Take special care with Actos 15 mg tablets:

Tell your doctor before you start to take this medicine:
- If you are planning to become pregnant.
- If you are breast-feeding.
- If you have polycystic ovary syndrome. There may be an increased possibility of your becoming pregnant because of how your medicine works.
- If you have a problem with your liver or heart.
- If you already take a sulphonylurea with metformin. This is because triple combination therapy is not recommended.
- If you are under 18 years of age because use in such patients is not recommended.

Taking Actos 15 mg tablets with food and drink:
You may take your tablets with or after a meal or on an empty stomach. You should swallow the tablets with a glass of water.

Pregnancy:
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding:
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:
Pioglitazone will not affect your ability to drive or operate machinery.

Taking other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

You can usually continue to take other medicines whilst you are being treated with Actos 15 mg tablets.

3. HOW TO TAKE ACTOS 15 MG TABLETS

One tablet should be taken once daily. If necessary your doctor may tell you to take a different dose. If you have the impression that the effect of Actos 15 mg tablets is too weak, talk to your doctor.

Actos 15 mg tablets can be taken with or without food.

As Actos 15 mg tablets is taken in combination with other medicines used to treat diabetes (such as chlorpropamide, glibenclamide, gliclazide, tolbutamide) your doctor will tell you whether you need to take a smaller dose of your medicines.

Your doctor will prescribe Actos 15 mg tablets in combination with another oral anti-diabetic medicine

Your doctor will ask you to have blood tests every two months during the first year of taking Actos 15 mg tablets and thereafter at regular intervals. This is to check that your liver is working normally.

If you are following a diabetic diet, you should continue with this while you are taking Actos 15 mg tablets.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

If you take more Actos 15 mg tablets than you should:

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately.

If you forget to take Actos 15 mg tablets:
Try to take Actos 15 mg tablets daily as prescribed. However if you miss a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up for the one you missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Actos 15 mg tablets can have side effects.

The following side effects have been experienced by some patients taking Actos 15 mg tablets:
- localised swelling (oedema)
- weight gain
- headache
- dizziness
- vertigo
- abnormal vision
- flatulence
- joint pain
- impotence
- sweating
- fatigue
- decreased blood sugar (hypoglycaemia), sugar in urine, proteins in urine, blood in urine
- in rare cases, impaired liver function
- a small reduction in red blood cell count.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING ACTOS 15 MG TABLETS

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton.

This leaflet was last approved on {date}

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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MEDICATION GUIDE

NOLVADEX® (NOLE-vah-dex) Tablets
Generic name: tamoxifen (ta-MOX-I-fen)

Written for women who use NOLVADEX to lower their high chance of getting breast cancer or who have ductal carcinoma in situ (DCIS)

This Medication Guide discusses only the use of NOLVADEX to lower the chance of getting breast cancer in high-risk women and in women treated for DCIS.

People taking NOLVADEX **to treat** breast cancer have different benefits and different decisions to make than high-risk women or women with ductal carcinoma in situ (DCIS) taking NOLVADEX to reduce the chance of getting breast cancer. If you already have breast cancer, talk with your doctor about how the benefits of treating breast cancer with NOLVADEX compare to the risks that are described in this document.

Why should I read this Medication Guide?

This guide has information to help you decide whether to use NOLVADEX to lower your chance of getting breast cancer.

You and your doctor should talk about whether the possible benefit of NOLVADEX in lowering your high chance of getting breast cancer is greater than its possible risks. Your doctor has a special computer program or hand-held calculator to tell if you are in the high-risk group. If you have DCIS and have been treated with surgery and radiation therapy, your doctor may prescribe NOLVADEX to decrease your chance of getting invasive (spreading) breast cancer.

Read this guide carefully before you start NOLVADEX. It is important to read the information you get each time you get more medicine. There may be something new. This guide does not tell you everything about NOLVADEX and does **not** take the place of talking with your doctor.

Only you and your doctor can determine if NOLVADEX is right for you.

What is the most important information I should know about using NOLVADEX to reduce the chance of getting breast cancer?

