

The knowledge and attitudes of North Wales healthcare professionals to bisphosphonate associated osteochemonecrosis of the jaws

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Abstract

Aim and objectives: The purpose of this study was to ascertain the level of knowledge of, and the attitudes to, bisphosphonate related osteochemonecrosis of the jaws (BRONJ) amongst healthcare workers in North Wales. The frequency with which patients undergoing bisphosphonate therapy are seen by these healthcare professionals was also to be established.

Design: A self-administered, postal questionnaire was sent to 26 community dentists, 132 general dental practitioners, 120 general medical practitioners and 60 pharmacists.

Results: The results indicated that patients using bisphosphonates are seen on a regular basis by many healthcare professionals, most commonly for the treatment of osteoporosis. Although the vast majority of the healthcare professionals approached claim to be aware of the side-effects of these drugs, very few have knowledge of osteochemonecrosis as an issue in this patient population. However, the vast majority of healthcare professionals requested further guidance on this issue. There are currently no guidelines on the effective treatment of osteochemonecrosis.

Conclusions: Knowledge among many healthcare professionals; GMPs, GDPs and pharmacists about bisphosphonates and the oral/dental consequences of patients prescribed these drugs is poor. As a result of this project, advice leaflets have been produced for dentists, general medical practitioners, pharmacists and patients.

Key words: Bisphosphonates, osteochemonecrosis, dental treatment, advice

Introduction

Bisphosphonates were first discovered in the mid nineteenth century when they were used for industrial corrosion prevention. The medical application was investigated in 1968 and later in the 1990s, when the mode of action in humans was demonstrated. The action of bisphosphonates is to inhibit bone resorption via the activities of osteoclasts. They are capable of localising to bone where they are adsorbed onto hydroxyapatite crystals, slowing down the rate of growth and dissolution of the crystals.

There are two main divisions of bisphosphonate, nitrogenous and non-nitrogenous.

(Table 1). Due to their actions on bone turnover they have become important in the treatment of metabolic bone disorders and in modifying the progression of bone metastases in a number of cancers. In 2003, there were 17 million prescriptions for an alendronate worldwide making it the nineteenth most commonly prescribed drug in the world (Krueger *et al.*, 2007).

The popularity of bisphosphonates has risen over the last decade to become the treatment of choice for a number of disorders. However, the side-effect of BRONJ has emerged as an alarming consequence; between 2001-2007 there were over 2,400 confirmed cases reported in the US alone (Krueger *et al.*, 2007). BRONJ has been

reported frequently in the literature over the last three years and has become a concern within the profession. At present there are numerous co-morbidities and local risk factors cited in the literature, which have been compiled in *Tables 2 and 3*. The occurrence of BRONJ has been very rarely reported among patients undergoing oral bisphosphonate therapy (0.01-0.04%, increased to 0.09-0.34% following an extraction), while the vast majority of reported cases have occurred in patients undergoing intravenous bisphosphonate therapy (incidence of 0.08-12%). (Ruggiero *et al.*, 2009)

There are currently no guidelines for the treatment of BRONJ, however advice on management is similar to that for the treatment to osteoradionecrosis. There is no evidence to support this and so clinicians are limited to a conservative management approach. Numerous healthcare professionals have contacted the North Wales dental public health department requesting advice regarding the treatment of patients receiving bisphosphonate therapy, highlighting the lack of guidance currently available. However, the American Association of Oral and Maxillofacial Surgeons (AAOMS) issued a position paper suggesting guidelines for the treatment of this group of patients in 2006 and updated it in 2009. The paper advises prevention and non-surgical intervention where possible for patients undergoing intravenous therapy, for example de-coronation and endodontic treatment of retained roots. The authors divide patients taking oral bisphosphonates into three groups: those with no other risk-factors and who have taken the drugs for less than three years can be treated as normal but have the risk fully explained to them. For patients who have taken the drugs for less than three years and who have other risk-factors, the advice is, on discussion with the prescribing provider, for there to be a three month cessation in therapy prior to treatment, with therapy not re-starting until osseous healing has completed. This advice is repeated for those patients who have taken oral bisphosphonates for over three years (Ruggiero *et al.*, 2009)

