

Information Meeting on Bonviva[®] Tablet

CHUGAI PHARMACEUTICAL CO., LTD.
TAISHO TOYAMA PHARMACEUTICAL CO., LTD.

April 5, 2016

Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. and Taisho Pharmaceutical Holdings Co., Ltd. (the “Companies”). These statements reflect the Companies’ current analysis of existing information and trends.

Actual results may differ from expectations based on risks and uncertainties that may affect the Companies’ businesses.

Although this presentation includes information regarding pharmaceuticals (including products under development), the information is not intended as any advertisement and/or medical advice.

Once monthly, alternative treatment option for your life



THERAPEUTIC AGENT FOR OSTEOPOROSIS

Powerful drug and Prescription drug†

Not on NHI price list

BONVIVA® Tablet 100 mg

Bonviva
ibandronate

Ibandronate Sodium
Hydrate Tablet

†Caution: Use only as prescribed
by physician, etc.

Launch in
preparation

Chugai Pharmaceutical Co., Ltd.
Bonviva Product Manager,
Takeshi Sakaguchi

BONVIVA is a trademark of F. HOFFMANN-LA ROCHE AG (SWITZERLAND)

BONVIVA[®] Tablet 100 mg



**Granted marketing approval
in Jan 2016**



Length	Approx. 12.2 mm
Width	Approx. 6.2 mm
Thickness	Approx. 4.5mm

[NAME]

Generic name: Ibandronate Sodium Hydrate

Brand name: BONVIVA Tablet 100 mg

[INDICATIONS]

Osteoporosis

[DOSAGE AND ADMINISTRATION]

The usual adult dosage is 100 mg as ibandronic acid once a month, taken by mouth with plenty of plain water (approximately 180 mL) when the patient gets out of bed.

For at least 60 minutes after taking BONVIVA, patients should not lie down and should avoid food or drink (except water) and other oral drugs.

Profiles of BONVIVA® Tablet 100 mg



- Once monthly oral bisphosphonate drug
- Two different monthly forms, BONVIVA tablet and BONVIVA IV injection, provide suitable treatment opportunities according to osteoporotic patients' lifestyle.
- BONVIVA tablet proved non-inferiority to BONVIVA IV injection in lumbar spine BMD gains in Japanese patients with osteoporosis.
- BONVIVA tablet demonstrated BMD gains at femur sites (proximal femur, femoral neck).
- BONVIVA tablet suppressed bone turnover markers from early phase (one month after treatment).
- In total, 141 adverse reactions occurred in 86 out of 311 patients (27.7%) evaluated for safety assessment in Japanese clinical trials. The most common adverse events included diarrhea (14 reports, 4.5%), back pain (13 reports, 4.2%), headache (9 reports, 2.9%), arthralgia (9 reports, 2.9%) and malaise (9 reports, 2.9%) [at approval].

Phase III (MOVEST Study)

Study design, materials and methods



※All patients received supplementary calcium 610mg and vitamin D₃ 400IU/day.

Objective

To examine the efficacy and safety of monthly oral ibandronate 100mg versus monthly intravenous ibandronate 1mg

Patients

Japanese patients aged ≥ 55 years with primary osteoporosis

- BMD of lumbar spine (L2-L4) $< 70\%$ YAM; BMD of lumbar spine (L2-L4) $< 80\%$ YAM with fragile bone fracture; BMD of total hip $< 70\%$ YAM

Study design

Prospective, multicenter, randomized, double-blind, double-dummy comparative study

Primary endpoint

The percentage change from baseline in lumbar spine (L2-L4) BMD at 12 months

Secondary endpoints

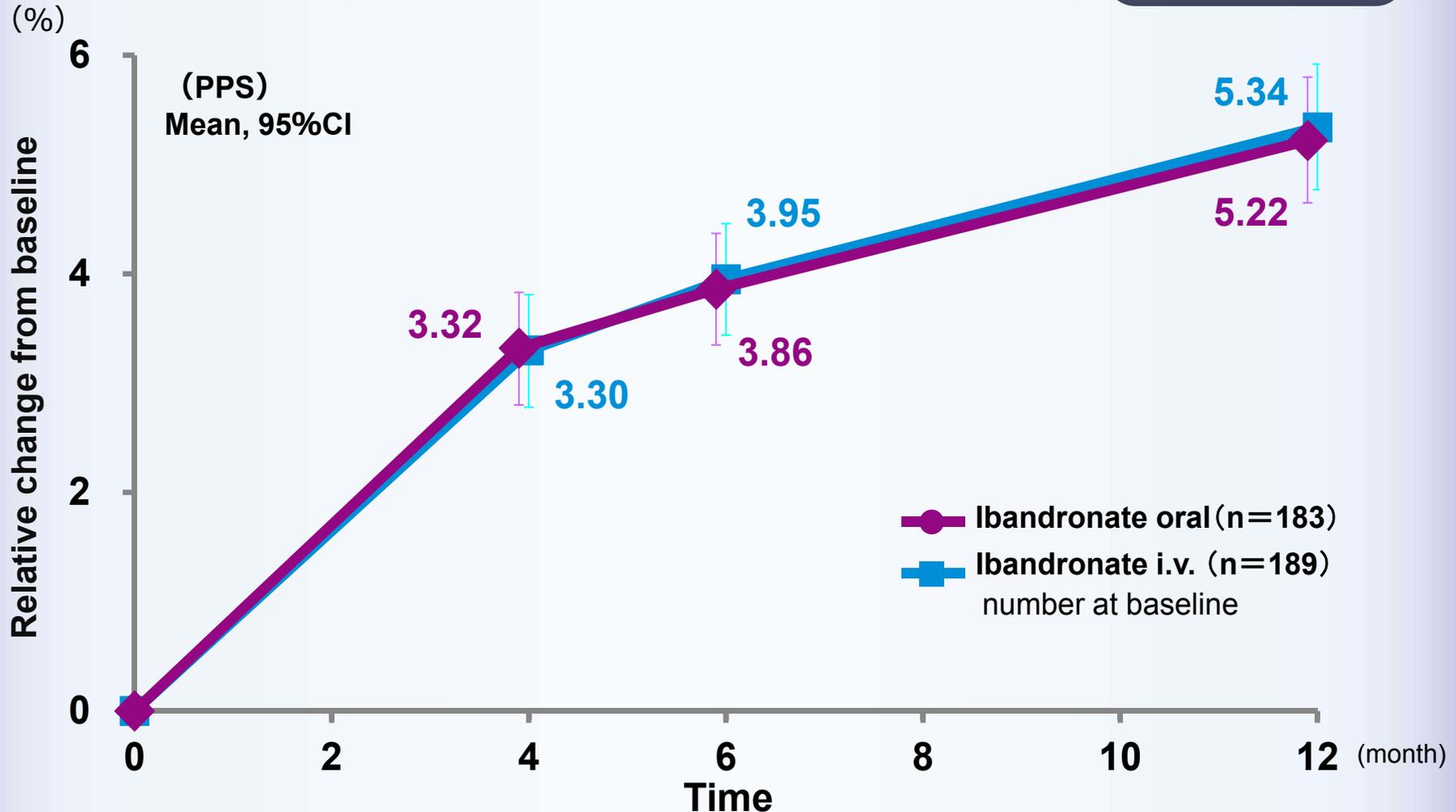
The percentage change from baseline in total hip, femoral neck, and trochanter BMD; change from baseline in bone turnover markers; incidences of non-traumatic new vertebral or non-vertebral fractures.

Phase III (MOVEST Study)

Relative change from baseline in lumbar spine (L2–L4) BMD



Primary Endpoint



For missing values, LOCF (Last Observation Carried Forward) approach was used.

CONTRAINDICATIONS



[CONTRAINDICATIONS (BONVIVA is contraindicated in the following patients.)]

1. Patients with abnormalities that delay oesophageal transit such as oesophageal stricture or achalasia [Delayed oesophageal transit of BONVIVA increases the risk of local oesophageal adverse reactions.]
2. Patients who are unable to stand or sit upright for at least 60 minutes after taking BONVIVA
3. Patients with a history of hypersensitivity to the ingredients of BONVIVA or other bisphosphonates
4. Patients with hypocalcaemia [Serum calcium levels may decrease and symptoms of hypocalcaemia may worsen (see Important Precautions and Adverse Reactions: Clinically Significant Adverse Reactions (Similar Drugs))]
5. Women who are pregnant or may be pregnant (see Use During Pregnancy, Delivery or Lactation)

INDICATIONS



Osteoporosis

Precautions Related to INDICATIONS

BONVIVA should only be administered to patients with an established diagnosis of osteoporosis with reference to the guidelines of the Japanese Society for Bone and Mineral Research.

DOSAGE AND ADMINISTRATION



The usual adult dosage is 100 mg as ibandronic acid once a month, taken by mouth with plenty of plain water (approximately 180 mL) when the patient gets out of bed. For at least 60 minutes after taking BONVIVA, patients should not lie down and should avoid food or drink (except water) and other oral drugs.

Precautions Related to DOSAGE AND ADMINISTRATION

Patients should be given the following instructions before taking BONVIVA.

- (1) BONVIVA should be taken with water. Taking BONVIVA with drinks other than water (including mineral water containing particularly high levels of calcium, magnesium, etc.), food or other medication may interfere with absorption. Therefore, BONVIVA should be taken after getting out of bed, before the first food or drink of the day, and food or drink other than water should be avoided for at least 60 minutes after taking BONVIVA.
- (2) To reduce the possibility of oesophageal or local adverse reactions, it is important that BONVIVA reaches the stomach quickly. When taking BONVIVA, patients should take the following precautions.
 - 1) Patients should not chew or suck BONVIVA because of a potential for oropharyngeal ulceration.
 - 2) Patients should take BONVIVA in an upright position with plenty of water (approximately 180 mL) and should not lie down for 60 minutes after taking BONVIVA.
 - 3) Patients should not take BONVIVA at bedtime or before getting out of bed.
- (3) BONVIVA should be taken once a month. If patients forget to take a dose, one BONVIVA tablet should be taken the following day after it is remembered, and then once a month from that point onward.

PRECAUTIONS



Careful Administration (BONVIVA should be administered with care in the following patients.)

- (1) Patients with upper gastrointestinal disorders such as dysphagia, oesophagitis, gastritis, duodenitis or ulcers [Possible irritant effects on the upper gastrointestinal mucosa may lead to worsening of the underlying disease.]
- (2) Patients with severe renal disorders [Excretion may be delayed. No clinical data are available, and safety has not been established. (See PHARMACOKINETICS in the Package Insert)]

Safety



In total, 141 adverse reactions (ARs) occurred in 86 out of 311 patients (27.7%) evaluated for safety in Japanese clinical trials. The most frequent ARs included diarrhea (14 reports, 4.5%), back pain (13 reports, 4.2%), headache (9 reports, 2.9%), arthralgia (9 reports, 2.9%) and malaise (9 reports, 2.9%) [at approval].

The clinically significant ARs may occur, such as upper gastrointestinal disorders, anaphylactic shock/reaction, osteonecrosis/osteomyelitis of the jaw, and atypical fractures of the subtrochanteric and proximal diaphyseal femur.

Hypocalcemia was also reported as the clinically significant ARs in similar drugs.

* Because similar ARs occurred in a single patient were counted as one AR, the above-mentioned number of ARs are different from that in Summary of ARs.

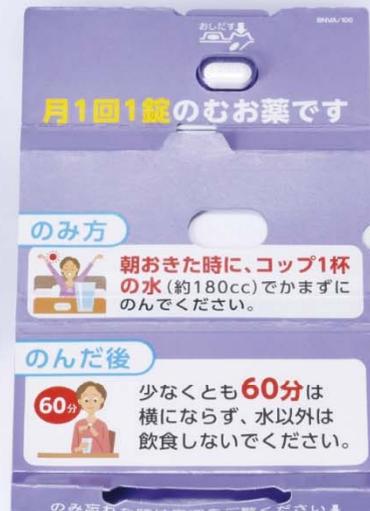
● Summary of ARs

Safety population	311 patients
No. of patient with ARs	86 patients
No. of ARs	142
Incidence of ARs in Safety population	27.7%

PACKAGES



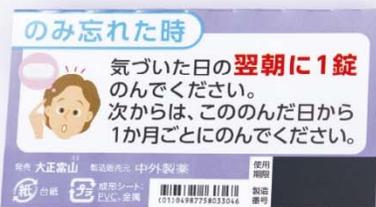
Taisho Toyama



Chugai

Record the date of taking BONVIVA tablet

Put the seal on your calendar



裏面(大正富山医薬品)



裏面(中外製薬)

Roll-type Package



Easy-to-open, easy-to-fold, and convenient to bring it with you!

Easy-to-understand how to take the tablet

In addition to the description emphasizing that BONVIVA tablet is taken “once a month”, icons and explanations; “how to take the tablet” is placed on the package.

