





BMJ Open Qualitative focus group interview study of communication between patients, dentists and physicians for efficient osteonecrosis of the jaw practices

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ABSTRACT

Objectives To investigate problems and the current status of existing methods of communication between patients, dentists and physicians for the prevention and treatment of medication-related osteonecrosis of the jaw (MRONJ).

Design A focus group interview study with a descriptive design using qualitative content analysis of transcripts.

Setting Secondary care in Korea.

Participants 3 patient groups and 4 health professional groups in a total of 32 participants including patients with osteoporosis or bone metastasis, dentists and physicians.

Results This study revealed that patients lacked medical knowledge of osteoporosis drugs, whereas dentists and physicians lacked each other's expertise. All patients reported undergoing dental treatments during the osteoporosis drug treatment, but dentists and physicians had different MRONJ experiences depending on their work setting in primary or secondary care. Patients expressed dissatisfaction with the current system of communication with health professionals via letter as they found this to be a slow process. Dentists and physicians reported the need for effective communication because they felt defensive when sending and receiving medical consults.

Conclusions Despite the low incidence of MRONJ among patients with osteoporosis, it is difficult to treat; thus, it is necessary to inform dentists, physicians and patients about the importance of MRONJ prevention. To this end, close communication among all involved stakeholders about osteoporosis drugs is required.

INTRODUCTION

Osteoporosis and osteoporotic fractures are associated with high morbidity and low quality of life due to exercise restriction, and the incidence of both is increasing worldwide.^{1 2} The increased understanding of osteoporosis and the development of drug therapies achieved over the past 50 years have allowed to prevent approximately 70% of spinal fractures and 30%–50% of non-vertebral fractures.³ To achieve these results, the discovery of bisphosphonate-based drugs has played a pivotal role. Bisphosphonates selectively adsorb onto the bone when absorbed,

Strengths and limitations of this study

- The strength of this study is the participation of patients, dentists and medical doctors for discussion of medication-related osteonecrosis of the jaw (MRONJ).
- Only one patient with MRONJ with bone metastasis participated in the interview and, therefore, varying opinions could not be obtained.
- Patient–dentist–physician communication about osteoporosis drug use does not occur spontaneously or rapidly.
- Dentists, physicians and patients all need to recognise the importance of MRONJ prevention, and cross-communication must be improved.

remaining there for several months and serving to suppress the formation of osteoclasts causing bone resorption, thereby maintaining bone mass and preventing fractures. In addition, the newly developed denosumab is a Receptor activator of nuclear factor-kappa B ligand (RANKL)-related agent with a mechanism to prevent bone resorption. Bisphosphonates and denosumab are used worldwide not only to treat osteoporosis due to its bone resorption inhibitory effects but are also widely used to treat malignant hypercalcaemia, bone metastasis of solid cancers (breast, prostate and lung cancer), and bone damage caused by multiple myeloma.^{4–6}

However, it has been reported that necrosis of the jaw may occur as one of the side effects of the bone resorption inhibitor.^{7 8} Osteonecrosis of the jaw (ONJ) refers to exposure of the dead bone, but with increasing use of bisphosphonate preparations, the associated bone necrosis is called bisphosphonate-related ONJ (BRONJ).⁹ Recently, it has been named MRONJ (medication-related ONJ) which includes denosumab and angiogenesis inhibitors.¹⁰ The problem with MRONJ is

that common treatments, including antibiotic therapies, topical resection and oral hygiene management, are not effective. Therefore, prevention is important as it is very difficult to treat owing to continuous recurrence after treatment.^{10 11}

Considering high-risk MRONJ, dentists advice physicians to terminate osteoporosis medication use before and after dental treatment.^{12 13} However, this is not followed generally because physicians consider the risk of fractures to be high while the incidence of MRONJ is low.¹⁴ Patients with cancer also have a higher incidence of MRONJ when using high doses of bisphosphonates, but this risk is often overlooked.^{15 16} These issues are barriers for effective MRONJ communications between dentists and physicians. Successful MRONJ treatment and prevention requires cooperation between dentists and physicians to share patient information.^{17 18}