NOLVADEX is a prescription medicine that is like estrogen (female hormone) in some ways and different in other ways. In the breast, NOLVADEX can block estrogen's effects. Because it does this, NOLVADEX may block the growth of breast cancers that need estrogen to grow (cancers that are estrogen- or progesterone-receptor positive).

NOLVADEX can lower the chance of getting breast cancer in women with a higher than normal chance of getting breast cancer in the next five years (high-risk women) and women with DCIS. **Because high-risk women don't have cancer yet, it is important to think carefully about whether the possible benefit of NOLVADEX in lowering the chance of getting breast cancer is greater than its possible risks.**

This Medication Guide reviews the risks and benefits of using NOLVADEX to reduce the chance of getting breast cancer in high-risk women and women with DCIS. This guide does **not** discuss the special benefits and decisions for people who already have breast cancer.

Why do women and men use NOLVADEX?

NOLVADEX has more than one use. NOLVADEX is used:

1. **to lower the chance** of getting breast cancer in women with a higher than normal chance of getting breast cancer in the next 5 years (high-risk women).

2. **to lower the chance** of getting invasive (spreading) breast cancer in women who had surgery and radiation for ductal carcinoma in situ (DCIS). DCIS means the cancer is only inside the milk ducts.

3. **to treat** breast cancer in women after they have finished early treatment. Early treatment can include surgery, radiation, and chemotherapy. NOLVADEX may keep the cancer from spreading to others parts of the body. It may also reduce the woman's chance of getting a new breast cancer.

4. in women and men, **to treat** breast cancer that has spread to other parts of the body (metastatic breast cancer).

This guide talks only about using NOLVADEX to lower the chance of getting breast cancer (#1 and #2 above).

What are the benefits of NOLVADEX to lower the chance of getting breast cancer in high-risk women and in women treated for DCIS?

A large US study looked **at high-risk women** and compared the ones who took NOLVADEX for 5 years with others who took a pill without NOLVADEX (placebo). High-risk women were defined as women who have a 1.7% or greater chance of getting breast cancer in the next 5 years, based on a special computer program. In this study:

- Out of every 1,000 high-risk women **who took a placebo**, each year about 7 got breast cancer.

- Out of every 1,000 high-risk women **who took NOLVADEX**, each year about 4 got breast cancer.

The study showed that on average, high-risk women who took NOLVADEX lowered their chances of getting breast cancer by 44%, from 7 in 1,000 to 4 in 1,000.

Another US study looked at **women with DCIS** and compared those who took NOLVADEX for 5 years with others who took a placebo. In this study:

- Out of every 1,000 women with DCIS **who took placebo**, each year about 17 got breast cancer.

- Out of every 1,000 women with DCIS **who took NOLVADEX**, each year about 10 got breast cancer.

The study showed that on average, women with DCIS who took NOLVADEX lowered their chances of getting invasive (spreading) breast cancer by 43%, from 17 in 1,000 to 10 in 1,000.

These studies do not mean that taking NOLVADEX will lower your personal chance of getting breast cancer. We do not know what the benefits will be for any one woman who takes NOLVADEX to reduce her chance of getting breast cancer.

What are the risks of NOLVADEX?

In the studies described under "What are the benefits of NOLVADEX?", the high-risk women who took NOLVADEX got certain side effects at a higher rate than those who took a placebo. **Some of these side effects can cause death.**

In one study, in women **who still had their uterus:**

- Out of every 1,000 women **who took a placebo**, each year **1 got endometrial cancer** (cancer of the lining of the uterus) and **none got uterine sarcoma** (cancer of the body of the uterus).

- Out of every 1,000 women **who took NOLVADEX**, each year **2 got endometrial cancer** and **fewer than 1 got uterine sarcoma.**

These results show that, on average, in high-risk women **who still had their uterus**, NOLVADEX doubled the chance of getting endometrial cancer from 1 in 1,000 to 2 in 1,000, and it increased the chance of getting uterine sarcoma. **This does not mean that taking NOLVADEX will double your personal chance of getting endometrial cancer or increase your chance of getting uterine sarcoma.** We do not know what this risk will be for any one woman. The risk is different for women who no longer have their uterus.