Once monthly, alternative treatment option for your life



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Bonviva Tablet: Clinical Utility and Our Expectation

**Univ. of Tottori
Hiroshi Hagino**

Today's topics

- ✓ **Current status and issues of osteoporosis medication in Japan**
- ✓ **New option for osteoporosis treatment**
- ✓ **Aiming to maintain a healthy life**

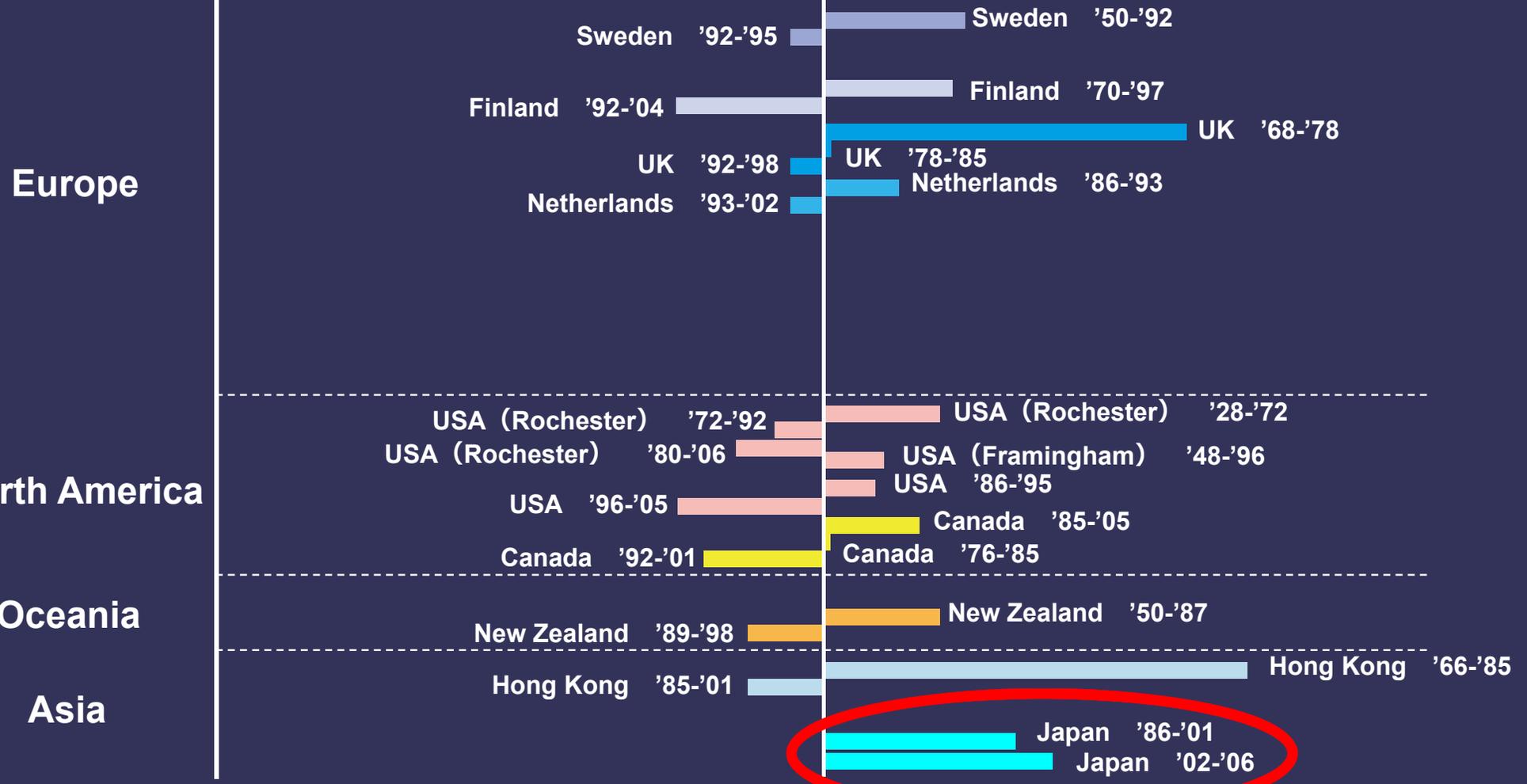
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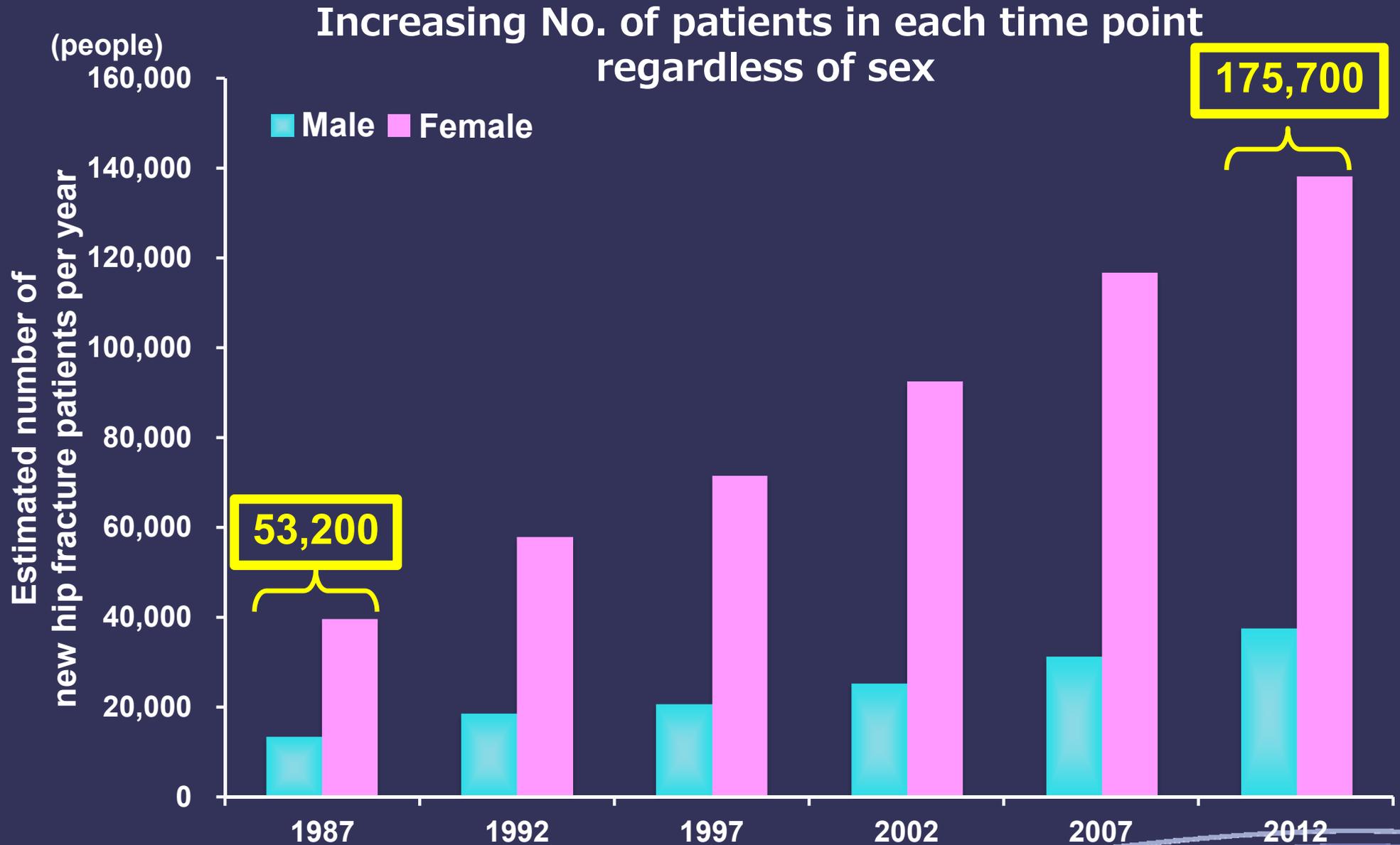
Trends in hip fracture (worldwide)

% Annual Change

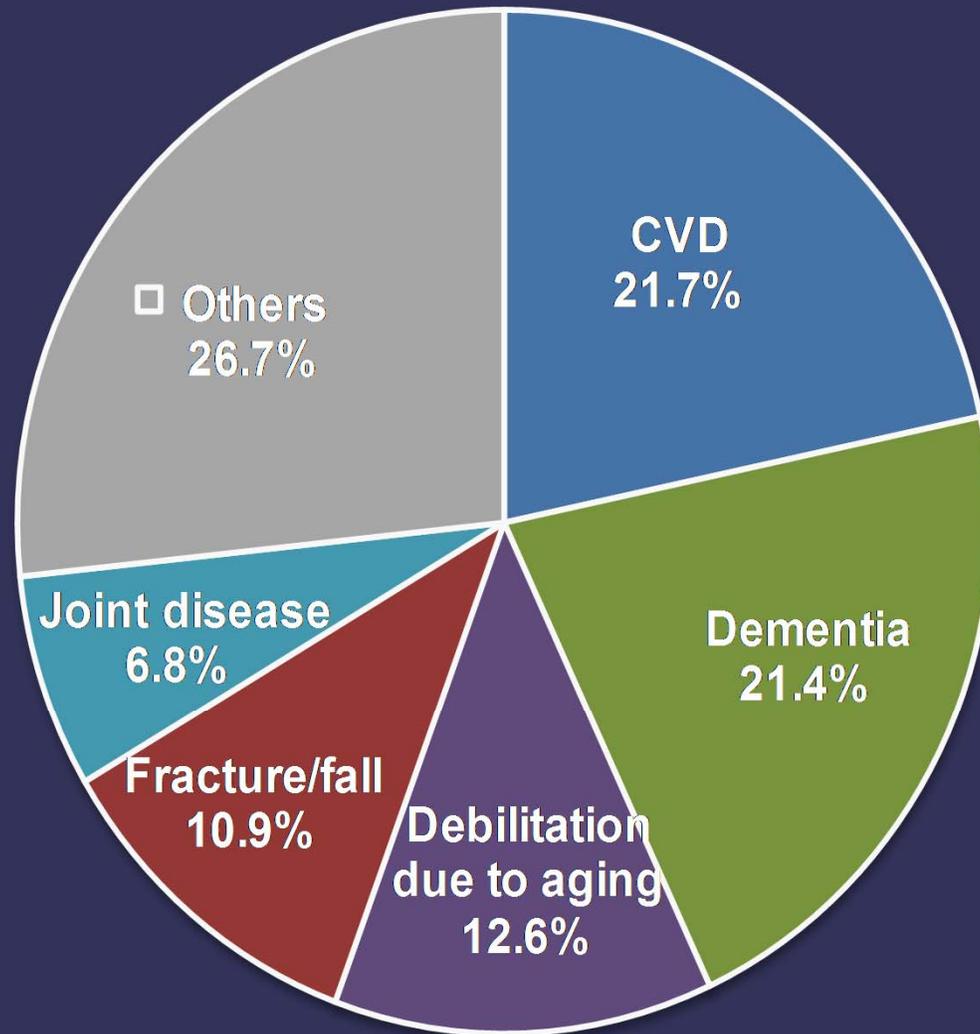
-10 -5 0 5 10



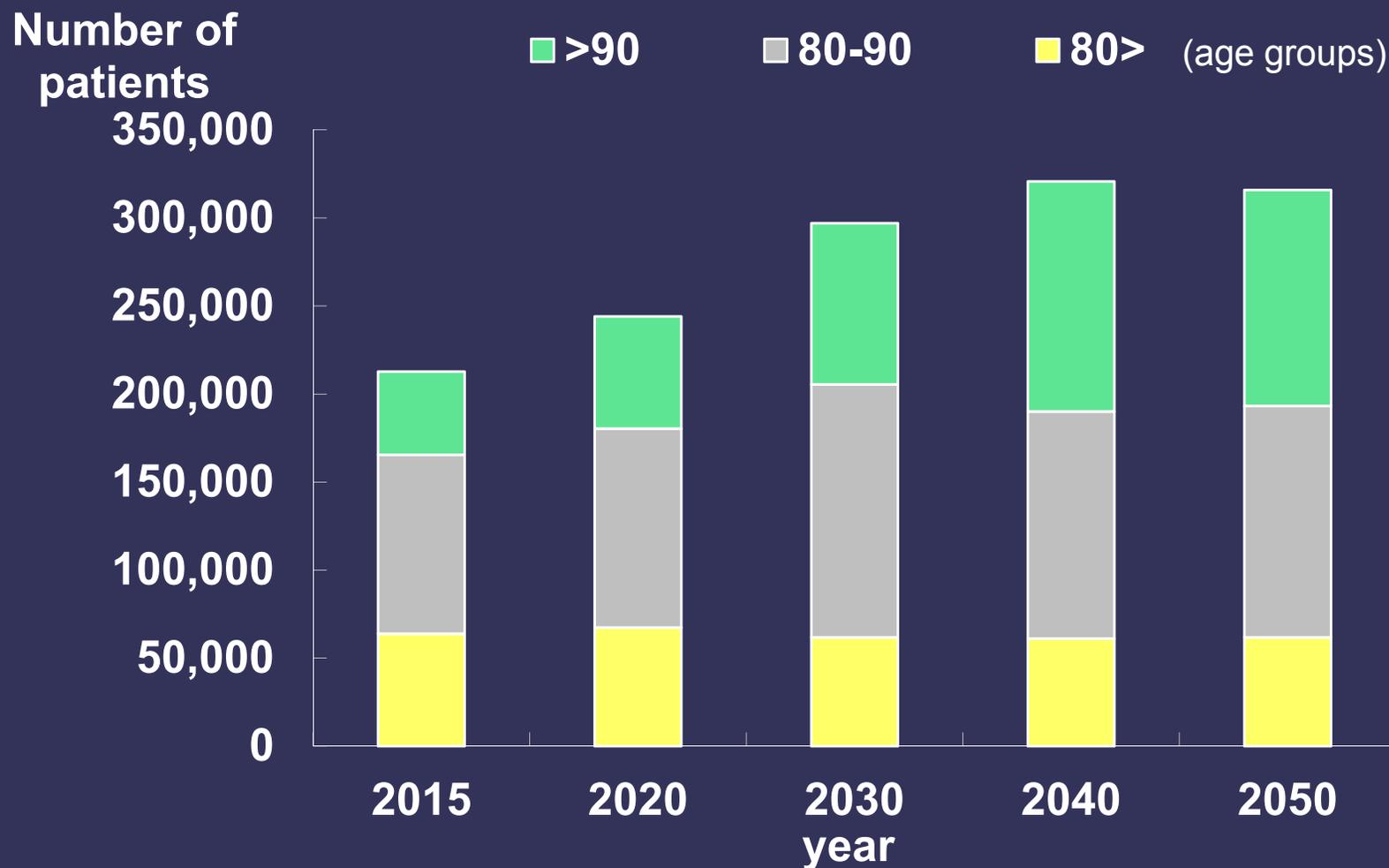
Trends in estimated number of new hip fracture patients per year



Proportions of major causes for being in need of care

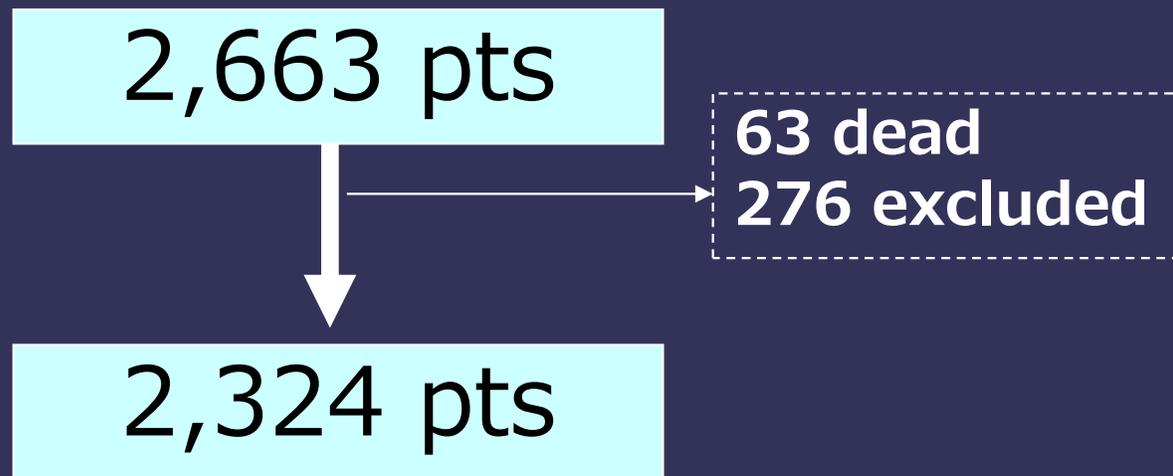


Estimated number of annual new patients with hip fracture in Japan



Data are calculated by adjusting to the population structure (≥ 35 years old, 2012 Japan) based on the age- and gender-specific incidence of hip fracture in Tottori Prefecture (2004-2006).