In Korea, the most representative method of cooperation between dentists and physicians for MRONJ prevention is through consultation letters. Phone calls, emails, messages and so on cannot be used as they are not acknowledged as legal records, and patients must visit the dentist or physician in person with a consultation letter. For fast communication, teleconsultation between dentists and physicians could be possible. However, although legal, telemedicine is rarely implemented in Korea because there are no systems and regulations related to it. To successfully treat MRONJ through dental treatment and successfully prevent MRONJ in patients with cancer, an effective communication system between dentists and physicians wherein decisions can be made smoothly through a concise process within a short period is necessary.^{19 20}

This study aimed to investigate the current status of existing communication methods between dentists and physicians for the prevention and treatment of MRONJ and to explore the development direction of medical consulting service.

METHODS

Design

This was a qualitative study based on focus group interviews to describe experiences of patients and health professionals on osteoporosis or bone metastasis treatment. This approach was chosen since it allows for a variety of opinions.

Participants

Patients who had been or were being treated at Severance Hospital's endocrinology department and Yonsei University Dental Hospital's department of advanced general dentistry within the last 2 years were asked to participate. Thirty-two participants including 10 patients and 22 health professionals meeting the inclusion criteria were divided into three patient groups and four doctor groups, respectively. Patients and health professionals were enrolled onto the study until data saturation was reached. Patient group criteria were: (1) patients with MRONJ due to osteoporosis, (2) patients with MRONJ due to bone metastasis or (3) patients undergoing osteoporosis treatment with no MRONJ. The selection criteria for the doctor group were being a: (1) primary care dentist; (2) primary care physician; (3) secondary care dentist and (4) secondary care physician. The doctor group was limited to physicians, oral and maxillofacial surgeons and advanced general dentists treating patients with osteoporosis or bone metastases (table 1). Participants were approached through a telephone call and informed about interview purpose, and those who agreed to data collection finally participated in the study.

Data collection

The focus group interviews were conducted at the interview-only mirror room for approximately 2 months from August to September 2018. The time required for the interview ranged between 1 and 1.5 hours for each group, totalling 8.5 hours. The number of participants per focus group varied from 4 to 7, and there was also an in-person interview group. The interview was led by a mediator with experience in conducting and analysing focus group interviews; on the other side of the mirror room, two researchers listened to the interview and took

Table 1 Overview of focus group participants

Focus group	Classification	Characteristics	Number of participants (n)
Group 1	Patient	MRONJ with osteoporosis	4
Group 2	Patient	Osteoporosis	5
Group 3	Health professional	Medical Doctor (working in primary healthcare)	7
Group 4	Health professional	Dentist (working in primary healthcare)	6
Group 5	Health professional	Medical Doctor (working in secondary healthcare)	4
Group 6	Health professional	Dentist (working in secondary healthcare)	5
Individual interview 1	Patient	MRONJ with bone metastasis	1

MRONJ, medication-related osteonecrosis of the jaw.

notes. To allow for research results' reliability, data collection excluded as many questions as possible to allow participants to freely express their thoughts.²¹

Prior to the beginning of the interview, the study objectives and procedures were explained to the participants, and they discussed experiences and opinions through questions according to the semistructured interview guide. The interview questions used to collect the data slightly differed between patient and health professional groups and were structured as follows:

First, an introductory question: *Do you know what osteoporosis (bone metastasis) is?*

Second, the main question: *Do you know what MRONJ is?*

Auxiliary questions:

1. Can you explain MRONJ?
2. Do you have objective information about the incidence of MRONJ during osteoporosis or bone metastasis treatment?
3. What is the treatment method for MRONJ?
4. Do you know the characteristics of osteoporosis or bone metastasis risk?
5. Do you know what to do with dental treatment for patients with osteoporosis drugs?