For all women in this study, taking NOLVADEX increased the risk of having a blood clot in their lungs or veins, or of having a stroke. In some cases, women died from these effects.

NOLVADEX increased the risk of getting cataracts (clouding of the lens of the eye) or needing cataract surgery. (See "What are the possible side effects of NOLVADEX?" for more details about side effects.)

What don't we know about taking NOLVADEX to reduce the chance of getting breast cancer?

We don't know:

- if NOLVADEX lowers the chance of getting breast cancer in women who have abnormal breast cancer genes (BRCA1 and BRCA2)
- if taking NOLVADEX for 5 years reduces the number of breast cancers a woman will get in her lifetime or if it only delays some breast cancers
- if NOLVADEX helps a woman live longer
- the effects of taking NOLVADEX with hormone replacement therapy (HRT), birth control pills, or androgens (male hormones)
- the benefits of taking NOLVADEX if you are less than 35 years old

Studies are being done to learn more about the long-term benefits and risks of using NOLVADEX to reduce the chance of getting breast cancer.

What are the possible side effects of NOLVADEX?

The most common side effect of NOLVADEX is hot flashes. This is **not** a sign of a serious problem.

The next most common side effect is vaginal discharge. If the discharge is bloody, it could be a sign of a serious problem. [See "Changes in the lining (endometrium) or body of your uterus" below.]

Less common but serious side effects of NOLVADEX are listed below. These can occur at any time. **Call your doctor right away if you have any signs of side effects listed below:**

- **Changes in the lining (endometrium) or body of your uterus.** These changes may mean serious problems are starting, including cancer of the uterus. The signs of changes in the uterus are:

  - Vaginal bleeding or bloody discharge that could be a rusty or brown color. You should call your doctor even if only a small amount of bleeding occurs.
  - Change in your monthly bleeding, such as in the amount or timing of bleeding or increased clotting.
  - Pain or pressure in your pelvis (below your belly button).

- **Blood clots in your veins or lungs.** These can cause serious problems, including death. You may get clots up to 2-3 months after you stop taking NOLVADEX. The signs of blood clots are:

  - sudden chest pain, shortness of breath, coughing up blood
  - pain, tenderness, or swelling in one or both of your legs

- **Stroke.** Stroke can cause serious medical problems, including death. The signs of stroke are:

  - sudden weakness, tingling, or numbness in your face, arm or leg, especially on one side of your body
  - sudden confusion, trouble speaking or understanding
  - sudden trouble seeing in one or both eyes
  - sudden trouble walking, dizziness, loss of balance or coordination
  - sudden severe headache with no known cause

- **Cataracts or increased chance of needing cataract surgery**. The sign of these problems is slow blurring of your vision.

- **Liver problems, including jaundice.** The signs of liver problems include lack of appetite and yellowing of your skin or whites of your eyes.

These are not all the possible side effects of NOLVADEX. For a complete list, ask your doctor or pharmacist.

Who should not take NOLVADEX?

Do not take NOLVADEX for any reason if you

- **Are pregnant or plan to become pregnant while taking NOLVADEX or during the 2 months after you stop taking NOLVADEX. NOLVADEX may harm your unborn baby.** It takes about 2 months to clear NOLVADEX from your body. To be sure you are not pregnant, you can start taking NOLVADEX while you are having your menstrual period. Or, you can take a pregnancy test to be sure you are not pregnant before you begin.

- **Are breast feeding.** We do not know if NOLVADEX can pass through your milk and harm your baby.

- **Have had an allergic reaction to NOLVADEX or tamoxifen** (the other name for NOLVADEX), or to any of its inactive ingredients.

If you get pregnant while taking NOLVADEX, stop taking it right away and contact your doctor. NOLVADEX may harm your unborn baby.

Do not take NOLVADEX to lower your chance of getting breast cancer if:

- You ever had a blood clot that needed medical treatment.
- You are taking medicines to thin your blood, like warfarin, (also called Coumadin®*).
- Your ability to move around is limited for most of your waking hours.
- You are at risk for blood clots. Your doctor can tell you if you are at high risk for blood clots.
- You do not have a higher than normal chance of getting breast cancer. Your doctor can tell you if you are a high-risk woman.