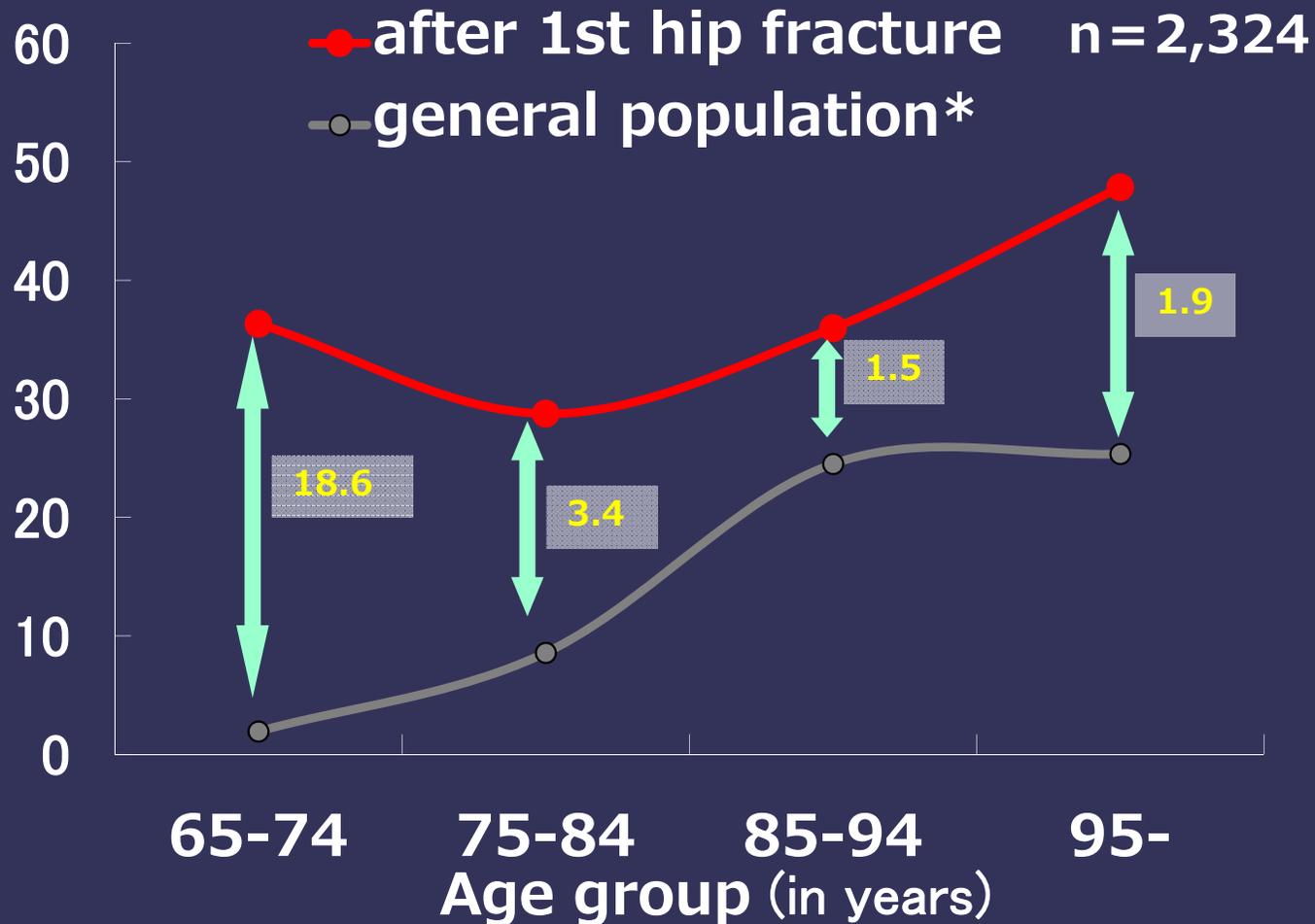
POSHIP study **P**revention of **S**econd **H**ip Fracture ~Number of 1st Hip Fracture~



Average age 83.6 years (range 65-104)
Femoral neck fracture 1,019,
Trochanteric fracture 1,300 (unknown 5)

Risk of hip fracture after 1st hip fracture

/1000 person · yr

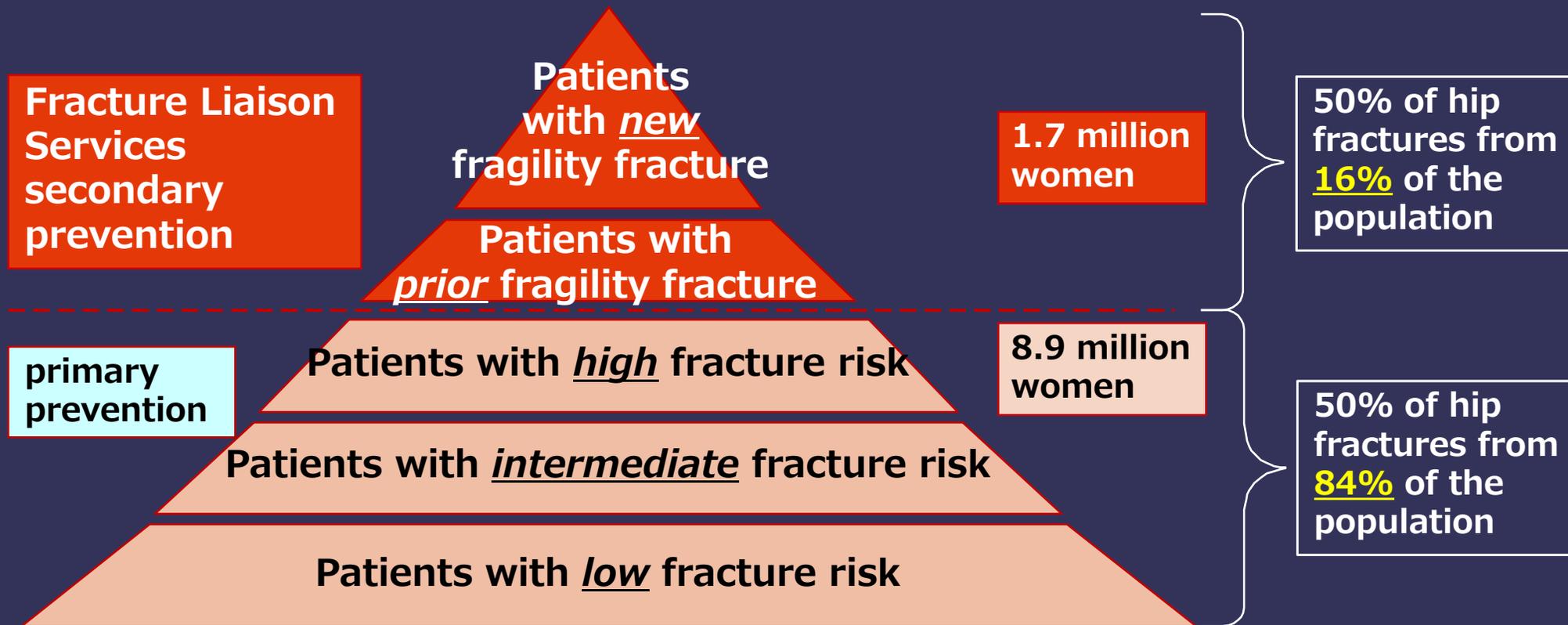


* Data of Tottori prefecture from 2004 to 2006
(Hagino H, et al, Osteoporos Int 2009)

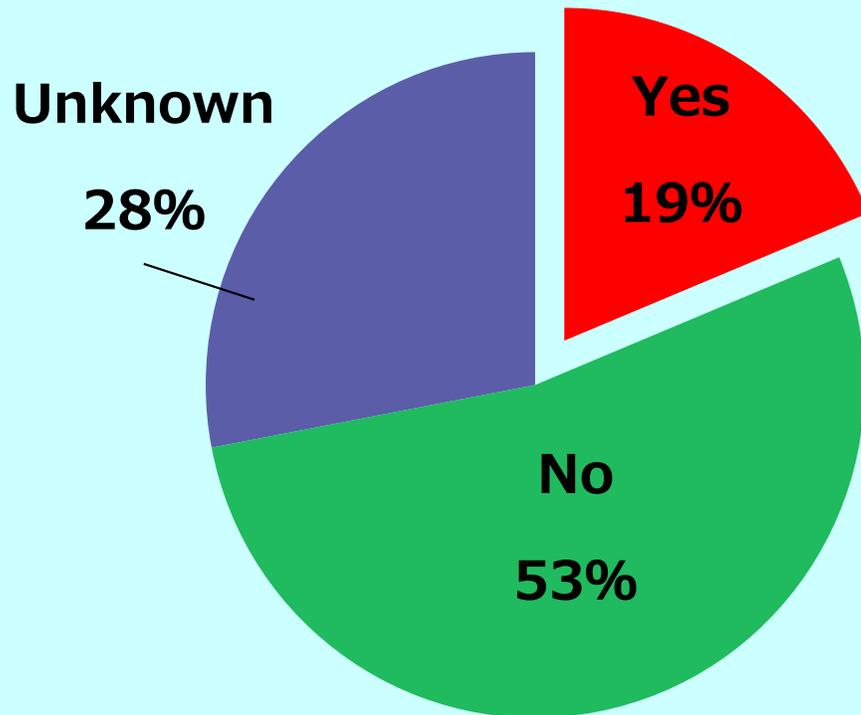
Associations between prior and subsequent fractures

<i>Location of prior fracture</i>	Location of subsequent fractures		
	wrist	vertebra	hip
wrist	3.3	1.7	1.9
vertebra	1.4	4.4	2.3
hip	-	2.5	2.3

Case finding & Fracture risk pyramid



Osteoporosis Treatment after Fragility Fractures



n=2,328 (1st hip fracture)

-POSHIP –



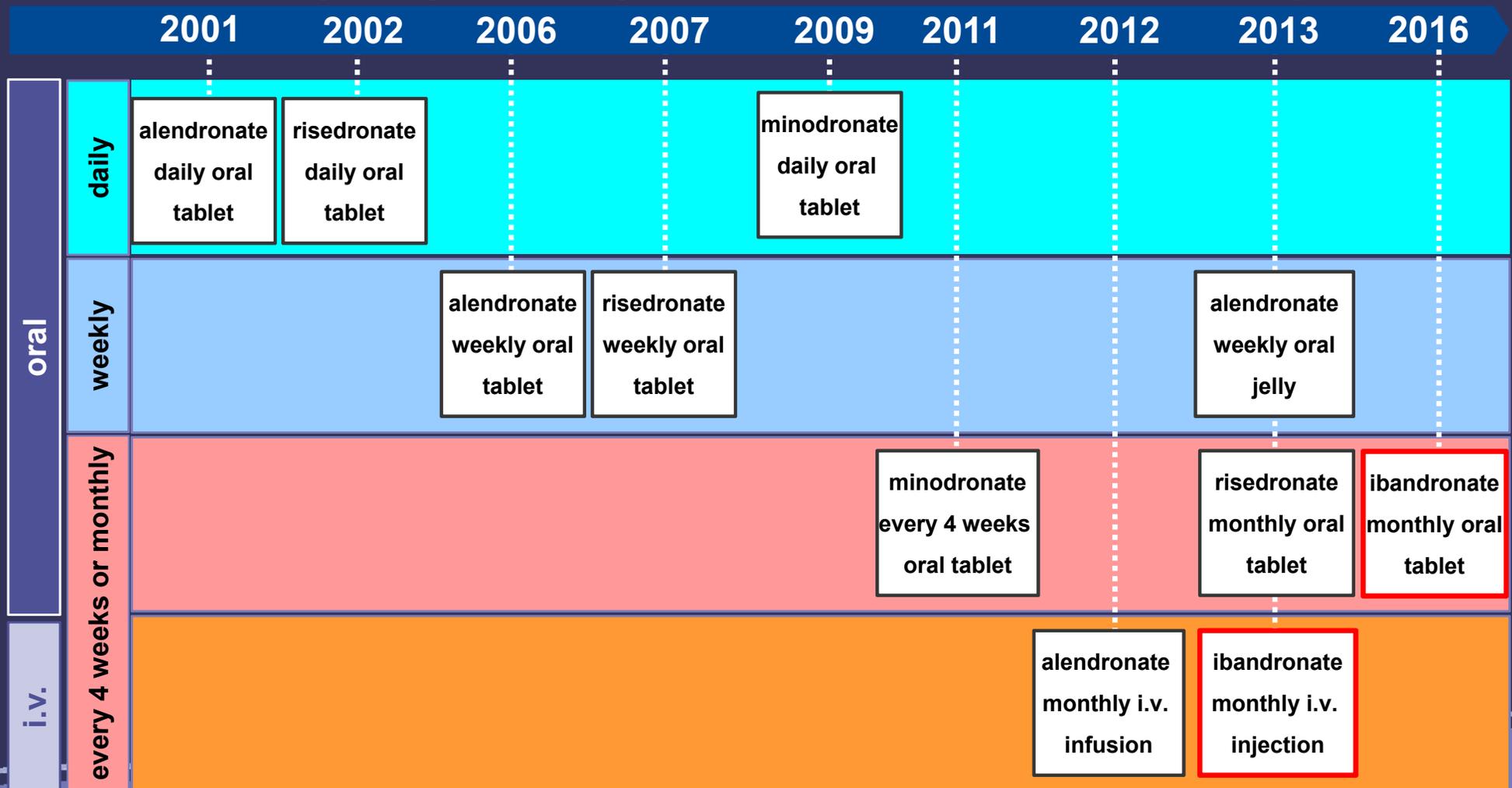
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- ✓ **New option for osteoporosis treatment**
- ✓ **Aiming to maintain a healthy life**