Finally, a closing question: *What was difficult and what needs to be improved in medical consulting services between dentists and physicians?*

After the interview, the mediator reviewed the main information through debriefing. All interviews were recorded in video and audio, and the interview records were scripted.

Data analysis

The focus group interviews were analysed inductively, and content analysis was performed to analyse transcript data excluding grounded theory or specific philosophical backgrounds.^{22–23} More specifically, the Elo and Kyngäs' method of analysis was performed for an overall understanding of data, open coding, grouping, categorisation and abstraction.^{24–25} After that two researchers independently read each full scripts to grasp the general meaning, and extracted main statements. Then, from the main statements, expressions, words and meanings were recorded, written as an open coding list, and abstracted into suitable subcategories according to the classification of open coding. Subcategories were abstracted into categories by assigning appropriate names to the meanings after integrating them according to similarities and differences of meanings and characteristics (table 2). Data saturation was reached when no additional code or additional subcategories were generated. In data analysis, we used a triangulation method to secure the validity of the data, and tried to exclude the personal biases of researchers.

Patient and public involvement

Ten patients participated in this study. Only informed patients, who understood and consented to participation over the phone participated in the interview. Interviews were conducted anonymously and the patient's attending physician did not know that the patient had participated in the interview. The study results were disseminated as a report to all participants after all interviews were finished.

Table 2 Overview of categories and subcategories

Group	Categories	Specific subcategories
Patients	Medical knowledge	Knowledge of osteoporosis or bone metastasis Knowledge of MRONJ
	Experience	Experience in dental treatment Osteoporosis-related questions in dentistry
	Medical consulting system	Consultation request experience Difficulties and improvements in consultation
Health professionals	Medical knowledge	Knowledge of bone metastasis Knowledge of osteoporosis Knowledge of MRONJ Knowledge of dental treatment
	Experience	Experiences in dental treatment for patients with ONJ Difficulties in treating ONJ and osteoporosis
	Medical consulting service	Experience in dental consulting for patients with osteoporosis or bone metastasis Experience in dental consulting for patients with ONJ Relationship of primary and secondary care health professionals

MRONJ, medication-related osteonecrosis of the jaw; ONJ, osteonecrosis of the jaw.

Table 3 Characteristics of focus group participants (n=32)

Characteristics	Patients	Health professionals
Age (range)	71.2 (58–84)	38.6 (29–57)
Sex (n)		
Female	8	6
Male	2	16
MRONJ experience*		
Experienced	5	10
Not experienced	5	12
Department	(To see physicians)†	(To see patients)†
Endocrinology	9	8
Oncology	1	1
Orthopaedics	0	2
Dentistry	5	11

*For physicians, experience treating patients with MRONJ.

†Duplicate response.

MRONJ, medication-related osteonecrosis of the jaw.

RESULTS

The study included 32 people, 10 patients and 22 health professionals, ranging in age from 29 to 84 years (mean 48.8 years), of whom 18 were men and 14 women (table 3).

Three topic categories emerged in the analysis process: (1) lack of medical knowledge, (2) experience and (3) medical consulting system. Each subcategory was appropriately investigated for patient and health professionals, and the results largely divided into patient and doctor answers (figure 1).

Lack of medical knowledge

The specific medical knowledge for osteoporosis or bone metastasis causes, treatment drugs, dental treatment and knowledge of MRONJ was analysed.

Osteoporosis or bone metastasis causes and treatment

Although all patients could explain the characteristics of their disease, such as height loss, fracture and weakness in the legs or arms, not all could explain the cause. Most patients did not know the precise name of their current treatment drug but remembered how to take them and the required precautions. In addition, these participants did not know about other therapeutic drugs and the side effects of long-term use apart from the drugs they themselves used.

I think there are several osteoporosis medications. The drug I took once a week should be taken before breakfast, and I should not lie down thereafter. Now, I get injections but I do not know any precautions regarding injections (Group 1, PT#02).