The British Dental Association (BDA) released a bisphosphonate fact file in September 2008, advising that while extractions were not contra-indicated for those patients taking oral bisphosphonates, non-surgical intervention should be favoured. For patients receiving intravenous forms of these drugs, the advice from the BDA is that extractions should be avoided wherever possible and careful follow-up should take place if extractions are unavoidable (BDA, 2008). Similar advice is echoed by Arrain and Masud, and Khan *et al.* in other notable papers on the topic (Arrain *et al.*, 2008; Khan *et al.*, 2008). The aim of this study was to improve the level of care provided to patients taking bisphosphonates prior to commencement, during and on completion of their therapy. This was done by establishing the level of knowledge and the attitudes of healthcare professionals of North Wales

towards bisphosphonate therapy and by increasing the awareness of bisphosphonates related osteochemonecrosis of the jaws (BRONJ). A further aim was to produce practical advice for healthcare professionals and patients on this subject.

Table 1 Divisions of bisphosphonates

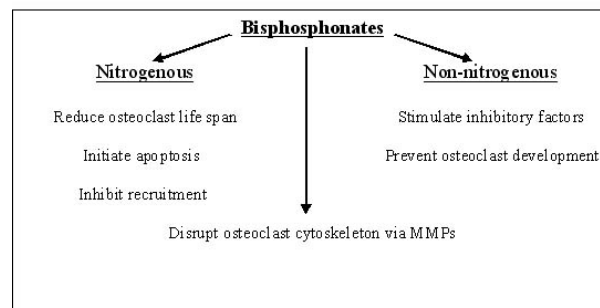


Table 2 Co-Morbidities

Diabetes Mellitus
Chemotherapeutic drugs
Immunocompromised state
Smoking
Advanced age
Alcohol abuse
Cortico-steroids

Table 3 Local Factors

Periodontal disease
Exodontia
Periapical disease
Anatomical variations (tori)
Recent trauma
LA with vasoconstrictors

Materials and method

The healthcare professionals targeted in this study were general dental practitioners (GDPs), community dental service dentists (CDS), general medical practitioners (GMPs) and pharmacists, as they would all be in regular contact with the relevant patient population. A self-administered postal questionnaire (Appendix 1) was formulated to collect information in three main areas:

- Frequency of seeing patients on bisphosphonate therapy
- Knowledge of side-effects (specifically *BRONJ*)

- Attitudes toward further exploration and understanding of the issue.

Each questionnaire was sent with a covering letter to explain the purpose of the study and a stamped addressed envelope for returning the completed questionnaire. The interval for return was set at three months, to allow for time in transit and for completion of the answers in light of the busy schedules of the respondents. To select candidates to receive a questionnaire the performer lists for GDPs, GMPs and pharmacists were obtained from the North Wales local health boards. Every third name on each list was selected and the relevant questionnaire was sent to them. All CDS dentists were sent a questionnaire as it was anticipated that they may treat a greater proportion of patients receiving bisphosphonate therapy.

During this time, further research into the current opinions on best practice for treatment and prevention of BRONJ was conducted. Other healthcare professionals were consulted on their thoughts and advice on the subject, including a consultant endocrinologist and consultant oral and maxillofacial surgeons.

Results

The questionnaires were sent to 132 GDPs, 26 CDS dentists, 120 GMPs and 60 pharmacists. The response rate for dentists was 55.70%, 43.0% from GMPs and 51.7% from pharmacists.

The frequency with which these healthcare professionals saw patients taking bisphosphonates is given in *Figure 1*. Whilst 77.4% of pharmacists saw patients taking bisphosphonates on a daily basis, 35.3% of GMPs and 3.4% of dentists saw patients with such frequency. In addition, pharmacists dispensed bisphosphonates on a daily basis in 80.7% of respondents, the remaining pharmacists reported dispensing the drugs on a weekly basis.