Development History of bisphosphonates in Japan

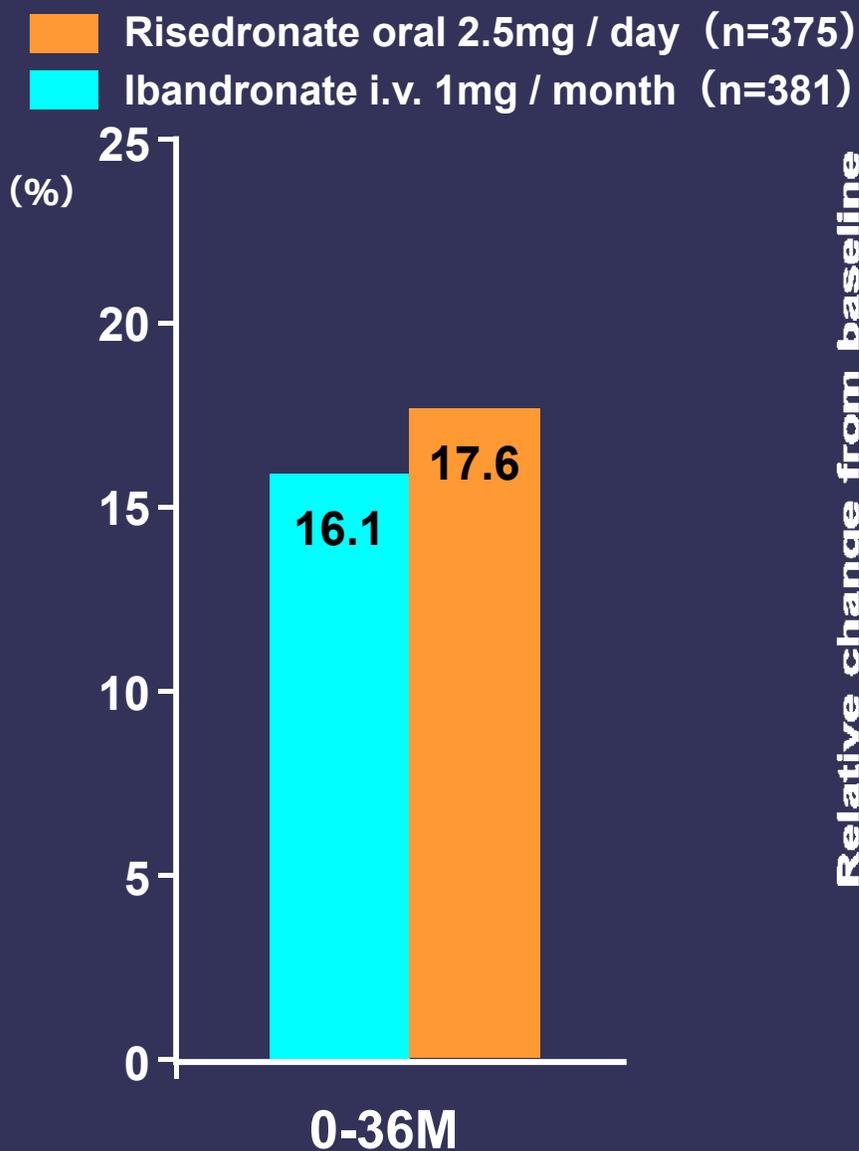
The history of developing bisphosphonate for treatment of osteoporosis represents the history of “extended dosing interval of oral formulation” & “development of injectable formulation”

● Launch of bisphosphonate products for treatment of osteoporosis

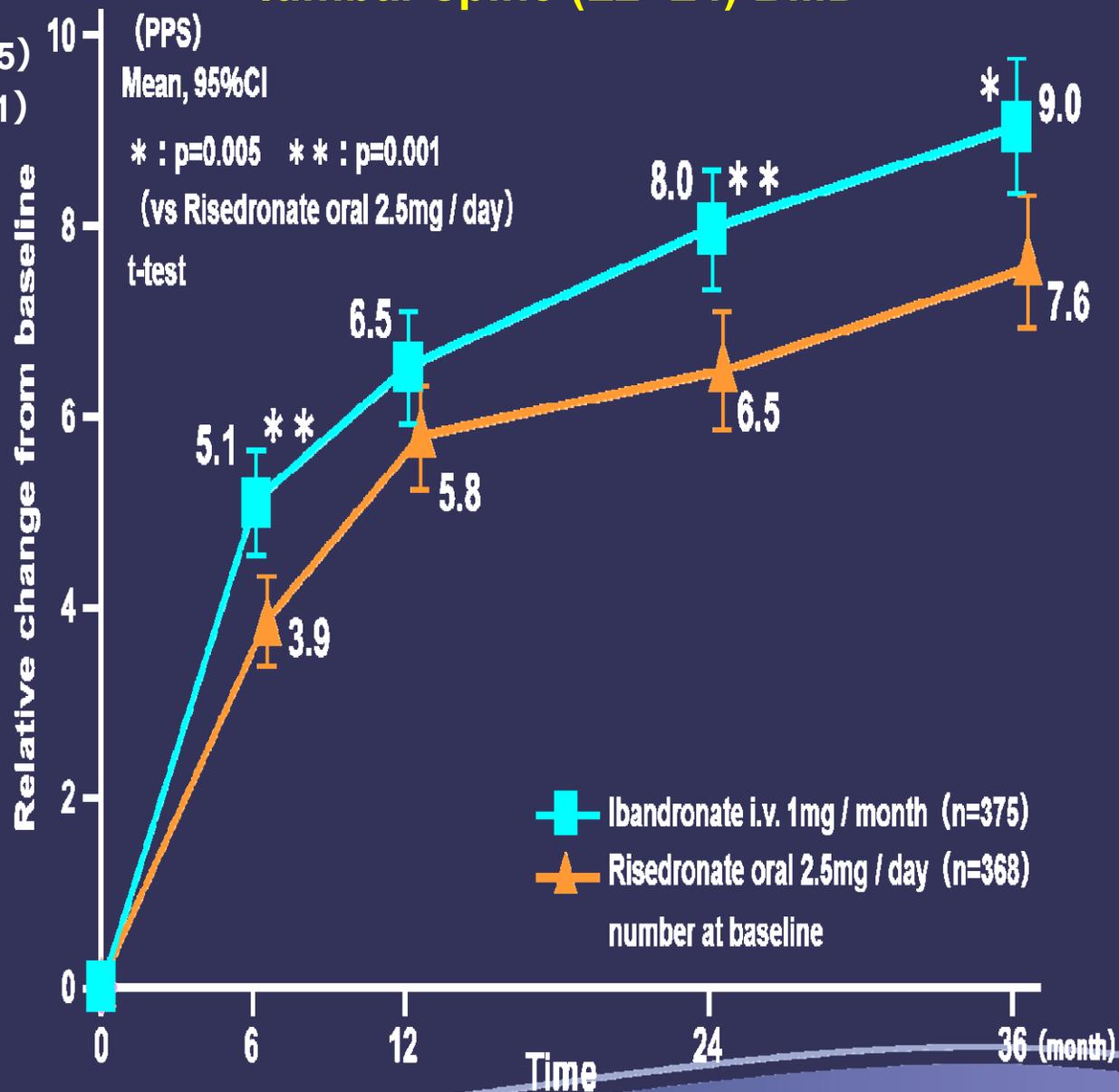


MOVER study (i.v. Phase 2/3 study)

Incidence of new or worsening vertebral fractures



Relative change from baseline in lumbar spine (L2-L4) BMD



P3 with oral ibandronate

MOVEST study

Monthly Oral Versus intravenous S ibandronaTe

**Clinical efficacy and safety of
monthly oral ibandronate 100mg versus monthly
intravenous ibandronate 1mg in Japanese patients with
primary osteoporosis**

**Nakamura T, Ito M, Hashimoto J, Shinomiya K, Asao Y, Katsumata K,
Hagino H, Inoue T, Nakano T, Mizunuma H, for the MOVEST Study Group**

Osteoporos Int (2015) 26: 2685-2693

Study design, Materials and methods



※All patients received supplementary calcium 610mg and vitamin D₃ 400IU/day.

Objective

To examine the efficacy and safety of monthly oral ibandronate 100mg versus monthly intravenous ibandronate 1mg in Japanese patients with primary osteoporosis

Patients

Patients with Primary Osteoporosis

Study design

Prospective, Multicenter, Randomized, Double-blind, Double-dummy Comparative study (non-inferiority trial)

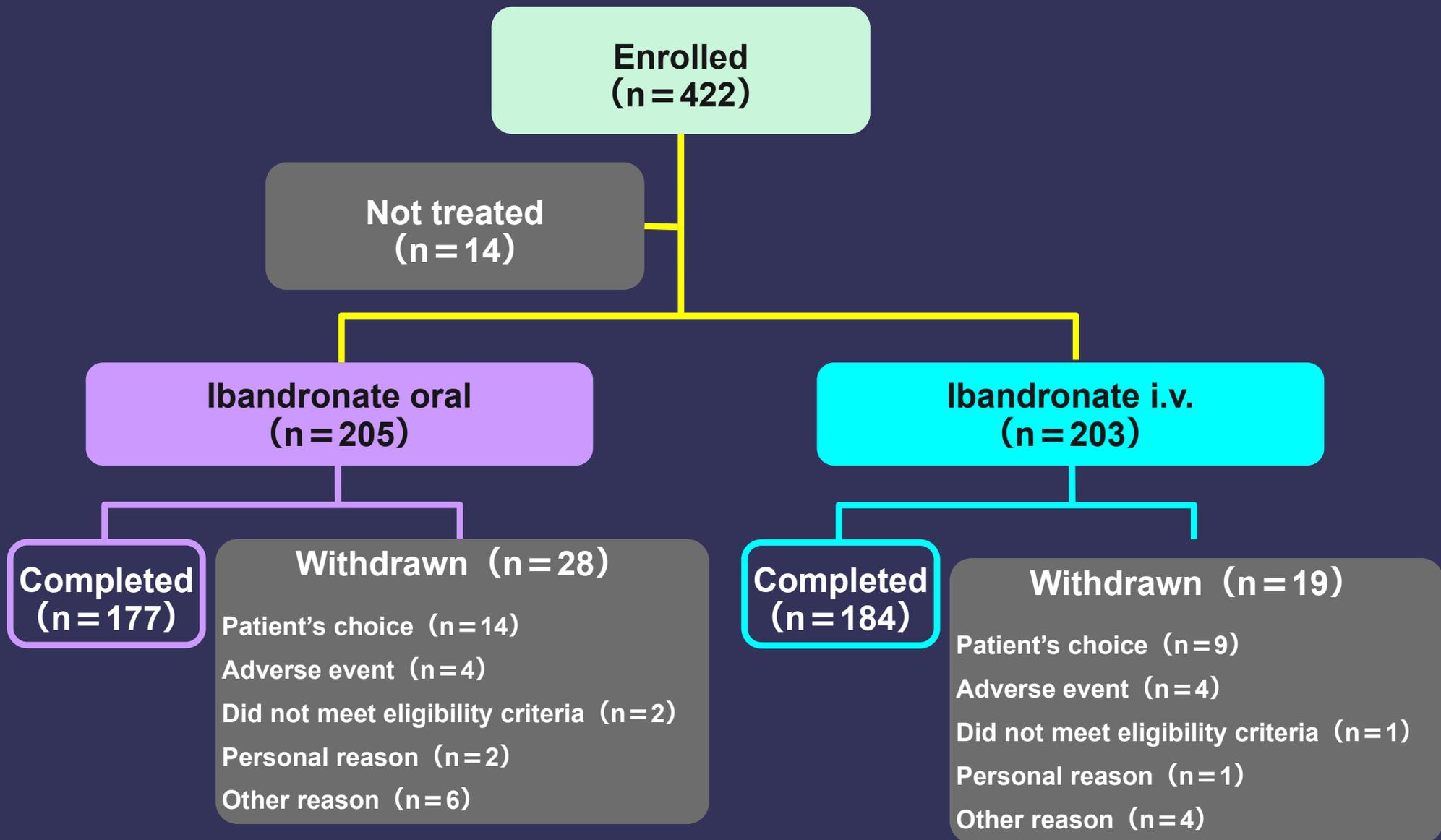
Primary endpoint

The percentage change from baseline in lumbar spine (L2–L4) BMD at 12 months

Secondary endpoints

The percentage change from baseline in femoral neck BMD at 12 months; change from baseline in BTMs; incidences of non-traumatic new fractures