How should I take NOLVADEX?

- Swallow the tablet(s) whole, with water or another non-alcoholic liquid. You can take NOLVADEX with or without food. Take your medicine every day. It may be easier to remember if you take it at the same time each day.

- If you forget a dose, take it when you remember, then take the next dose as usual. If it is almost time for your next dose or you remember at your next dose, do not take extra tablets to make up the missed dose.

- Take NOLVADEX for 5 years, unless your doctor tells you otherwise.

What should I avoid while taking NOLVADEX?

- **Do not become pregnant while taking NOLVADEX or for 2 months after you stop.** NOLVADEX can stop hormonal birth control methods from working. Hormonal methods include birth control pills, patches, injections, rings and implants. Therefore, while taking NOLVADEX, **use birth control methods that don't use hormones,** such as condoms, diaphragms with spermicide, or plain IUD's. If you get pregnant, stop taking NOLVADEX right away and call your doctor.

- **Do not breast feed.** We do not know if NOLVADEX can pass through your milk and if it can harm the baby.

What should I do while taking NOLVADEX?

- Have regular gynecology check-ups ("female exams"), breast exams and mammograms. Your doctor will tell you how often. These will check for signs of breast cancer and cancer of the endometrium (lining of the uterus). Because NOLVADEX does not prevent all breast cancers, and you may get other types of cancers, you need these exams to find any cancers as early as possible.

- Because NOLVADEX can cause serious side effects, pay close attention to your body. Signs you should look for are listed in "What are the possible side effects of NOLVADEX?"

- Tell all of the doctors that you see that you are taking NOLVADEX.

- Tell your doctor right away if you have any new breast lumps.

General information about the safe and effective use of NOLVADEX
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Your doctor has prescribed NOLVADEX only for you. Do not give it to other people, even if they have a similar condition, because it may harm them. Do not use it for a condition for which it was not prescribed.

This Medication Guide is a summary of information about NOLVADEX for women who use NOLVADEX to lower their high chance of getting breast cancer or who have DCIS. If you want more information about NOLVADEX, ask your doctor or pharmacist. They can give you information about NOLVADEX that is written for health professionals. For more information about NOLVADEX or breast cancer, please visit www.NOLVADEX.com or call 1-800-236-9933.

Ingredients: tamoxifen citrate, carboxymethylcellulose calcium, magnesium stearate, mannitol and starch.

*Coumadin® is a registered trademark of Bristol-Myers Squibb Pharmaceuticals.

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Rev 05-29-03 SIC XXXXX-XX

This Medication Guide has been approved by the US Food and Drug Administration

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分担研究報告

医薬品の製品管理情報のあり方に関する研究

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【研究要旨】
医薬品の有効性を最大限に発揮させ、リスクを最小限に抑えることで患者の安全を確保する第一義的責任が医療従事者にあることは当然のことである。しかし、医療従事者が関与できるのは投薬までであり、薬剤交付後はその使用・管理ともに患者に委ねられることになる。医薬品の有害事象は、不適切な使用や管理が原因となる場合もあり、医薬品の安全性は患者により大きく左右されるためその役割は極めて大きく、医療従事者と患者双方がそれぞれの責任を果たすことが医薬品適正使用のために重要となってくる。しかし、交付後、患者がどのように医薬品を使用・管理しているかは不明確であり、適切に使用・管理されているとは必ずしもいえない。そこで、交付後の薬剤の管理、また残薬が生じた場合にその原因、さらには残薬に対してどのように対処しているのか患者側の現状を把握することを目的とし、患者を対象としてアンケート調査を行った。その結果、74%の患者に残薬が生じていたことから、残薬に関する注意・説明が必要なことも分かった。