Most participating dentists had a higher level of knowledge about osteoporosis or bone metastasis than the general public, but it was unreasonable to say that they had expertise at the physician level. They were aware of the high-risk group classification of osteoporosis and bisphosphonates, ONJ-related drugs, but did not know specific treatment methods. Many were not able to judge osteoporosis by checking serum biomarker tests, such as serum C-terminal telopeptide (CTx), and had to follow a physician's opinion.

If the key-score of the femur neck is minus 2.5 or less, the patient is diagnosed with osteoporosis, and if it

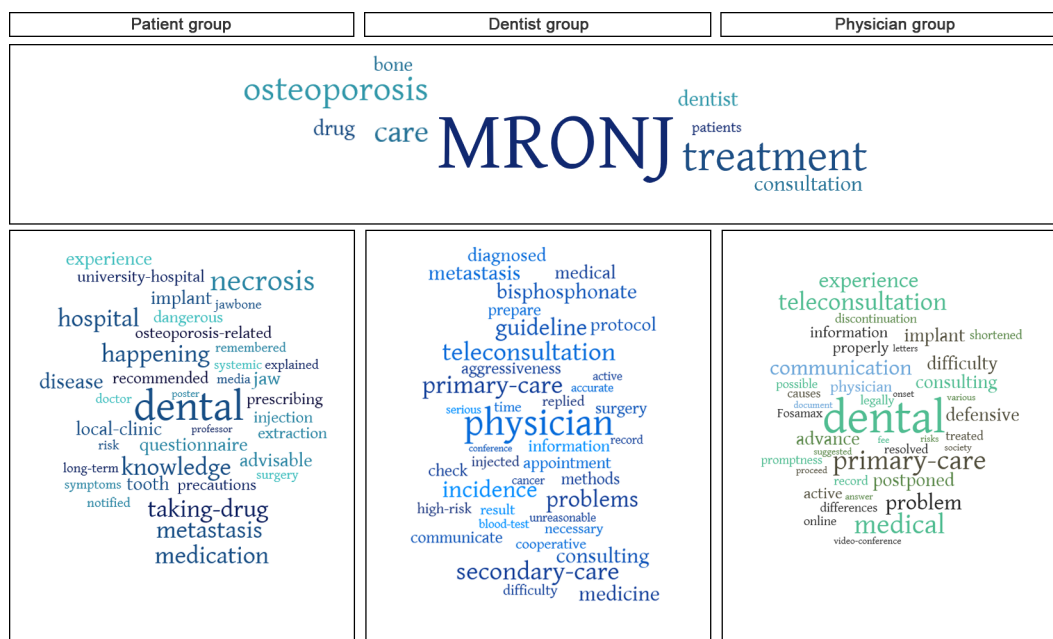


Figure 1 Word cloud of interview content per group. Higher frequency is represented by a larger word size. A total of nine words coincided in the three groups, and the most frequent word was 'MRONJ'. MRONJ, medication-related osteonecrosis of the jaw.

belongs to a high-risk group between 2.5 and 1.0, the drug is prescribed. I usually prescribe bisphosphonates, and I know that MRONJ problems are very unlikely, but very serious. There is the newly developed denosumab, but I know that bisphosphonate is used the most because it has the best cost-effectiveness (Group 4, DR#9).

All participants in the dentist group were aware of bone metastasis, but unsure of the treatment protocol. In addition, they did not know exactly which drugs should be maintained or discontinued before dental treatment.

Dental treatment of patients with osteoporosis or bone metastasis

None of the patient groups knew that it was advisable to start dental treatment before beginning osteoporosis or bone metastasis treatment. In addition, they did not know that taking or injecting medication to treat osteoporosis influences dental treatment.

The doctor did not ask if I had a dental check-up before prescribing osteoporosis medication. I went to the dentist after taking the osteoporosis medicine. Thereafter, I went to the dentist, but I did not know the osteoporosis drug was affecting dental treatment because the dentist did not even ask me if I take it (Group 2, PT#07).