Patient flow through the study



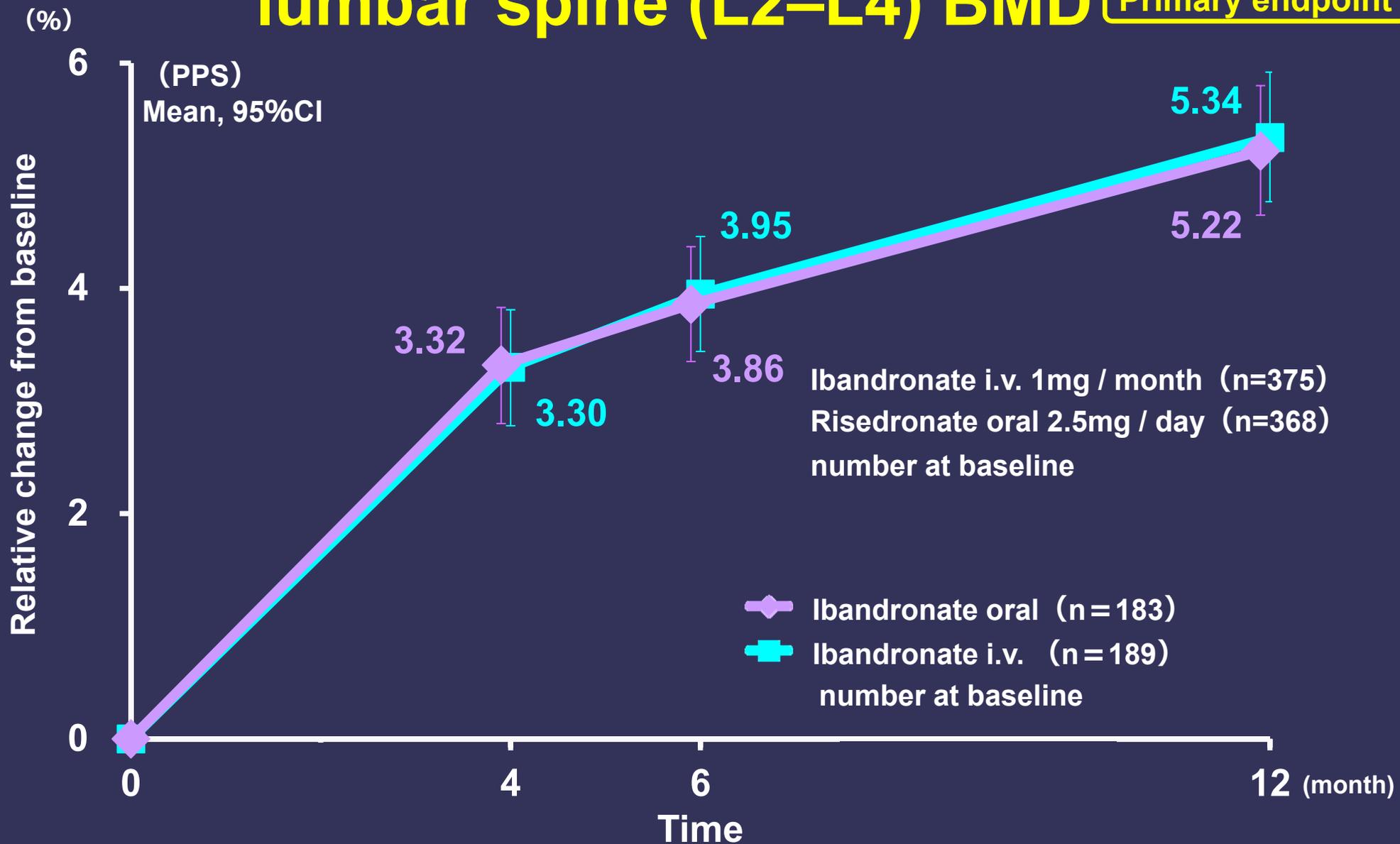
Baseline patient characteristics (PPS)

Characteristic		Ibandronate oral (n=183)	Ibandronate i.v. (n=189)
Women, n (%)		177 (96.7%)	186 (98.4%)
Age, years (mean±SD)		68.8 ± 6.9	69.3 ± 6.0
Weight, kg (mean±SD)		49.5 ± 7.2	49.2 ± 6.7
Height, cm (mean±SD)		152.2 ± 6.5	151.6 ± 6.1
BMD T-score (mean±SD)	Lumbar spine (L2–L4)	−3.09 ± 0.58	−3.14 ± 0.60
	Total hip	−2.41 ± 0.84*	−2.47 ± 0.79
	Femoral neck	−2.98 ± 0.82*	−2.99 ± 0.78
Prevalent vertebral fractures, n (%)	0	124 (67.8%)	130 (68.8%)
	1	34 (18.6%)	34 (18.0%)
	≥2	25 (13.7%)	25 (13.2%)
Bone turnover markers (mean±SD)	uCTX, µg/mmol CR	247.9 ± 138.8	249.4 ± 166.4
	TRAP 5b, mU/dL	387.4 ± 131.6	389.2 ± 152.8
	P1NP, µg/L	50.6 ± 21.4	49.0 ± 22.3
	BALP, µg/L	17.1 ± 6.8	16.5 ± 6.9
	25-OH(D), ng/mL	25.3 ± 6.3	25.3 ± 5.8

PPS: Per Protocol Set, BALP: bone-specific alkaline phosphatase, BMD: bone mineral density, CR: creatinine, i.v.: intravenous, P1NP: procollagen type 1N-terminal propeptide, SD: standard deviation, TRAP 5b: tartrate-resistant acid phosphatase 5b, uCTX: creatinine-corrected urinary collagen type 1 cross-linked C-telopeptide, 25-OH(D): 25-hydroxyvitamin D
*n = 181

Relative change from baseline in lumbar spine (L2–L4) BMD

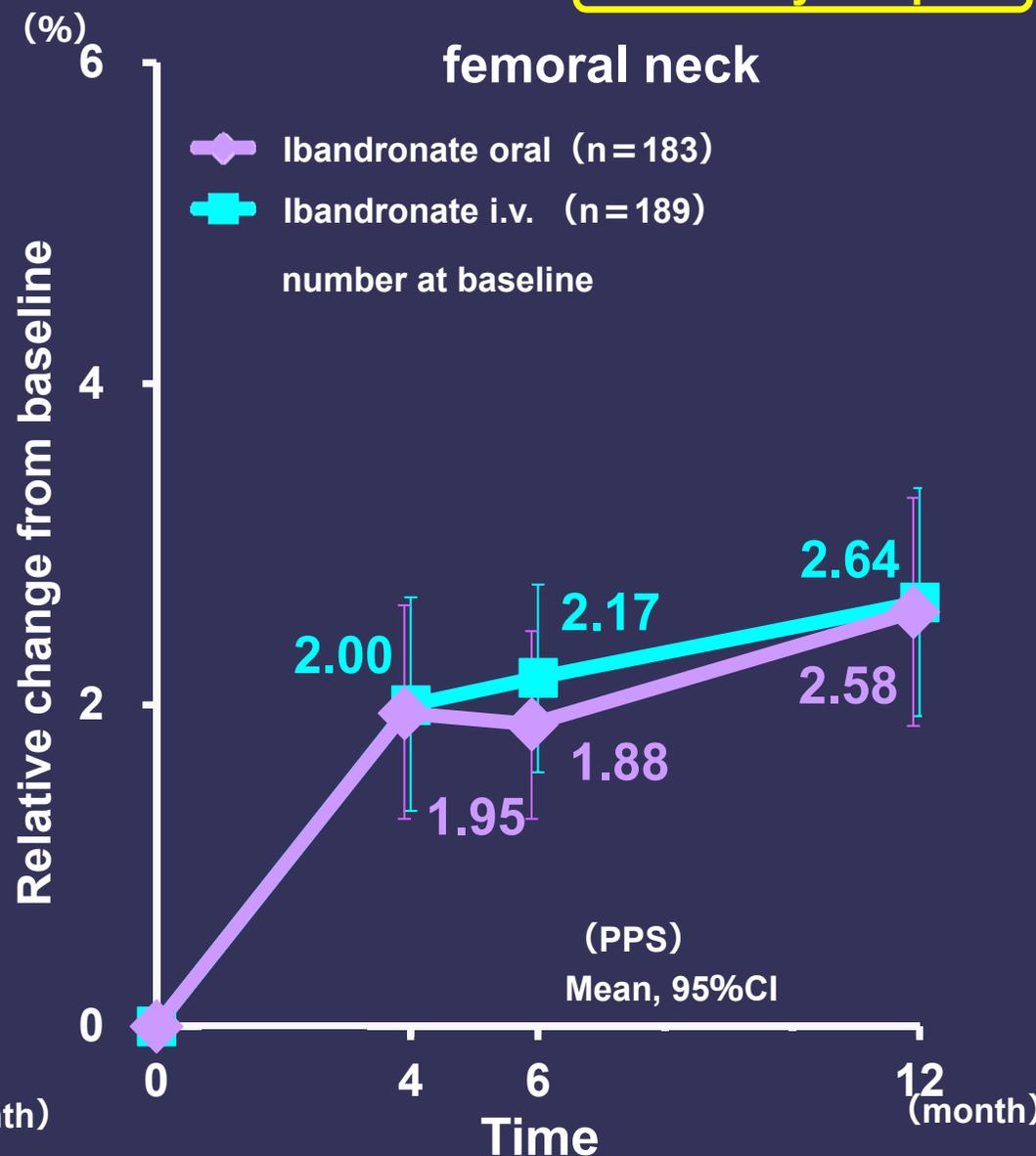
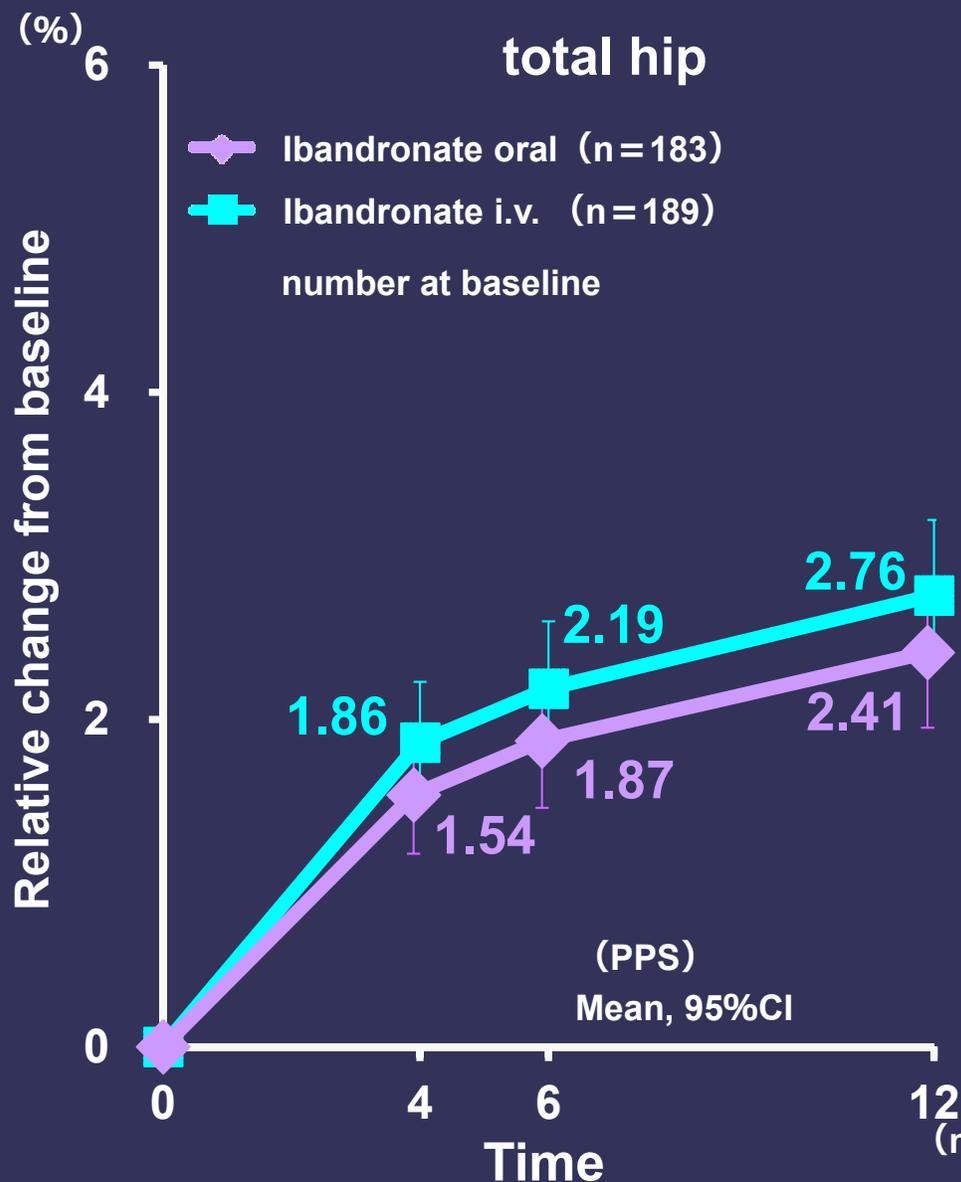
Primary endpoint



For missing values, LOCF (Last Observation Carried Forward) approach was used.