The conditions being treated with bisphosphonates as indicated by the dentists and GMPs are given in *Figure 2*. When asked of the dental relevance of these drugs, 43.8% of dentists stated osteochemonecrosis, while 48.9% were aware of issues regarding extractions in these patients. When asked what they would do for patients requiring extractions, dentists reported the following: 17.1% would refer patients requiring extractions and 4.5% would seek advice from an oral surgeon. None of the dentists responding to the questionnaire were aware of any guidelines available to them for the treatment of patients on bisphosphonate therapy. It was re-assuring that 48.9% of dentists did recommend maintenance of recall appointments and reported that they promoted preventive dentistry to their patients taking bisphosphonates.

When asked about side-effects of the drugs there were some worrying responses from dentists, including the following: photosensitivity, bone cancer and periodontal bone loss. One dentist stated that they had never heard of

bisphosphonates, while another stated that they had only recently started looking in the British National Formulary. The frequency with which GMPs prescribed bisphosphonate therapies to their patients is shown in *Figure 3*. An alternative treatment modality to bisphosphonates is considered by 85.3% of GMPs. Bisphosphonate therapy had been stopped by 97.1% of the GMPs questioned; but all of these cases were due to the side-effect of gastrointestinal disturbance rather than oral/dental reasons. All of the GMPs questioned stated they were aware of the side-effects of the drugs, yet only 11.8% stated osteochemonecrosis as one of these. Only 58.8% of GMPs claimed to be aware of the NICE prescribing guidance for prevention of osteoporotic fractures, which shows bisphosphonates to be an effective method of prevention in high risk patients (National Institute for Health and Clinical Excellence, 2008).

For pharmacists, when asked if they were aware of the drugs' side-effects 90.3% claimed they were, however none of them stated osteochemonecrosis as one of them. At the time the questionnaire was administered, only 11.8% of GMPs and 9.7% of pharmacists advised patients to warn their dentist they were using bisphosphonates.

When asked whether they would appreciate further guidance on managing patients using bisphosphonates 88.2% of GMPs and 80.6% of pharmacists said 'yes'.

Figure 1 How often are patients on bisphosphonates seen by the different professional groups?

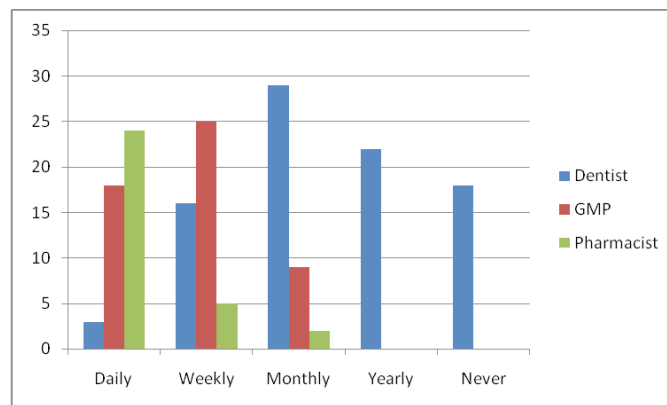


Figure 2 What condition was being treated with bisphosphonates by the GDPs and GMPs?

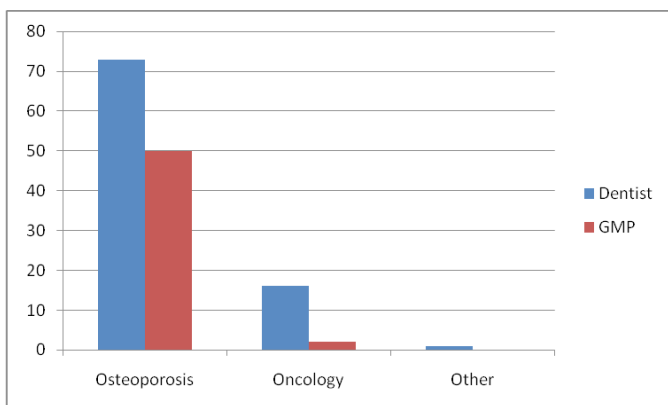
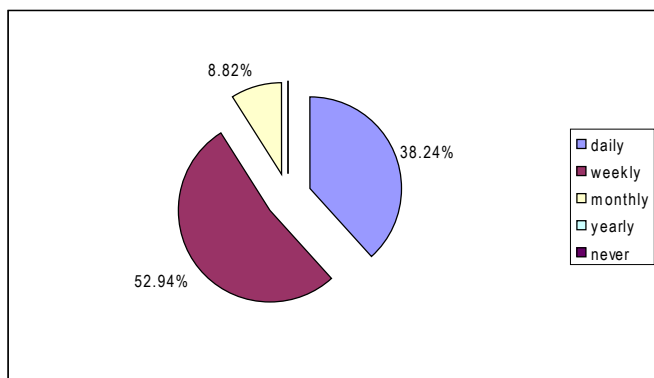