In the case of physicians working in primary care, they reported frequently advice for discontinuation of osteoporosis drugs through medical consultation from dentists, recognising that osteoporosis drugs affect dental treatment. In contrast, physicians working in secondary care suggested to start dental treatment before osteoporosis treatment in case of necessary treatments, such as extraction of dental implants, because MRONJ can occur during surgery for implants or extractions. In addition, they answered that if a patient with cancer has bone metastasis, treatment cannot be postponed, while dental treatment could.

Knowledge of MRONJ

Most patients who had already experienced MRONJ had never heard of MRONJ or were unaware of its characteristics before onset, but they did know about it after diagnosis. Moreover, they reported having received explanations from the dentist about the cause of MRONJ.

I didn't know that the jaw necrosis was happening, I went to the dentist and extracted tooth one, and it was so painful. After that, I came to the university dental hospital and heard necrosis was happening after taking X-ray (Group 1, PT#02).

Among osteoporosis patients who had not experienced MRONJ participating in the interview, some heard about MRONJ for the first time during the interview, but many were aware about its cause and characteristics. Those who had heard previously about MRONJ did so through a TV broadcast or poster in a dentist's office. In other cases, high-risk MRONJ was recognised through consultation

with a dentist. This particular patient reported that the dentist explained that MRONJ could occur after tooth extraction, although the probability was low.

I went to a local dentist and one day I saw the poster 'Dental treatment before taking osteoporosis medicine'. After reading this, I was interested in MRONJ (Group 2, PT#07).

Dentists reported having become aware of objective information such as causes, incidence, treatment methods of MRONJ, as it has recently become an issue. However, given the low incidence of MRONJ, primary dentists reported not much interest. The lack of precise guidelines for MRONJ treatment warrants further development in this respect.

There are no guidelines that can be accurately indexed in primary clinics. It seems that it will be easier to explain to patients only if systematic guidelines are prepared (Group 5, DR#13).

In the case of the physician group, there were differences in response of workers in primary and secondary care. Physicians in primary care acquired information about MRONJ through academic conference but had doubts about the incidence because it was not commonly encountered during treatment. In contrast, physicians in secondary care were more likely to encounter patients with MRONJ; therefore, they knew in detail about the risks and causes and were deeply aware of its severity after onset.

I have been in medical practice for 25 years and have been using a bisphosphonate drug called Fosamax for over 20 years. I haven't seen MRONJ in 20 years, so I'm not sure how probable it is (Group 3, DR#01).

I usually tell my patients to have a dental check-up before they start using osteoporosis medications. Although the incidence of MRONJ is low, I am always thinking that patients should be careful with their dental care after using osteoporosis medications. (Group 5, DR#15).

Experience

The differences between experiences of dental treatment during medication treatment for patients and that of treating patients with MRONJ for physicians and dentists were considered.

Experience of dental treatment during medication treatment

All patients reported experience in dental treatment during treatment for osteoporosis or bone metastasis. Most patients were not educated on whether to tell their dentist they were on osteoporosis medication, and very few patients reported telling their dentist that they were taking osteoporosis medication during dental treatment. Patients had to visit the internal medicine department for dental treatment, receive a response to the consultation letter for medication information and submit it

to the dentist again to prepare a dental treatment plan. Patients warned of a high risk of jaw necrosis during tooth extraction or dental implant treatment had their treatment plan changed to non-surgical treatment or were recommended secondary care treatment.

At the local dentist, he said I needed a dental implant, but visit to a university dental hospital to be examined. At the university dental hospital, professor changed only the prosthesis because (the) implant surgery was dangerous to the jawbone (Group 2, PT#10).

Experience of treating patients with MRONJ

When visiting a patient with MRONJ, the primary care dentist responded that the patient was sent to secondary care with rich clinical experience rather than administering direct treatment. Otherwise, they informed of the risk of MRONJ to a patient and suggested a non-invasive treatment method such as a denture. The dentist at the secondary care reported treating patients with MRONJ according to the treatment protocol and consulting with the physician for information about the treatment drug.