Relative change from baseline in hip BMD

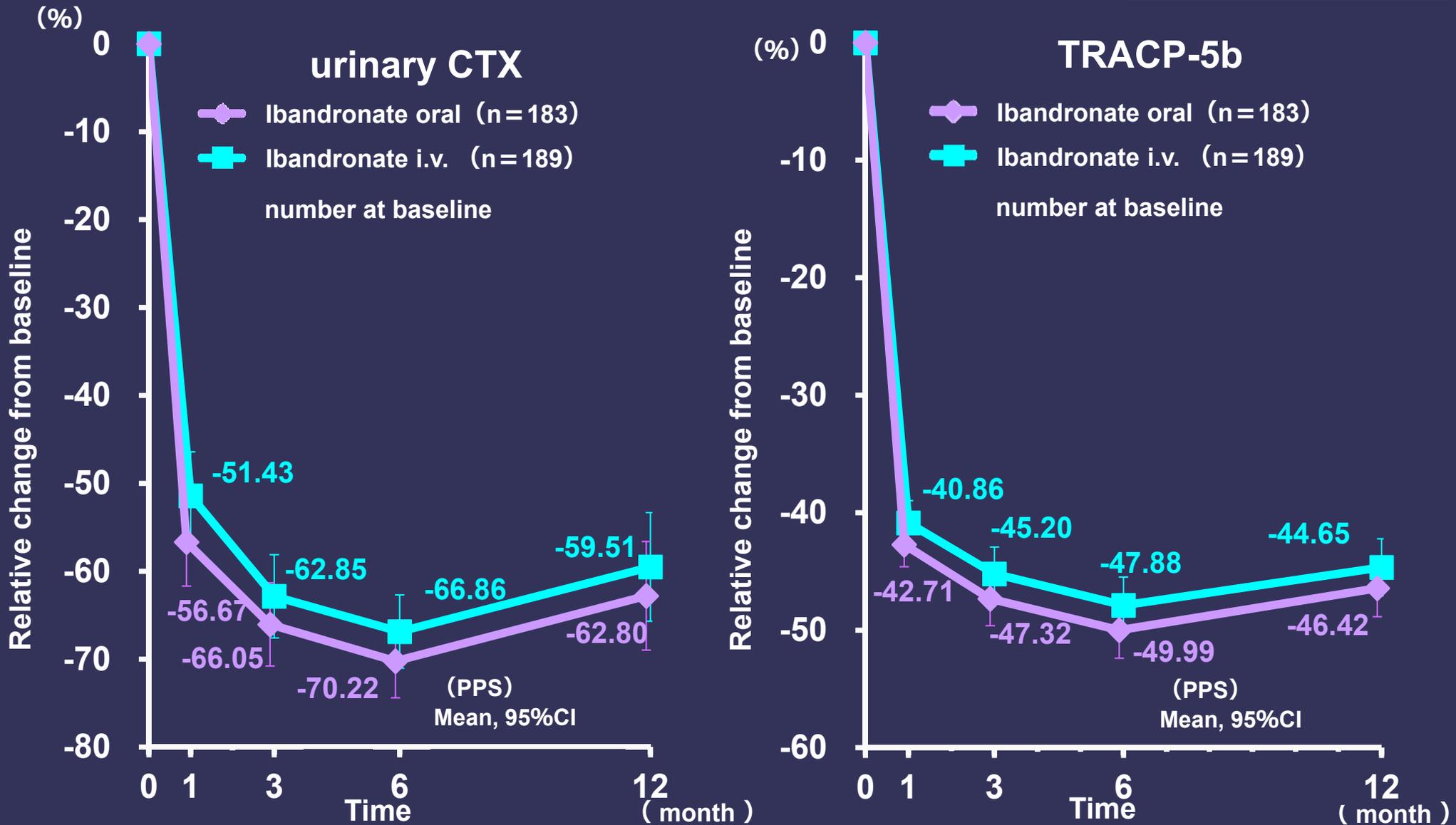
Secondary endpoint



For missing values, LOCF (Last Observation Carried Forward) approach was used.

Relative change from baseline in bone turnover markers

Secondary endpoint



For missing values, LOCF (Last Observation Carried Forward) approach was used.

Incidences of osteoporotic fractures

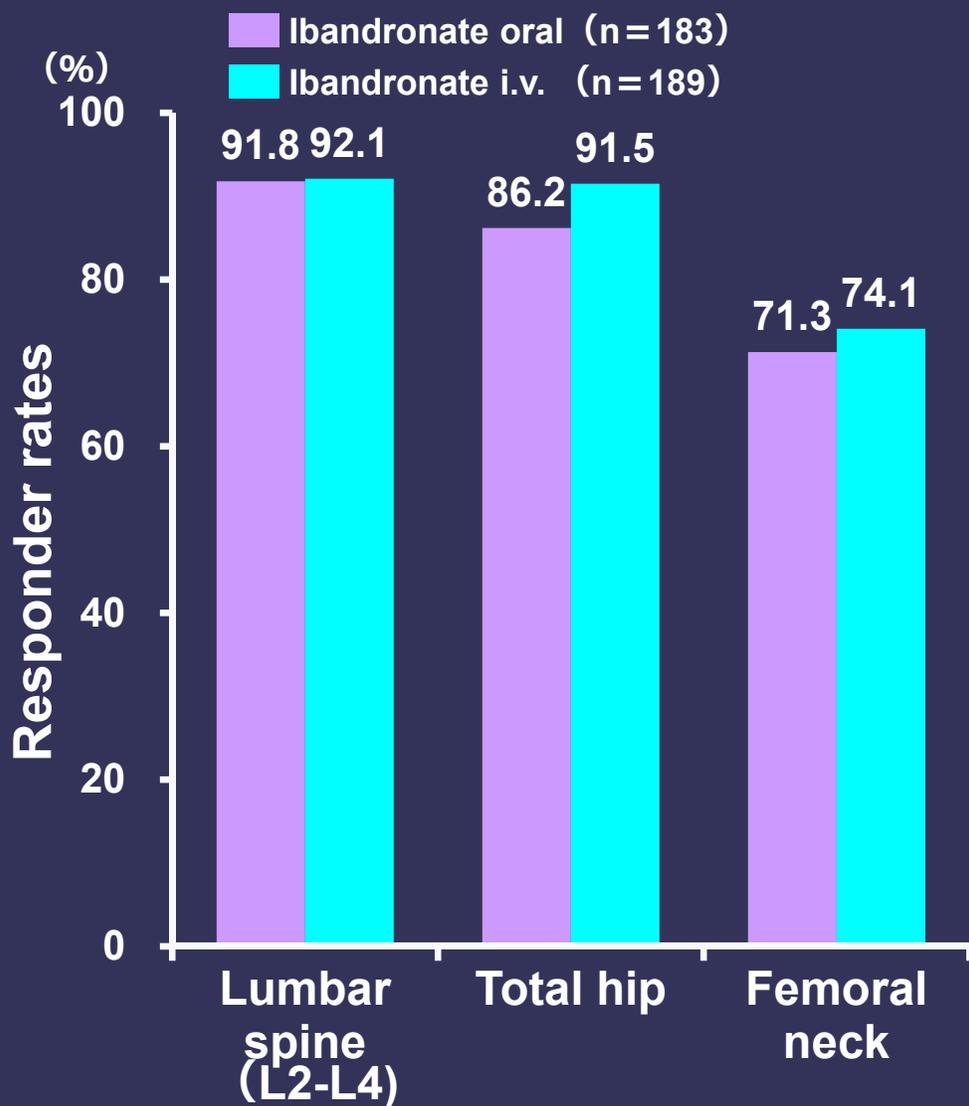
Secondary endpoint

(PPS)

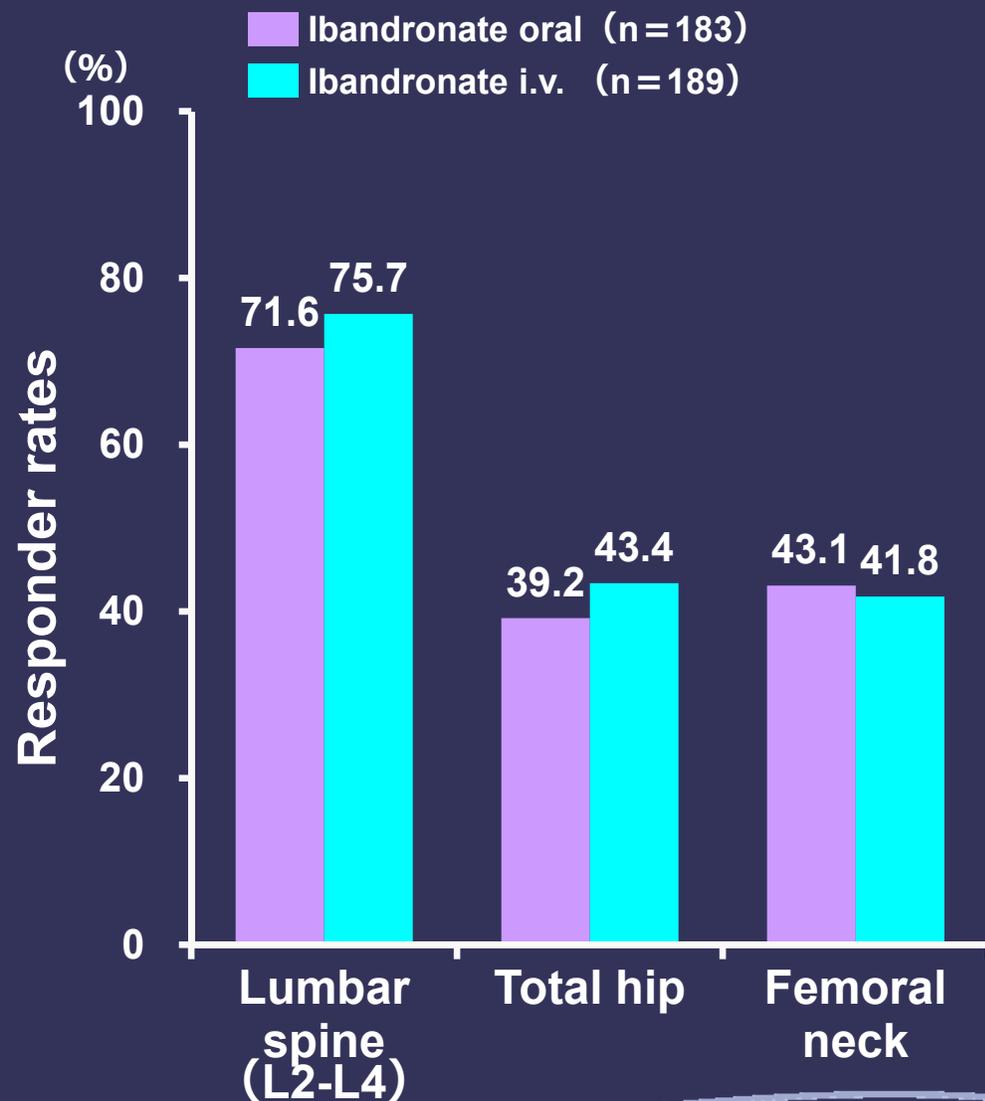
	Ibandronate oral (n=183)	Ibandronate i.v. (n=189)
vertebral fracture	2 (1.1%)	1 (0.5%)
non-vertebral fractures	2 (1.1%)	5 (2.6%)
sites of fracture	Radius fracture Leg fracture	Radius fracture (n=3) Wrist joint fracture Hand fracture

Responder rates (with 95 % CI) after 12 months of treatment

Patients with >0 % increase in BMD



Patients with ≥3 % increase in BMD



Summary of adverse events

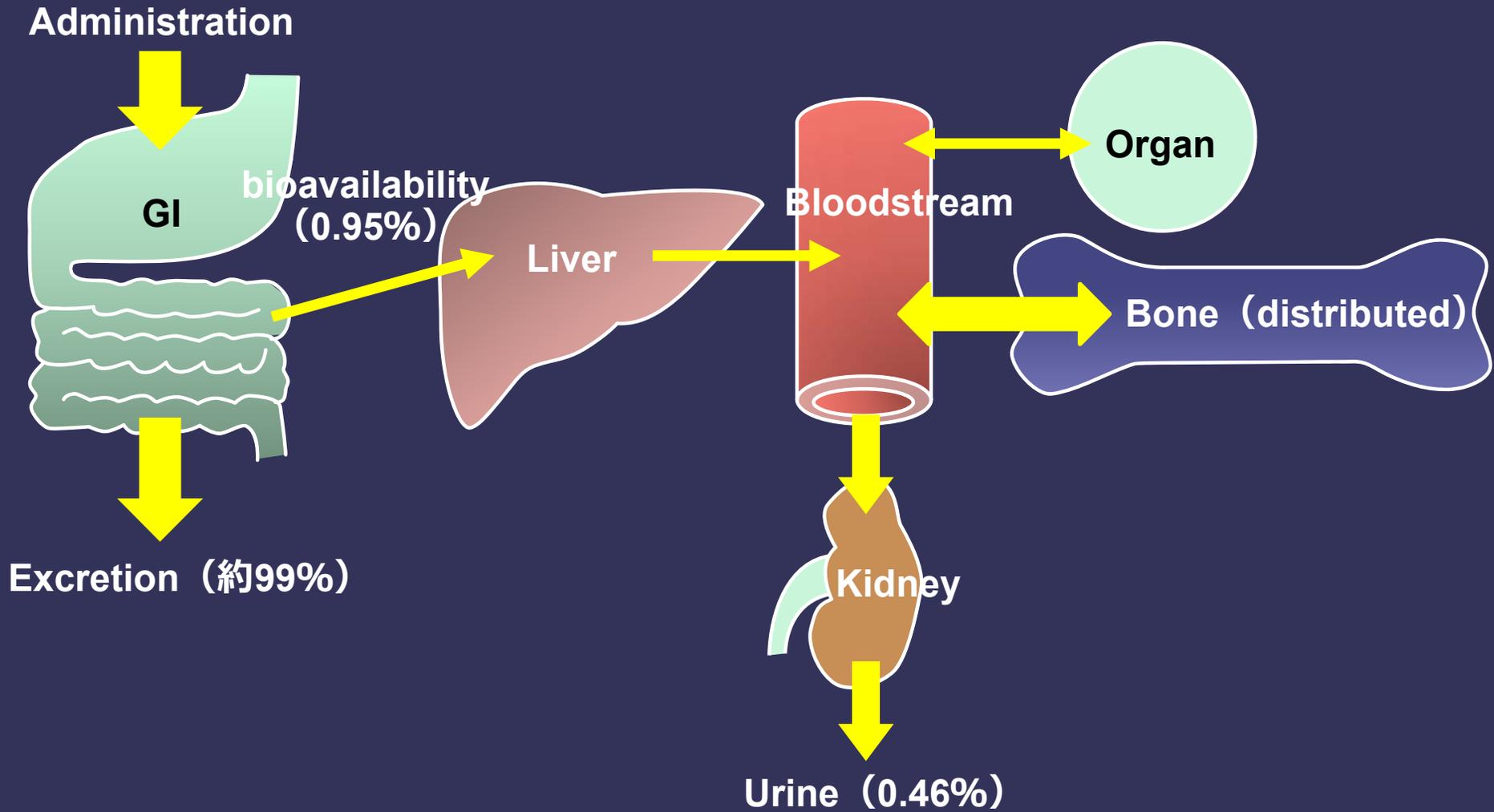
(safety population)