A. 研究目的

近年の本邦での急激な高齢化や生活習慣病の増加により疾病構造の変化が生じ多くの薬剤が処方されるケースや平成 14 年 4 月の一部の薬剤を除いた長期投与の解禁により従来にまして多くの患者が服用薬を自己管理する必要性が生じた。このような状況下での患者の服用薬の自己管理に関したアンケート調査はあるものの、そのアンケート平成 14 年以前のものがほとんどであり、現状を把握したものとは必ずしも言い難い。そこで、医薬品の有効性を最大限に発揮させ、リスクを最小限に抑え患者の安全を確保する目的で、自己管理に関する実態

を把握すべく患者アンケートを実施した。

B. 研究方法

患者アンケートは、2003 年 9 月～2004 年 1 月までの間に、本調査に十分ご理解いただき、ご協力していただける施設として、三愛記念病院、北海道がんセンター、ソウマ薬局、病院前薬局の 4 施設において、来院または来局した外来患者 184 名を対象とし、薬剤師による患者へのアンケートの記入依頼にて調査を行った。

アンケートは①回答者背景(性別、年齢)に関する質問、②薬剤の受け取りと管理に関する質問、③薬の説明と理解度に関する質問、④残薬の有無と残薬がある場合にはその理由と対処に関する質問、の 4 つの項目より構成されており、無記名、選択式(一部記入式)で実施した。

C. 研究結果

アンケート回答者 184 名のうち入院患者 1 名、記入率 50%未満であった 1 名、及び回答者が 4 歳であった 1 名の計 3 名を除外し、181 名について解析を行った。

1) 患者背景

回答者の内訳は「男性」96 名(53%)、「女性」85 名(47%)で男女比はほぼ同等であった。年齢層は「60 代」が最も多く 36.5%、ついで「70 代」24.3%、「50 代」16.0%と 60 代以上の高齢者が半分以上を占めていた(Fig.1)。通院間隔は「1 週間」7.73%、「2 週間」15.5%、「一ヶ月」17.1%、「2 ヶ月以上」7.2%であり、「その他」の 47.5%の回答では透析患者の「週 3 回」が多かった。服用している薬剤の種類は 1 種類は 2%で、10 種類以上を服用している患者が 27%であった。(Fig.2)

アンケート回答者のうち、薬の使用期限を「知っている」と回答した患者が 64.6%であるのに対し、「知らなかった」は 7.7%であった。服用している薬剤がどんな疾患を治療する薬であるのかを知っている患者は 72.9%で、毎日薬剤を使用している患者は 67.2%であった。

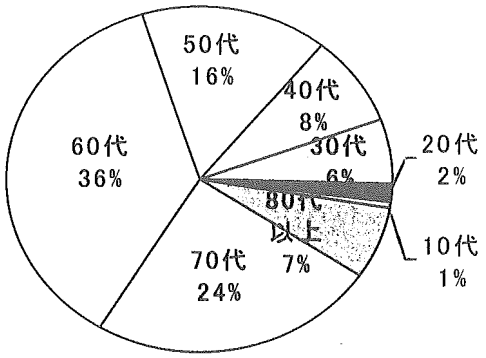

Fig.1 年齢 (n=181)

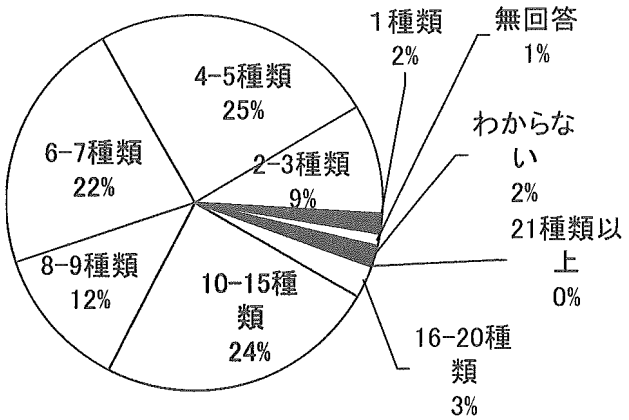

Fig.2 服用薬剤数 (n=181)

