and non-adjustment disorder groups.

Table 3 State-Trait Anxiety Inventory/Mausley Personality Inventory (STAI/MPI) results and explanation in the adjustment disorder and non-adjustment disorder groups at pre-surgery (Time 1)

| | Adjustment disorder group ($n = 9$) | Non-adjustment disorder group ($n = 18$) |
|---|---|---|
| STAI trait anxiety score | 38.6 ± 6.42 | 36.6 ± 5.57 |
| STAI state anxiety score† | 56.9 ± 7.72 | 45.9 ± 9.55 |
| MPI extroversion scale | 33.1 ± 6.99 | 28.4 ± 10.22 |
| MPI neuroticism scale | 11.3 ± 6.08 | 6.7 ± 6.54 |
| MPI lie scale | 16.7 ± 4.80 | 18.8 ± 6.04 |
| Probability of cancer‡ (moderate or high) | 9 (100%) | 12 (66.7%) |

†The STAI state anxiety score in the adjustment disorder group was significantly higher than in the non-adjustment disorder group ($P = 0.006$); ‡degree of probability of cancer mentioned by physicians in the preoperative explanation of the probability of cancer to the patient.

Table 4 State-Trait Anxiety Inventory (STAI) state anxiety scores and explanation in the malignant and benign groups at pre-surgery (Time 1)

| | Malignant group ($n = 12$) | Benign group ($n = 15$) |
|---|---|---|
| STAI state anxiety score | 50.1 ± 10.72 | 49.1 ± 10.31 |
| Probability of cancer† (moderate or high) | 12 (100.0%) | 9 (60.0%) |

†Degree of probability of cancer mentioned by physicians in the preoperative explanation of the probability of cancer.

remained above the cut-off point at T2 (43.2 ± 11.37). However, the score significantly decreased at T3 ($P = 0.044$) because some participants reported that they felt that they were free from cancer as a result of the surgery, or they were prepared to fight against cancer after the cancer diagnosis was clarified. At T3, the mean score of the seven participants who were recommended to undergo chemotherapy was high (50.2 ± 11.43) because they had received the explanation about adjuvant chemotherapy and the risk of
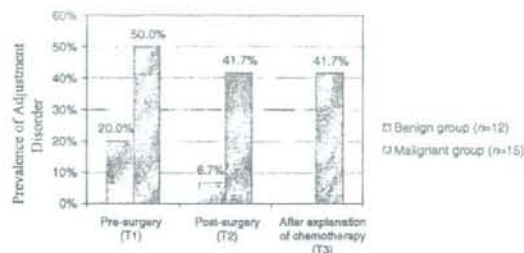
Figure 2 Prevalence of adjustment disorder in the malignant and benign groups at times T1, T2 and T3. The prevalence of adjustment disorder in the malignant group tended to be higher than that in the benign group at T2.
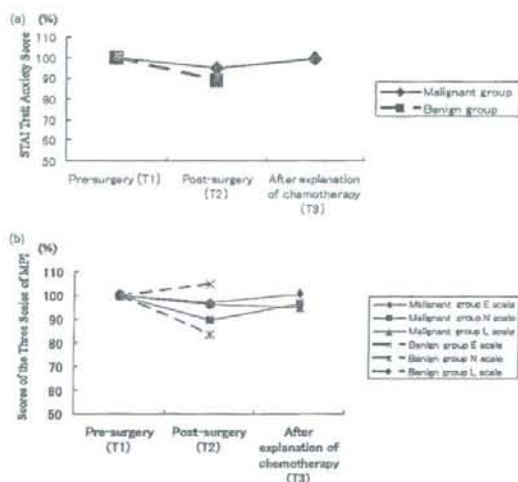


Figure 3 (a) Transitions in the STAI trait anxiety score in the malignant and benign groups during the study. In the malignant group (n = 12), the STAI trait anxiety score did not significantly change from T1 to T3. However, in the benign group (n = 15), the score decreased at T2. Scores are expressed as a percentage of the respective score at T1. (b) Transitions in three scales of the Mausley Personality Inventory (MPI) in the malignant and benign groups during the study. The scores of the three scales of the MPI did not change during the study in either group. Scores are expressed as a percentage of the respective score at T1. (Malignant group n = 12; benign group n = 15).

recurrence. In contrast, the mean level of anxiety in the five participants who were not recommended to undergo chemotherapy in the malignant group decreased slightly (38.8 ± 14.27) because the status of
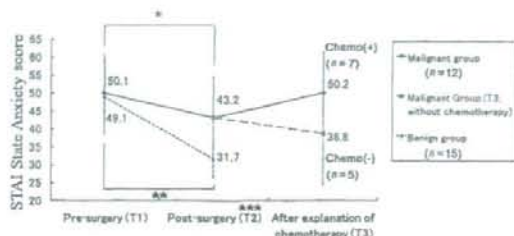


Figure 4 Transitions of the STAI state anxiety score of the malignant and benign groups during the study. *In the malignant group, the STAI state anxiety score at T2 was significantly lower than that at T1, although it remained above the cut-off point (43.2 ± 11.37; P = 0.043). **In the benign group, the STAI state anxiety score decreased immediately after the patients were told that their tumors were benign (P = 0.000007). ***At pre-surgery (T1), the STAI state anxiety score of the benign group did not significantly differ from that of the malignant group. However, at post-surgery (T2), the STAI state anxiety score of the benign group became significantly lower than that of the malignant group (P = 0.005).

cancer was not as bad as they had expected. After the surgery, the STAI state anxiety score of the benign group decreased immediately (T2, 31.7 ± 5.32; P = 0.000007) and fell below the cut-off point. At T2, the STAI state anxiety score of the benign group was significantly lower than that of the malignant group (P = 0.005).

## Discussion

Anxiety and psychological distress among ovarian cancer patients have been reported in several studies, but little research into the prevalence of psychiatric disorders diagnosed by DSM-IV[17] has been carried out among pre-surgical ovarian tumor patients. In the present study, adjustment disorder was diagnosed in one-third (9/27) of suspected ovarian cancer patients waiting for primary surgery. This prevalence is similar to the rate of adjustment disorder among general cancer patients (32%) reported by Derogatis et al.[1] Before the surgery (T1), the STAI state anxiety score of the 27 participants was high (49.5 ± 10.30). One of the influential factors that increased the level of anxiety was the fear of surgery. In addition, the possibility of ovarian cancer might affect the pre-surgical anxiety. Lalinec-Michaud and Engelsmann[18] examined 102 women undergoing hysterectomy for reasons other than cancer, and their mean pre-operative STAI state