AE, n (%)	Ibandronate oral (n=205)	Ibandronate i.v. (n=203)
Any AE	175 (85.4)	177 (87.2)
Drug-related AE	47 (22.9)	38 (18.7)
Severe intensity AE	2 (1.0)	0
Serious AE	9 (4.4)	6 (3.0)
AEs leading to death	0	0
AEs leading to treatment withdrawal	4 (2.0)	4 (2.0)

Oral bisphosphonates are absorbed from upper gastrointestinal tract

image

- Pharmacokinetics after oral administration of bisphosphonates



AUC_{inf} for ibandronate in serum after oral and intravenous administration of ibandronate

Population	Dose/route	Body weight (kg)	Creatinine clearance (mL/min)	AUC _{inf} (ng h/mL)
Postmenopausal healthy women + postmenopausal women with osteoporosis (Domestic Study)	100mg/oral	53 ± 7 (n = 14)	94 ± 20 (n = 14)	219 ± 114 (n = 14)
Postmenopausal women with osteopenia (Domestic Study)	1.0 mg/i.v.	57 ± 7 (n = 10)	110 ± 29 (n = 10)	240 ± 22.7 (n = 10)

Values are mean ± SD

AUC_{inf}: the area under the serum ibandronate concentration–time curve

AUC_{last} for ibandronate in serum fasting interval of 30 min vs. 60 min

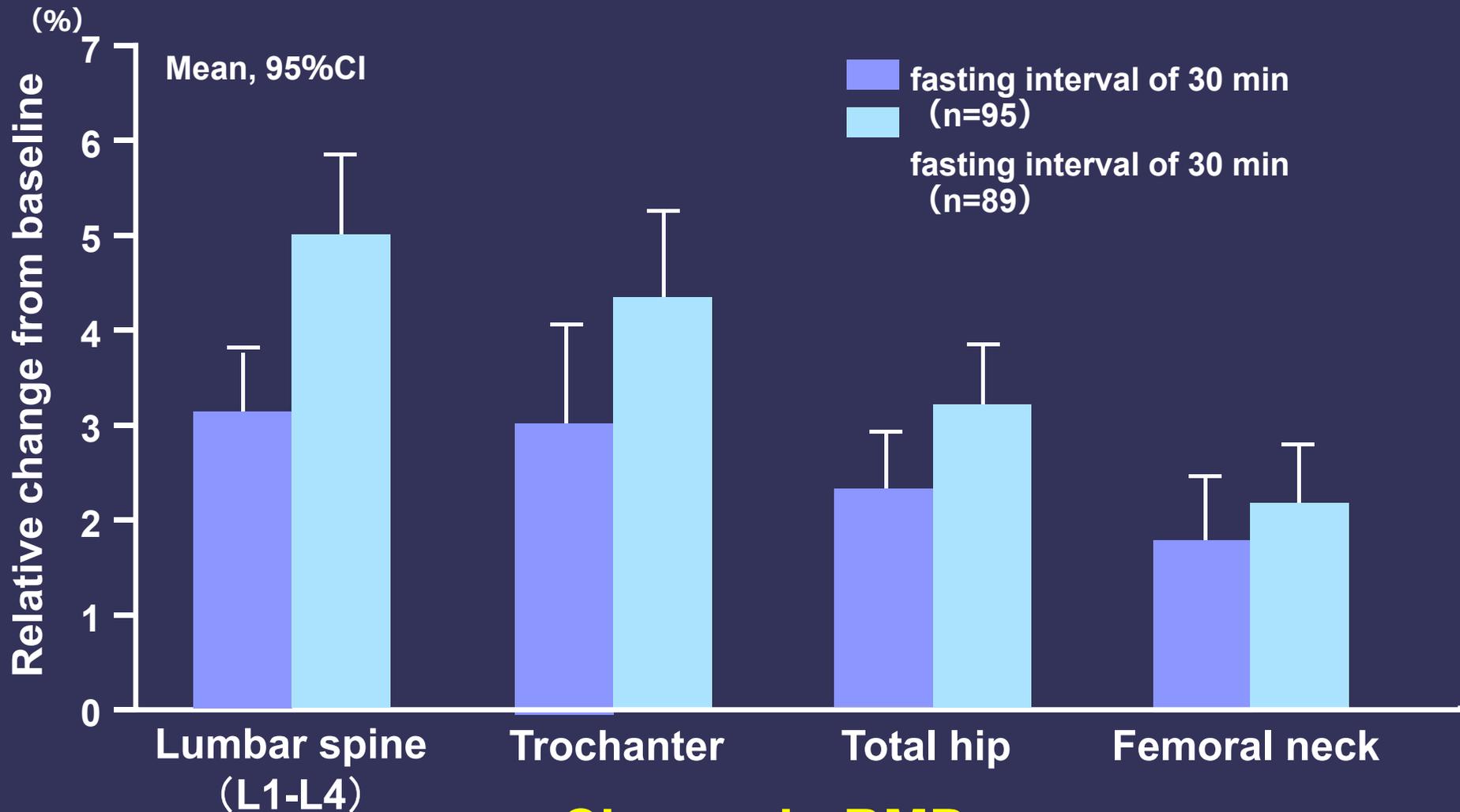
Study	Dosage	AUC _{last} (ng·h/mL)	
		fasting interval of 30 min	fasting interval of 60 min
Study I (n = 24)	2.5mg ibandronate	1.12 ± 0.950 (84.8%)	1.40 ± 0.774 (55.3%)
Study II (n = 24)	50mg ibandronate	11.1 ± 23.5 (212%)	16.0 ± 15.6 (97.5%)

Values are mean ± SD (coefficient of variation)

AUC_{inf}: the area under the serum ibandronate concentration–time curve

AUC :
fasting interval of 60 min after oral administration
>30 min after oral administration

The mean percentage change in the lumbar spine (L1-L4) and hip BMD from baseline of 48-week oral ibandronate treatment in postmenopausal osteoporosis



Change in BMD :
fasting interval of 60 min > fasting interval of 30 min

Survey and analysis on fasting interval elongation in oral bisphosphonate therapies among patients with osteoporosis

Objective

To demonstrate what impacts on patient preference and what factor is related to the impact by elongating fasting interval from 30 min to 60 min in oral bisphosphonate (BP) therapies

Patients

148 orthopedic outpatients with osteoporosis visiting any of 4 institutions from March to November 2015 who received BP therapies (11 males and 137 females)

Method

We studied whether patients might get bothered by change in fasting interval of the currently taken BP agents from 30 min to 60 min by using a questionnaire.

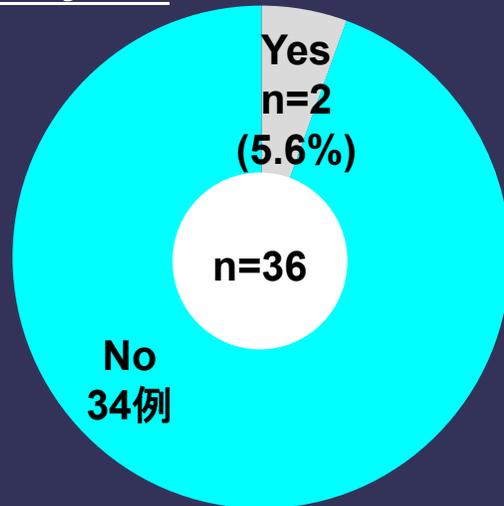
Answers (bothered/not bothered) were defined as an objective variable in the multivariate analysis with gender, age, duration of BP therapies, BP dosing interval (daily, weekly, or monthly) and BP agent type as explanatory variables in order to explain what factor has an influence when choosing either “bothered” or “not bothered”.

Assessments on bisphosphonate therapies

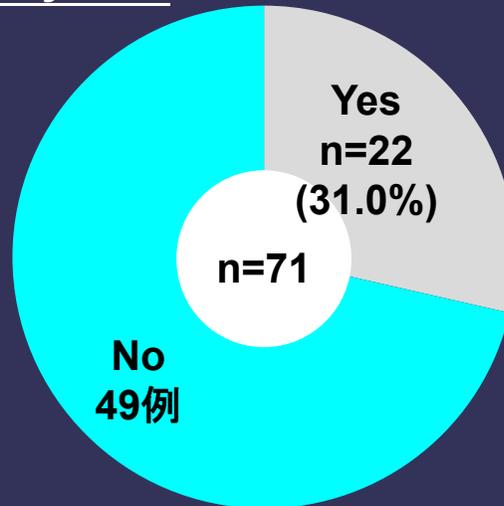
”Do you get bothered?”

Duration of BP therapies

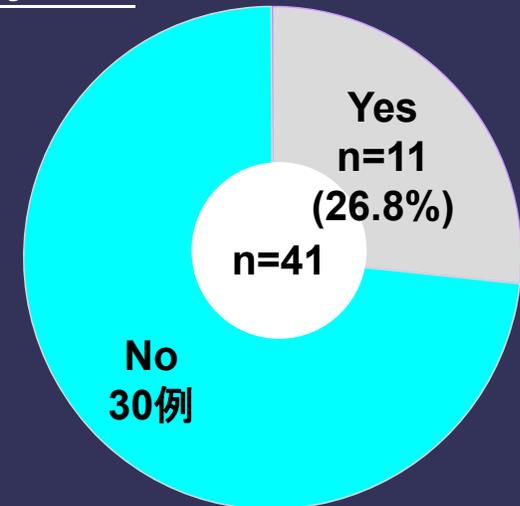
≤1 year



>1 to ≤3 years

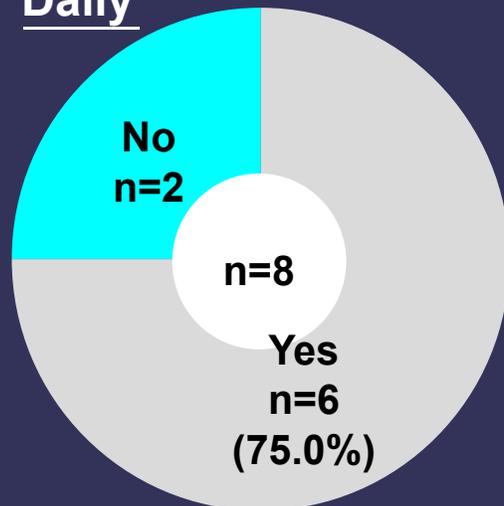


>3 years

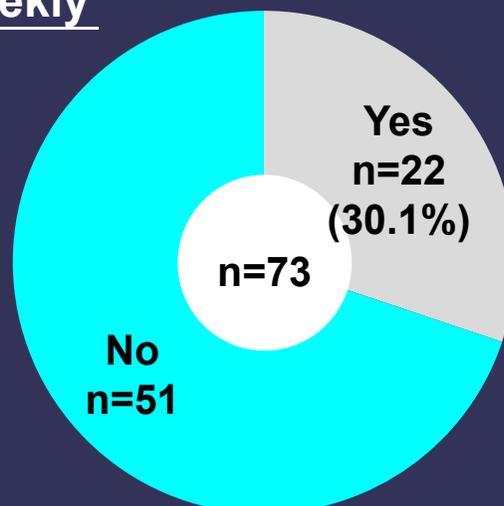


BP dosing interval

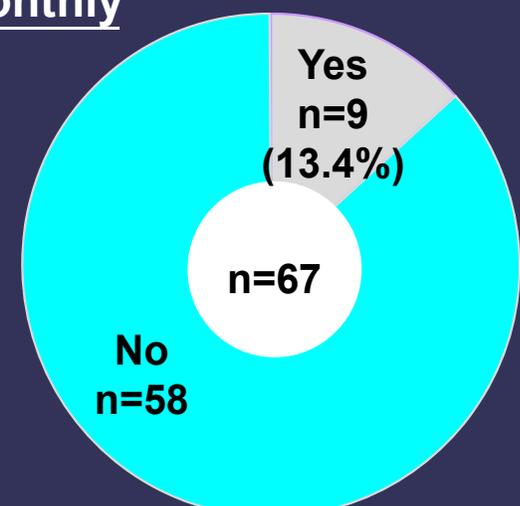
Daily



Weekly



Monthly



Wake-up Time And Breakfast Time Among Elderly People (The Survey on Time Use and Leisure Activities of Japan in 2011)

Mean wake-up time* ¹	Male			Female		
	Weekdays	Saturday	Sunday	Weekdays	Saturday	Sunday
All	6:46	7:19	7:28	6:28	6:59	7:07
60-64 years	6:19	6:35	6:36	6:11	6:26	6:36
65-69 years	6:17	6:25	6:34	6:09	6:24	6:21
70-74 years	6:13	6:26	6:33	6:13	6:19	6:21
≥75 years	6:27	6:31	6:32	6:28	6:33	6:32
Mean breakfast time* ²	Male			Female		
	Weekdays	Saturday	Sunday	Weekdays	Saturday	Sunday
All	7:05	7:31	7:38	7:15	7:35	7:43
60-64 years	7:00	7:16	7:18	7:11	7:22	7:29
65-69 years	7:08	7:14	7:23	7:13	7:21	7:23
70-74 years	7:10	7:17	7:20	7:17	7:19	7:19
≥75 years	7:19	7:23	7:23	7:25	7:27	7:29

*1: Finish time of the first sleep period starting from before 12:00 am lasting for >60 min

*2: The first meal time after 4:00 am before 11:00 am

● What is the Survey on Time Use and Leisure Activities of Japan?