2) 薬の受け取りと管理

薬の受け取りは「本人」が 76.9%を占め、次いで「同居家族」が 14%、「別居家族」が 6.3%で、「施設の職員やヘルパー」が 2.3%であった。通院期間と受け取る人の間には特に関連は認められなかった。また、管理もほとんど本人が行っており(85.2%)、管理場所として「専用の入れ物がある」と回答した患者は 74.9%、「冷蔵庫」は 3.7%であった。本人または同居家族が薬を管理している場合、「専用の入れ物がない」との回答はそれぞれ約 20%であるに対し、別居家族またはヘルパーが管理している場合には、100%の患者で専用の入れ物または冷蔵庫で管理されていた(Fig.3)。

3) 薬の説明と理解度

薬の説明は「説明書と口頭で説明」を受けた患者が 51.1%と最も多く、「口頭で説明」が 22.6%、「説明書のみ」と回答した患者が 20.5%であった。説明が「理解できた」との回答は 86%で、「理解できなかった」6%の理由は「時間がなかった」「病院で十分な説明を受けていた」「薬局での説明が難しい」であった。

薬の飲み方・使い方を「覚えている」は 80%で、「だいたい覚えている」が 18.2%であった。説明書のみでは「覚えている」と回答した患者がやや少なかったが、説明方法による大きな違いは見られなかった。正しく覚えていない理由として、「説明書を見ている」50%、「忘れてしまった」20.6%で、他には「理解できなかった」、「他人が管理している」等の回答があった。

4) 残薬の有無と残薬が生じた理由

薬が余ったことがある患者は 74%(134/181)、余ったことがない患者が 26%(47/181)であった(Fig.4)。処方薬が余った患者のうち、意図的に薬を使用しなかった事がある患者が 51.5%おり、「常に使用しない」(6.7%)との回答も含まれていた。

余りやすい薬として、毎食後服用する薬が 57.6%を占めており、余った理由としては

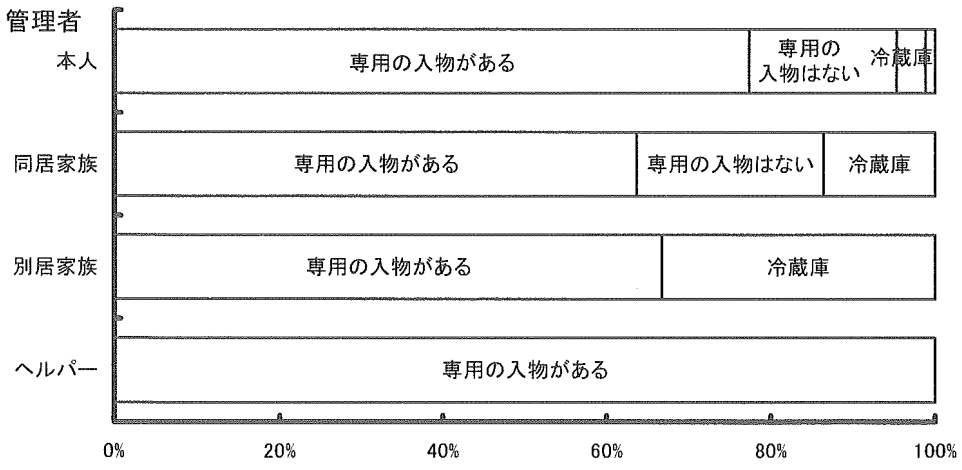

Fig.3 薬の管理者と管理場所の関連 (n=181)

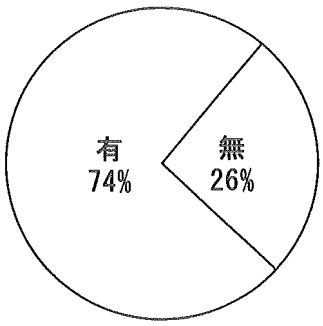

Fig.4 残薬の有無

(n=181)

「うっかり忘れた」が最も多く 26.3%、「外出時等飲めなかった」20.3%、「自分で判断し量を調節していた」が 9.6%であった(Fig.5)。

「うっかり忘れる」と回答した患者への「どのくらいの種類であるとうっかり飲み忘れるか」という質問に対し、「1 種類」が最も多く 14.1%で、種類が増加するにつれて忘れるとの回答は減少していた(Table.1)。飲み忘れの時期としては昼食後が最も多かった(Table.2)。