If a patient has been diagnosed with MRONJ, we check the dead bone, and if surgery is required, the date of surgery. In case of MRONJ risk, we usually check with the physician the type of prescribed medication, whether they were injected, or what they were injected for. Prophylactic treatment was prioritised by checking drug duration and blood test results with CTx level or osteocalcin (Group 6, DR#22).

Primary care physicians reported no experience related to patients with MRONJ. On the other hand, secondary care physicians had experience in treating patients who developed MRONJ due to osteoporosis, but had difficulty in explaining the cause of MRONJ to the patient. Osteoporosis drugs were used to prevent fractures, but patients did not easily understand that MRONJ occurred as a side effect during dental treatment. This worsened the doctor–patient–dental relationship, causing patients who develop MRONJ to often refuse resuming osteoporosis treatment.

Medical consulting system

The current medical consulting system evaluation and future development directions were analysed as well.

Current medical consulting system evaluation

Primary care dentists answered that with a cooperative physician, the consultation period could be short and that the required time varied depending on the patient's willingness. However, they found difficulties in consulting without a cooperative physician and in figuring out suitable consulting means when requesting secondary care.

Both secondary care dentists and physicians responded that individuals who answer consulting responses through letters are very defensive. They considered it necessary

to communicate with the physician referring the patient and that it was the same for dentists in the primary care as the answer to the consultation determined promptness according to the patient's willingness.

I might have a communication problem with the physician. One problem I feel is that my perspective is different. When I talk to patients, ONJ has a low incidence, but once it occurs, it is difficult to treat and it lasts very long. But in internal medicine, the ONJ incidence rate is considered to be low, so it is considered okay, and it is not easy to talk to a physician about it (Group 6, DR#21).

We have to be very defensive with each other because we have to communicate through letters and cannot speak face to face. Even though there is a third way to treat patient properly, consulting is not appropriately done because direct communication is not possible when sending and receiving written statements (Group 5, DR#17).

Future development direction

Both dentists and physicians consider faster consultation feasible with teleconsultation. In addition, real-time video conferences can facilitate active communication among medical professionals, and many medical professionals would actively answer consultations if a teleconsultation fee was set. However, they would use teleconsultation only once the legal liability issues caused by teleconsultation were resolved. They also pointed out a problem with using teleconsultation as medical records.

I think it would be more efficient to use an online application, rather than using a document. If you can transfer various information with just a few clicks, the consulting time will be shortened. But I am worried about how to use it legally (Group 4, DR#08).

It is not a teleconsultation, but the dentist asked me for comments online. Doctor-to-doctor communication is possible without restrictions. I just need to be able to communicate my opinion remotely to the dentist. Instead of treating the patient, let the dentist and the physicians solve each other's questions (Group 5, DR#17).

DISCUSSION

Interpretation of study findings

The analysis focused on three themes: 'lack of medical knowledge', 'experience' and 'medical consult service'; seven subcategories per theme were extracted and structured.

Analysis of the study interview responses revealed that patients lacked medical knowledge of osteoporosis drugs and that dentists and physicians lacked the respective knowledge of the other discipline. Even when visiting the same patient, the dentist and physician communicated each with the patient according to their medical

knowledge, confusing the patient. Although dentists advised patients to discontinue osteoporosis drugs by focusing on MRONJ with prolonged use of bisphosphonate drugs, physicians believed that discontinuation of osteoporosis drugs is dangerous for patients because of the side effects of bone fractures.

Second, all patients reported dental treatment experience during osteoporosis drug treatment, and most primary or secondary dentists had experienced at least once either MRONJ or high-risk patients. On the other hand, physicians in the primary care reported no experience related to patients with MRONJ, whereas in secondary care, all had encountered patients with MRONJ and had many difficulties in explaining its causes.