Figure 3 How often do GMPs prescribe bisphosphonate therapy to patients?



Discussion

The majority of dentists see patients undergoing bisphosphonate therapy regularly, some as frequently as weekly or monthly. A significant number of dentists (20.4%) reported never seeing patients undergoing bisphosphonate therapy. This may be due to dentists being unaware that their patients are taking this particular group of drugs. If awareness of bisphosphonates and the sequelae of treatment with these agents were increased, the reported frequency would change considerably.

The frequency of contact with patients undergoing bisphosphonate therapy is vastly increased amongst GMPs, daily or weekly (82.4%). Pharmacists have contact with these patients almost daily (77.4%), although consideration should be given to the likelihood of a carer collecting pharmacy prescriptions on behalf of patients. This type of drug is the treatment of choice in many metabolic bone disorders; whilst 85.3% of GMPs consider an alternative, they ultimately prescribe bisphosphonates.

The disease that this group of drugs is most commonly prescribed for among this patient population is osteoporosis (GMPs 97.1%, GDPs 82.9%). This is not surprising as this disease affects 1.2 million people in the UK and there are 275,000 females in England and Wales on bisphosphonate therapy currently for osteoporosis (Khan *et al.*, 2008).

When the large number of patients currently undergoing some form of bisphosphonate therapy is considered, the number of healthcare professionals aware of osteochemonecrosis as a side-effect is low. It is reported that 43.8% of dentists, 11.7% of GMPs and no pharmacists are aware of osteochemonecrosis as a side-effect of bisphosphonate therapy. This is of even more concern in the light of the Chief Medical Officer (CMO) statement issued by the Welsh Assembly Government (Jewell, 2007). It is, therefore, predictable that few GMPs (11.7%) or pharmacists (9.7%) advise patients to inform their dentist when taking bisphosphonates. However, the vast majority of GMPs (88.2%) and pharmacists (80.7%) would appreciate further guidance on the best course of action for their patients.

Conclusions

A large number of a dental patient population are currently undergoing a form of bisphosphonate therapy and their dentists do not seem to be aware of this. It is also apparent that those dentists who are fully aware of their patients' drug regimes are not always aware of the side effects of these medications and the potential implications of poorly planned dental treatment. In addition, patients are not aware of the side effects so are not informing their dentist that they are taking these drugs. However, the onus should not be on the patient, the dentist should be asking the appropriate questions prior to dental treatment.

Bisphosphonates have become the drug of choice for treating osteoporosis, a disease which already affects a large number of our population. As it is a disease which is seen more prominently amongst the older age range, it is set to increase in prevalence as the population increases, both in terms of numbers and age. There is a number of brand-named bisphosphonates described in the British National Formulary; dentists have a duty to familiarise themselves with these. The commonly used oral and intravenous bisphosphonate drugs are listed in *Tables 4 and 5*.

The responses received not only highlight the lack of knowledge among healthcare professionals relating to BRONJ but also show an interest in guidance on managing patients with respect to BRONJ. For these reasons, using the information gathered during the research phase of the study, evidence-based advice leaflets have been produced for the three healthcare professions involved in this study as well as patients themselves (*Appendix 2*).

These outline the background to BRONJ and bisphosphonates themselves as well as individual guidance for the four groups in relation to their bisphosphonate therapy.