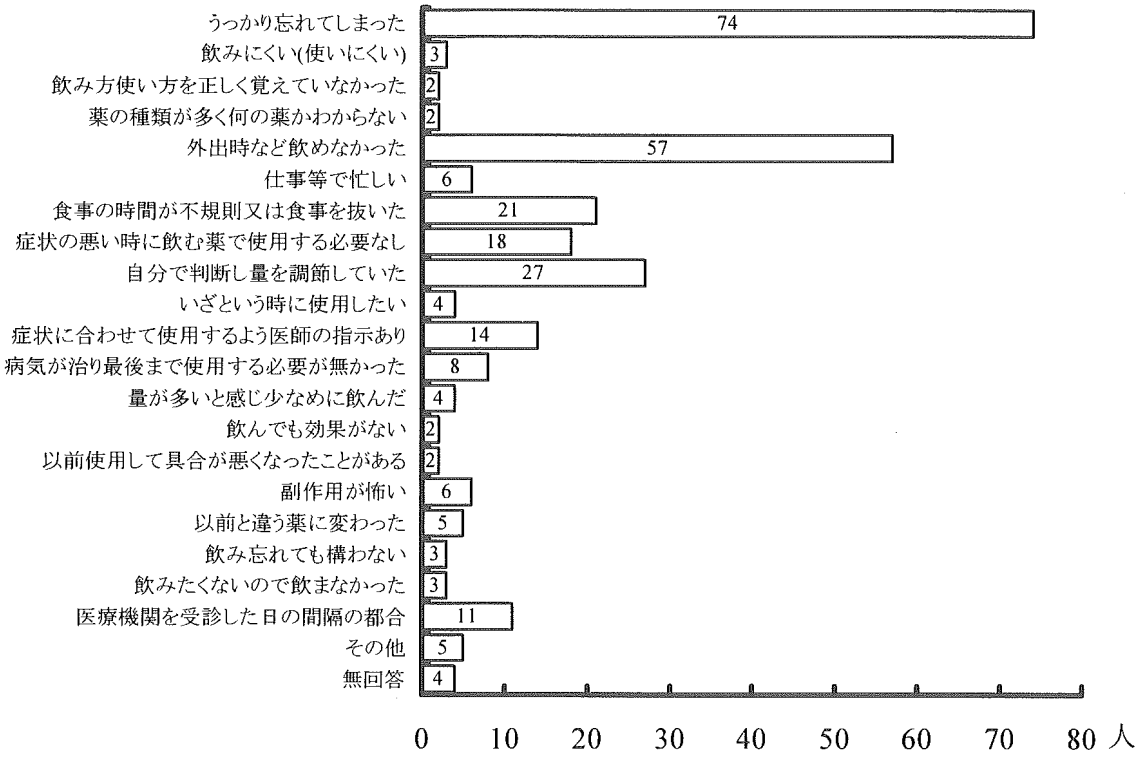

Fig.5 薬が余った原因　　(n=130 複数回答)

Table.1 飲み忘れた時の薬剤数

薬剤数	人数(%)
1種類	11(14.1)
2-3種類	8(10.3)
4-5種類	6(7.7)
6-7種類	5(6.4)
8-9種類	3(3.9)
10-15種類	2(2.6)
16-20種類	1(1.3)
21種類以上	0(0)
わからない	8(10.3)
その他	17(21.8)
無回答	17(21.8)

(n=78)

Table.2 飲み忘れ時期

時期	人数(%)
起床後	0(0)
朝{食前}	5(7.4)
朝{食後}	11(16.2)
昼{食前}	12(17.6)
昼{食後}	39(57.4)
夜{食前}	5(7.4)
夜{食後}	19(27.9)
食間	3(4.4)
寝る前	5(7.4)
その他	4(5.9)
無回答	10(14.7)

(n=135 複数回答)

使用しにくい薬としては、「散剤」、「坐剤・浣腸剤」、「味が気になる薬」、「大きい薬」、「一回の量が多い薬」が挙げられた。

薬の説明方法による残薬への影響は、説明書のみと回答している場合は、89.7%に残薬が生じていたのに対し、口頭または口頭と説明書により説明を受けた場合では残薬の発生は約70%に留まっていた(Fig.6)