The purpose of the Survey on Time Use and Leisure Activities of Japan is to take a survey about the use of living hours and major activities in their free time among Japanese people for providing basic data for various kinds of administrative programs, conducted every 5 year since the first survey in fiscal 1976. In the Survey conducted in 2011, about 0.2 million members age 10 or older in about 83,000 families were randomly selected across the nation as of October 20 2011. After providing the initial result about time use, the detailed data on time use according to various activities were released in December 2012.

Today's topics

- ✓ **Current status and issues of osteoporosis medication in Japan**
- ✓ **New option for osteoporosis treatment**
- ✓ **Aiming to maintain a healthy life**

Identification of fracture (emergency, orthopedics)

New radiology report of fracture

Previous fragility fracture

High risk except previous fracture

Referred by primary care physicians

Referred by primary care physicians

Three steps

- identification
- fracture risk assessment
- appropriate intervention



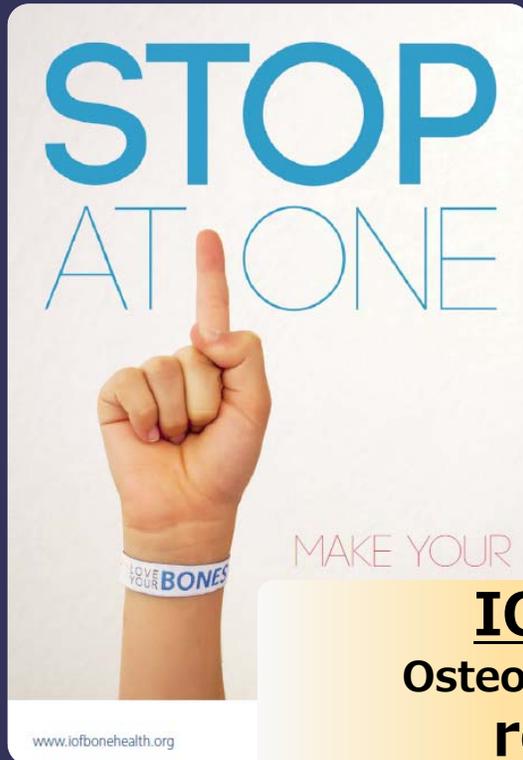
Liaison
(Osteoporosis manager)

Liaison Service (secondary prevention)

Not only “secondary prevention” but also “primary prevention” in Japan

FLS frequently used in UK and other countries is “**Fracture Liaison Service**” mainly for **secondary prevention for fracture**

OLS in Japan is “**Osteoporosis Liaison Service**” including **primary prevention for fracture**

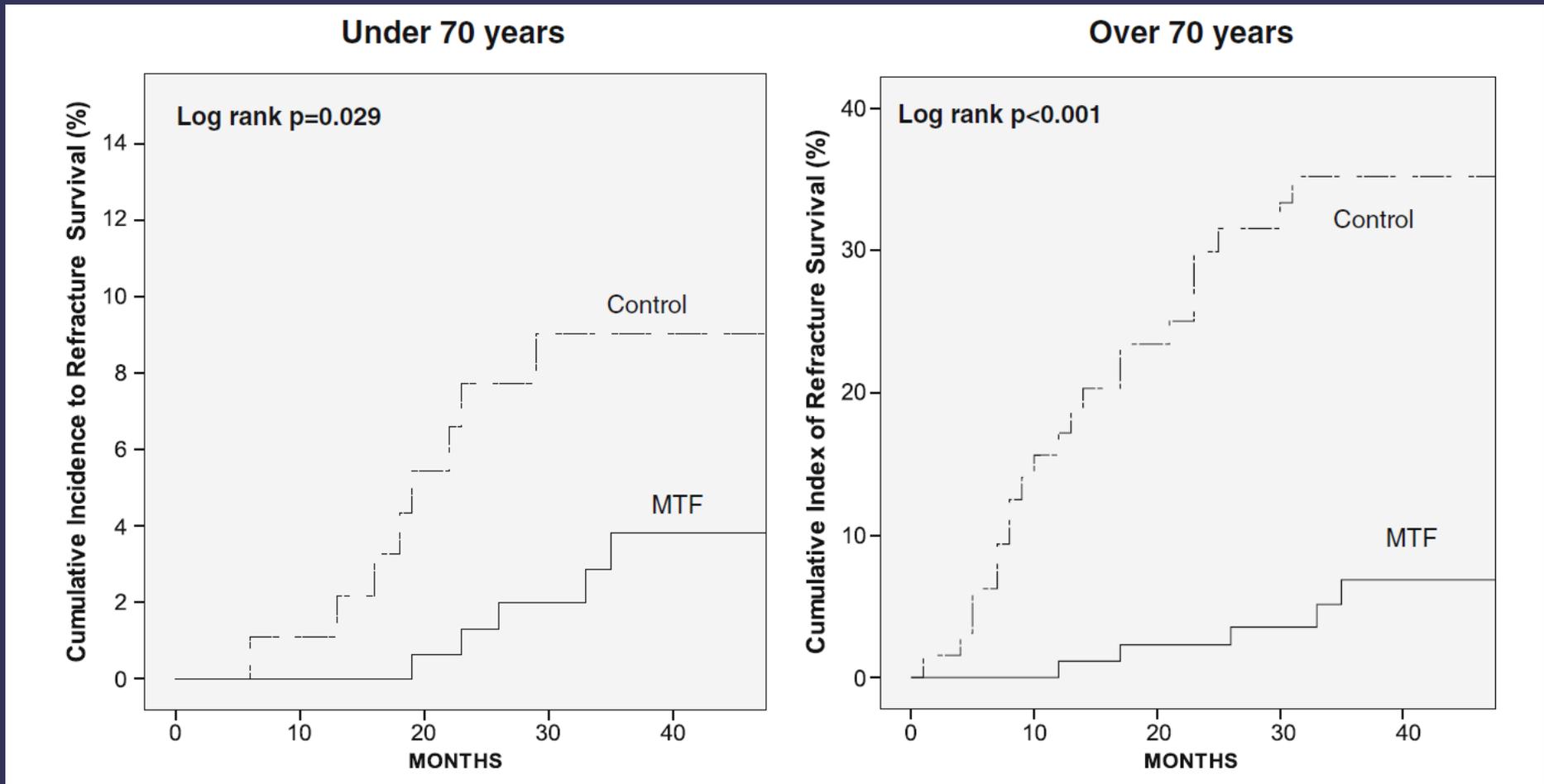


IOF (International Osteoporosis Foundation) recommends **secondary prevention**



Japan targets **also primary prevention**

Liaison service reduces secondary fracture



Cumulative refracture incidence by age and group

MTF: minimal trauma fracture (intervention program)



骨の健康手帳

再骨折予防のための転ばぬ先の杖



受診の際には、この手帳を必ずご持参ください

氏名:

連絡先:

この手帳を受け取った日: 年 月 日



最初の骨折を最後の骨折に!

骨折をしたあなたへ
 骨がもろくなると骨折を繰り返す心配があります。
 骨を丈夫にして再骨折を予防していくことが大切です。
 元気で健やかな生活が送れるよう、お手伝いさせていただきます。



看護師 医師 薬剤師 理学療法士 栄養士



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JOS activities for OLS

To promote OLS (Osteoporosis Liaison Service) ,
JOS (Japan Osteoporosis Society) implements:

- accreditation system for **osteoporosis manager**
- educational program (osteoporosis manager lecture course)

Osteoporosis Manager Accreditation System

Osteoporosis manager®



【Eligible person】
Persons who belong to hospital/clinic/
care service facility/pharmacy/clinical
laboratory/local government/health
center/educational institution, etc. and
engage in medical/health/educational
activities (health nurses, nurses, clinical
radiologists, clinical laboratory
technicians, PTs, OTs, clinical engineers,
STs, pharmacists, registered dietitians,
social workers, care workers)

【Validity】
5 years (from April 1st in the year
accredited to March 31st after 5 years)

【Announcement】
Name and work site of OLS managers
are published in the journal and
homepage of JOS in principle.



Physician



Pharmacist

OLS

- Prevention for osteoporotic fracture
- Improvement of treatment persistence rate
- Osteoporosis enlightenment
- Organic collaboration among medical resources etc.



Care worker



Nurse



PT

Liaison conference / Regional alliance conference

osteoporosis manager

orthopedic chief nurse

clerk

research collaborator

orthopedist



In-house liaison conference

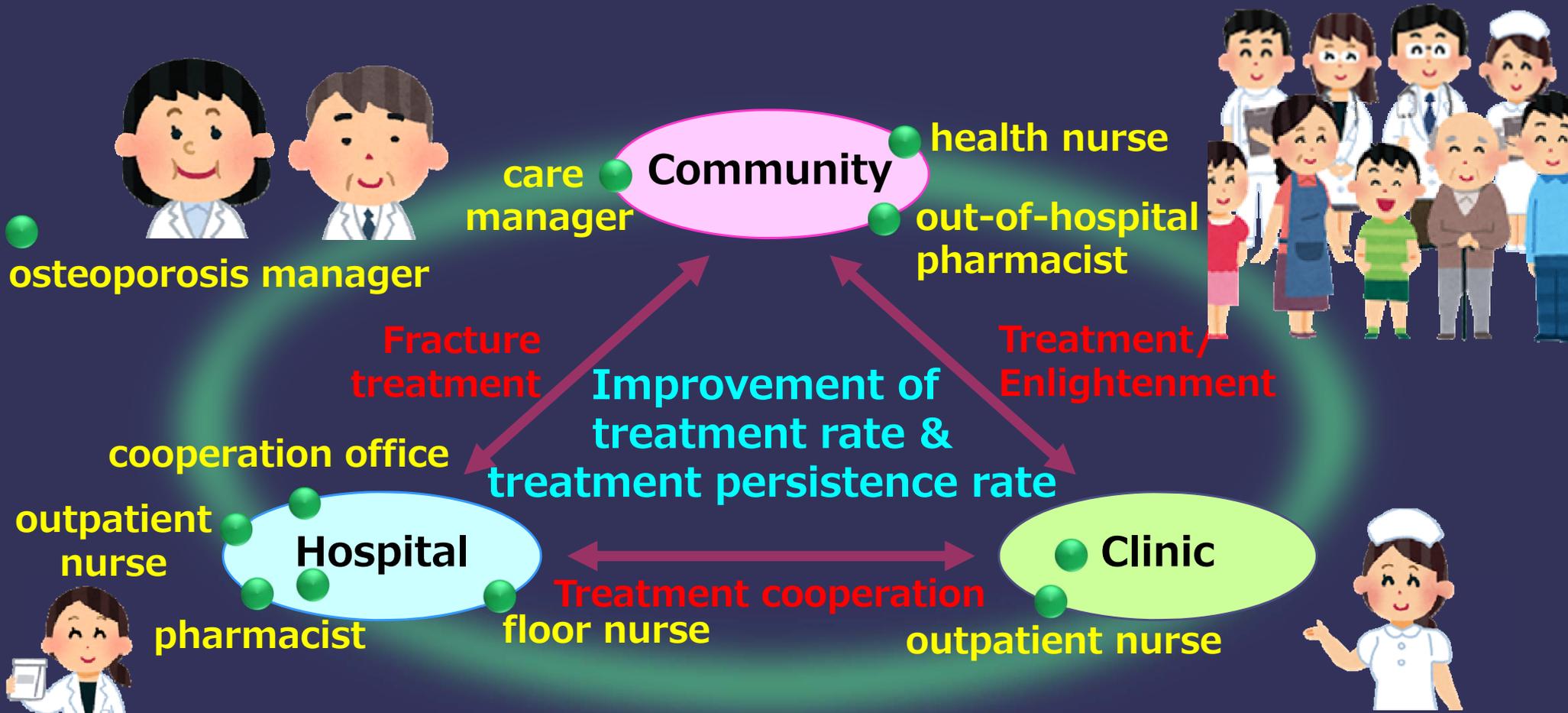


Regional alliance pathways conference

Osteoporosis Manager Network



Community osteoporosis managers cooperate with hospital/clinic osteoporosis managers for treatment by sharing patient information.



Cooperation Network

OLS Provider



Physicians (**certified osteoporosis specialists**)

cooperation

Medical staff (osteoporosis manager)

health nurses, maternity nurses, nurses, clinical radiologists, clinical laboratory technicians, PTs, OTs, clinical engineers, STs, pharmacists, registered dietitians, social workers, care workers etc.

Prevention/improvement of osteoporosis and prevention of fracture

**9th Osteoporosis manager lecture course
October 8th 2016, Sendai**

**3rd Osteoporosis manager accreditation exam
October 30th 2016, Tokyo**

Qualifications of candidacy:

health nurse, nurse, clinical radiologist, clinical laboratory technicians, PTs, OTs, clinical engineers, STs, pharmacists, registered dietitians, social workers, care workers and other national qualified medical staff

**680 candidates passed the 1st exam on April 1st 2015:
nurse 48%, pharmacist 19%, PT 19%,
clinical radiologist 5%, registered dietitians 4%**

For more details refer to the JOS homepage

Contacts

Chugai Pharmaceutical Co., Ltd.

Corporate Communications Dept.

Media Relations Group

Tel: +81 (0)3-3273-0881

e-mail: pr@chugai-pharm.co.jp

Koki Harada, Hiroshi Araki, Sachiyo Yoshimura, Mitsuka Saito

Investor Relations Group

Tel: +81 (0)3-3273-0554

e-mail: ir@chugai-pharm.co.jp

Toshiya Sasai, Takayuki Sakurai, Tomoko Shimizu, Tomoyuki Shimamura

Taisho Pharmaceutical Holdings Co., Ltd.

Corporate Communications

Media Relations Group

Tel: +81 (0)3-3985-1115

e-mail: pr@so.taisho.co.jp

Masahiro Shibata

Investor Relations Group

Tel: +81 (0)3-3985-1115

e-mail: ir@so.taisho.co.jp

Shin-ichi Tanaka