Further research is indicated to investigate the knowledge and attitudes of healthcare professionals more likely to prescribe intravenous bisphosphonates, for example, the specialities of rheumatology, oncology and endocrinology. An audit of the outcome for patients receiving bisphosphonate therapy who also require invasive dental treatment would yield important results to inform clinical decision-making.

Table 4 Oral Bisphosphonate Drugs

Brand Name	Generic Name
Actonel	Risedronate
Bonviva	Ibandronate
Fosavance	Alendronate
Fosamax	Alendronate
Fosamax Plus D	Alendronate
Skelid	Tiludronate
Didronel	Etidronate
Loron	Clodronate

Table 5 Intravenous Bisphosphonate Drugs

Brand Name	Generic Name
Aredia	Pamidronate
Zometa	Zoledronic acid
Bonefos	Clodornate
Aclasta	Zoledronic acid

Acknowledgements

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Appendix 1: Questionnaires

Dentist Questionnaire

How often do you treat a patient on Bisphosphonates?

daily weekly monthly yearly

For what conditions do your patients take Bisphosphonates most commonly?

osteoporosis oncology other (if other please specify)

Are you aware of any side effects of Bisphosphonates?

yes no (if yes please mention briefly)

Would you treat a patient on these drugs differently?

yes no (if yes please explain)

Are you aware of any guidelines for the treatment of patients taking Bisphosphonates?

yes no (if yes please mention briefly)

What advice would you give to patients taking Bisphosphonates?

All responses are anonymous

How many dentists work in your practice? 1 2 or more

Are you male or female ?

What age are you?

20-30 30-40 40-50 50-60 60-70 70+

Thank you for your time, please return in the envelope provided

GMP Questionnaire

1. How often do you see a patient on bisphosphonates?

Daily Weekly Monthly

2. Do you prescribe bisphosphonates?

Yes No

If yes, how often?

Daily Weekly Monthly

3. Do you consider alternatives?

Yes No

4. For what conditions do your patients require bisphosphonates?

Osteoporosis Oncology Other

5. Have you ever stopped a patient's bisphosphonates?

Yes No

If yes, why?

Alternative therapy No longer required Other

6. Are you aware of any side-effects?

Yes (please specify) No

7. Are you aware of any guidelines for treatment of patients taking bisphosphonates?

Yes (please specify) No

8. What advice do you give patients on bisphosphonates?

9. Do you ask patients to inform their dentist if they are taking bisphosphonates?

Yes No

10. Would you find it useful to have a patient information resource on bisphosphonates?

Yes No

Thank you

Pharmacist Questionnaire

1. How often do you see a patient on bisphosphonates?
Daily Weekly Monthly
2. Do you dispense bisphosphonates?
Yes No

If yes, how often?
Daily Weekly Monthly
3. Are you aware of any side-effects
Yes (please specify) No
4. Are you aware of any guidelines for treatment of patients taking bisphosphonates?
Yes (please specify) No
5. What advice do you give patients on bisphosphonates?
6. Do you ask patients to inform their dentist if they are taking bisphosphonates?
Yes No
7. Would you find it useful to have a patient information resource on bisphosphonates?
Yes No

Thank you

Appendix 2

Dentist Information

Bisphosphonates are a class of drug that inhibit osteoclast action and the resorption of bone. Bisphosphonates are most commonly used for:

- Prophylaxis and treatment of osteoporosis
- Paget's disease
- Multiple myeloma
- As part of some anti-cancer regimes.

Dental surgery may exacerbate or cause osteochemonecrosis in patients during or after Bisphosphonate therapy. Although this is more prevalent in those taking high dose or intravenous Bisphosphonates, it has also been reported in those taking these drugs orally. Concomitant risk factors include poorly controlled diabetes mellitus and other immuno-compromised states, concurrent use of corticosteroids, chemotherapeutic drugs, radiotherapy, advanced age, alcohol abuse and smoking.