Third, in this study, participants were interviewed about the current medical consult system, and patients expressed dissatisfaction with the long time required for cross-consultation between physicians and dentists. Dentists and physicians want better communication because they feel defensive when sending and receiving written medical questions. Most participants had a positive view of the use of teleconsultation instead of consultation letters to improve communication between dentists and physicians. To this end, teleconsultation data should be recognised as legal data and regulations on the cost of teleconsultation should be established in Korea.

Comparison to the existing literature

Focus group interview and qualitative studies focusing on osteoporosis or MRONJ have been introduced in the last decade.^{26–31} To investigate the perception of osteoporosis or MRONJ, studies on patients, or on health professionals, were conducted to develop a decision support tool for managing osteoporosis. A focus group interview study analysed factors affecting adherence to osteoporosis medications with providers and patients; eliciting attitudes, beliefs and barriers to adherence to osteoporosis drugs and helping to develop a multimodal intervention strategy to address system-based problem raised by the focus group.³¹ In addition, qualitative studies between general practitioners (GPs) and pharmacists have aimed to analyse attitudes and perceptions of BRONJ prevention. As a result, both GPs and pharmacists showed limited knowledge of BRONJ, and all reported that communication with dental practitioners was limited or non-existent, thereby improving this relationship and introducing a BRONJ prevention strategy is necessary.²⁸

In addition to qualitative research, survey-based research has focused on communication issues related to ONJ between dentists and physicians, reporting that the lack of communication between dentists and physicians threatened ONJ prevention and the necessity to establish a forum to share information about ONJ between health-care professionals, dentists and patients.^{17 18 32 33} A study in Australia analysed the communication among physicians, dentists and pharmacists regarding ONJ, showing that important communication targets could vary depending on each country's medical system.³⁴

Most previous MRONJ-related communication studies were conducted based on providers, excluding patients, who should be the centre of attention, whereas the current study interviewed not only dentists and physicians but also their patients; this way, it was possible to grasp the differences in opinions between health professionals and patients as well as patient needs.

In the present study, by inquiring about the future development direction of medical consult service, we found teleconsultation as a possible alternative. However, the legal responsibility for the side effects of patients following the recommendation to discontinue the drug on teleconsultation is unclear and further consideration is needed. In addition, the patient consent procedure should first be established for the transmission of personal information, medical information and medical images in the case of text-based teleconsultation rather than video conference.

Study limitations

Complaints and biases in group interviews can inject a negative mood and distorted perspective into other participants. A physician said that a discussion about MRONJ is meaningless for physicians because of its low incidence. These remarks made other physicians passive. In addition, participants hesitant about public speaking were reluctant to voice their opinions. However, the mediator constantly reminded the purpose of the discussion to change the negative mood and encouraged the participants to equally report their opinions.

Although this study tried to recruit ≥ 2 people per group for the group interviews, only one patient with MRONJ due to bone metastasis was recruited and an individual interview was conducted. The survival rate of patients with bone metastases is low, affecting the number of recruits, and survivors could not respond to the interview due to physical discomfort. Nevertheless, the individual interview was an opportunity to improve dentist-to-physician communication focused on the personal experience of patients with MRONJ with bone metastasis.

Conclusions and future considerations

This study investigated the opinions of patients and health professionals on how to improve communication to prevent MRONJ. Among the various methods for improving communication, digital applications or video chat was most mentioned. However, further research is needed to extend this research and prepare clear guidelines.

Both dentists and physicians work on patient care with relatively limited knowledge of osteoporosis, bone metastasis and MRONJ. Dentists need to cooperate with physicians to review the drug history and general health of patients during dental treatment in patients with osteoporosis with bone metastasis. The physician's explanation of MRONJ to the patient may increase their interest in oral health. Given the increasing use of osteoporosis drugs such as bisphosphonates in ageing societies, it is

necessary to inform dentists, physicians and patients about the importance of MRONJ prevention and of close communication among all involved stakeholders.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the institutional Review Board of Yonsei University Severance Hospital (IRB number: 4-2018-0561). All participants provided written consent form. Participants were given information regarding the study and that discussions would be recorded. All data were anonymised to ensure participant confidentiality.

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