5) 残薬への対処

残薬が生じた事を医療従事者に相談した事がある患者は 37%であり、相談した事がないと回答した 52%を下回った。相談した医療従事者は「医師」「看護師等の医療従事者」がそれぞれ 38%と同等であるのに対し、「薬剤師」は 17%と低かった(Fig.7)。相談した結果、「処方変更」が 40.8%、「普段通り処方」28.6%、「処方中止」が 22.5%となっていた(Fig.8)。

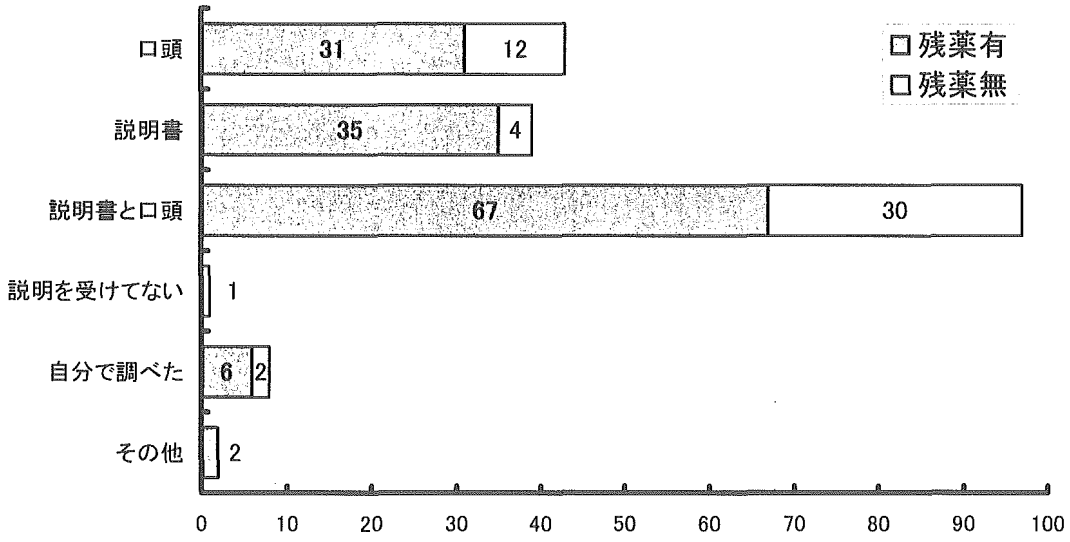

Fig.6 説明方法と残薬の有無　　(n=190 複数回答)

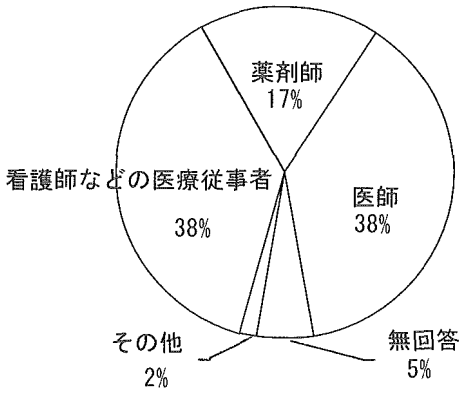

Fig.7 相談した医療従事者
(n=49)

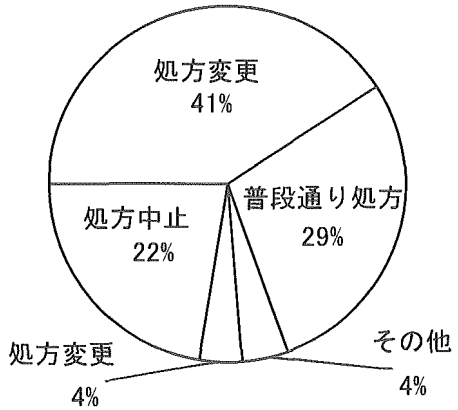

Fig.8 相談の結果
(n=49)