It is estimated that the majority of osteochemonecrosis cases are preceded by dental surgical treatment, with twice as many occurring in the mandible as the maxilla. It has been suggested that Bisphosphonate treatment should be postponed during dental treatment to minimise risk however this is inadvisable. Local contributing risk factors include anatomical variations such as mandibular tori, periodontal disease, periapical disease and recent trauma. Prevalence of osteochemonecrosis amongst IV Bisphosphonate patients is estimated at 0.8-12% and the prevalence among oral bisphosphonate users is 0.01-0.04%.¹ Other dentally relevant side effects of these

drugs include dyspepsia and gastric reflux, possibly leading to dental erosion.

Commonly used Bisphosphonates

Oral	Brand Name	Generic Name
	Actonel	Risedronate
	Bonviva	Ibandronate
	Fosavance	Alendronate
	Fosamax	Alendronate
	Fosamax Plus D	Alendronate
	Skelid	Tiludronate
	Didronel	Etidronate
	Loron	Clodronate
IV	Brand Name	Generic Name
	Aredia	Pamidronate
	Zometa	Zoledronic Acid
	Bonefos	Clodronate
	Aclasta	Zoledronic Acid

Please refer to BNF as drug formulations may vary and new drugs may become available

Management of Bisphosphonate Patients

- A comprehensive oral evaluation for all patients before commencing Bisphosphonate treatment
- Emphasis needs to be placed on excellent oral hygiene so as to minimise risk factors for infection

- Regular supragingival scaling as indicated using prophylactic Chlorhexidine rinse
- Avoid invasive dental treatment i.e. extractions, root planning, soft tissue damage
- Removable partial dentures need to be checked and adjusted if appropriate to avoid soft tissue damage
- Aggressive and non surgical management of dental infection where possible
- Endodontic treatment as avoidance of extraction is especially important in these patients
- Treatments such as coronal amputation and endodontic treatment of retained roots is advised for unrestorable teeth.

If surgery is unavoidable, focus on conservative procedures with proper sterile technique and effective antibiotic therapy

Please prioritise appointments if you are contacted by a patient or their GP about dental examination prior to Bisphosphonate therapy. It is essential they are dentally fit before commencing this therapy and any delay can affect their long term medical prognosis

If you have any further concerns, please contact your local Oral Surgery/ Maxillofacial Dept for advice, these patients do not automatically require referral

Useful resources:

Jewell T. Dental treatment for patients on or prior to taking bisphosphonate medication. CMO Update (Welsh Assembly Government). 2007. Vol 45.

Arrain Y, Masud T. Recent recommendations on bisphosphonate-associated osteochemonecrosis of the jaws. Dental Update. 2008. Vol 35. 238-242.

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Ruggiero SL *et al.* American Association of Oral and Maxillofacial Surgeons position paper on bisphosphonate-related osteochemonecrosis of the jaws. Journal of Oral and Maxillofacial Surgery. 2009. Vol 67. Issue 5. 2-12

Doctor Information

Bisphosphonates are a class of drug that inhibit osteoclast action and the resorption of bone. Bisphosphonates are most commonly used for:

- Prophylaxis and treatment of osteoporosis
- Paget's disease
- Multiple myeloma
- As part of some anti-cancer regimes.

Dental surgery may exacerbate or cause osteochemonecrosis in patients during or after Bisphosphonate therapy. Although this is more prevalent in those taking high dose or intravenous Bisphosphonates, it has also been reported in those taking these drugs orally. Concomitant risk factors include poorly controlled diabetes mellitus and other immuno-compromised states, concurrent use of corticosteroids, chemotherapeutic drugs, radiotherapy, advanced age, alcohol abuse and smoking.

It is estimated that the majority of osteochemonecrosis cases are preceded by dental surgical treatment, with twice as many occurring in the mandible as the maxilla. It has been suggested that Bisphosphonate treatment should be postponed during dental treatment to minimise risk however this is inadvisable. Prevalence of osteochemonecrosis amongst IV Bisphosphonate patients is estimated at 0.8-12% while the prevalence amongst oral bisphosphonate users is 0.01-0.04%¹ Local contributing risk factors include anatomical variations such as mandibular tori, periodontal disease, periapical disease and recent trauma.

Recommended Precautions

If you are considering prescribing Bisphosphonate therapy for a patient, please consider the following:

- Before commencing Bisphosphonate therapy, all patients should have a dental examination
- Emphasis needs to be placed on excellent oral hygiene so as to minimise risk factors for infection
- Emphasise the importance of informing their current dentist and future dentists of their drug regime
- Emphasise the importance of informing any surgeons they are currently attending or may attend in the future of their Bisphosphonate history.

Useful resources:

[As for Dentist Information]

Pharmacist Information

Bisphosphonates are a class of drug that inhibit osteoclast action and the resorption of bone. Bisphosphonates are most commonly used for:

- Prophylaxis and treatment of osteoporosis
- Paget's disease
- Multiple myeloma
- As part of some anti-cancer regimes.

Dental surgery may exacerbate or cause osteochemonecrosis in patients during or after Bisphosphonate therapy. Although this is more prevalent in those taking high dose or intravenous Bisphosphonates, it has also been reported in those taking these drugs orally. Concomitant risk factors include poorly controlled diabetes mellitus and other immuno compromised states, concurrent use of corticosteroids, chemotherapeutic drugs, radiotherapy, advanced age, alcohol abuse and smoking. It is estimated that 60% of osteochemonecrosis cases are preceded by dental surgical treatment, with twice as many occurring in the mandible as the maxilla. It has been suggested that Bisphosphonate treatment should be postponed during dental treatment to minimise risk however, this is inadvisable. Prevalence of osteochemonecrosis amongst IV Bisphosphonate patients is estimated at 0.8-12%; while amongst oral bisphosphonate patients prevalence is estimated at 0.01-0.04%¹ Local contributing risk factors include anatomical variations such as mandibular tori, periodontal disease, periapical disease and recent trauma.

Recommended Advice

If you are dispensing Bisphosphonates for a patient, please consider the following:

- Before commencing Bisphosphonate therapy, all patients should have a dental examination
- Emphasis needs to be placed on excellent oral hygiene so as to minimise risk factors for infection
- Emphasise the importance of informing their current dentist and future dentists of their drug regime
- Emphasise the importance of informing any surgeons they are currently attending or may attend in the future of their Bisphosphonate history.

Useful resources:

[As for Dentist Information]

Patient leaflet

Bisphosphonates:

Throughout life there is a constant turnover of bone cells in the body, Bisphosphonates are a class of drug that prevent this natural process. They are most commonly used in the treatment of: osteoporosis, Paget's disease, multiple myeloma and as part of some anti cancer regimes.

Side effects:

It is very important that you take this medication as directed by your doctor. As with many drugs, there are side effects as listed on the information sheet provided within the packaging. If you have any questions or concerns about these side effects, your doctor or pharmacist will be happy to help.

Osteochemonecrosis:

One such side effect is osteochemonecrosis of the jaws, the death of bone cells in the jaws due to the effects of a drug. This has been reported following certain dental treatments in patients taking these drugs. Dental infection increases the risk of developing this condition. Osteochemonecrosis is extremely rare, in patients taking these drugs by mouth (0.01-0.04% chance of it happening) and is only slightly higher in patients receiving the drugs by injection (0.8-12% chance of it happening).¹ It is often preventable but is difficult to treat when it does occur.

What to do:

- Always inform your dentist that you are taking these drugs
- Make sure your dentist knows if you have taken these drugs in the past
- Ensure any doctor or hospital you attend knows that you are taking or have taken these drugs
- Always attend your dentist for regular dental check-ups
- Brush your teeth twice daily
- Avoid sugary foods and drinks
- Tell your dentist immediately if you notice any changes in your mouth

A clean and healthy mouth reduces your risk of this condition

¹Ruggiero SL *et al.* American Association of Oral and Maxillofacial Surgeons position paper on bisphosphonate-related osteochemonecrosis of the jaws. *Journal of Oral and Maxillofacial Surgery*. 2009. Vol 67. Issue 5. 2-12