

Appendix 6

Protocol for Surgical Dental Treatment of Patients Taking Bisphosphonates

Introduction and background

The use of bisphosphonates is associated with the production of osteonecrosis of the jaws (ONJ). ONJ is defined as exposure of the bone of the jaws that does not heal within 8 weeks after identification by a healthcare worker in a patient taking bisphosphonates. The condition may be asymptomatic or present with pain, soft-tissue swelling and loosening of teeth in addition to exposure of bone.

Bisphosphonates are inhibitors of osteoclastic activity and their presence in the body may last for years. These drugs are used in the management of the following:

- Malignancy:
 - To prevent hypercalcaemia
 - To reduce bone loss
- Osteoporosis
- Paget's disease of bone
- Osteogenesis imperfecta

When used in the management of malignancy the drugs are usually administered intravenously (IV). In the treatment of osteoporosis, the drug is normally taken orally. Although intravenous bisphosphonates may be used in the management of osteoporosis, the cumulative dose is lower than that used to manage the malignancy population. It is the intravenous route that is most commonly associated with the production of ONJ. The risk of ONJ in patients taking oral bisphosphonates is thought to be low but has been reported. Concomitant steroid therapy may increase the risk in the latter group.

It has been estimated that the percentage of patients receiving bisphosphonates for management of malignancy who develop ONF is between 4%

and 10%. Around 60% of cases arise after tooth extraction or dento-alveolar surgery. The mandible is more susceptible than the maxilla.

In summary, it appears that the most at-risk group are patients receiving intravenous bisphosphonates during the management of malignancy.

The bisphosphonate drugs

- Alendronic acid (Fosavance)
- Disodium etidronate (Didronel)
- Disodium pamidronate^a (Aredia)
- Ibandronic acid^a (Bondronat, Bonviva)
- Risedronate sodium (Actonel)
- Sodium clodronate^a (Bonefos, Loron)
- Tiludronic acid (Skelid)
- Zoledronic acid^a (Zometa)

^aMay be administered IV.

Local risk factors for ONJ

The following are considered local risk factors for the production of ONJ:

- Poor oral hygiene
- Oral infection
- Dental extractions
- Bone manipulation
- Trauma from dentures
- Vasoconstrictors in local anaesthetics

Management of patients taking bisphosphonates

There are currently no evidence-based protocols for the management of patients at risk of, or suffering from bisphosphonate-induced ONJ. Recommendations are based on expert opinion and can be considered under the headings of prevention, routine dental treatment of patients taking bisphosphonates and treating the patient with ONJ. The following recommendations should be followed when dealing with patients receiving intravenous bisphosphonate therapy; however, they should be considered in patients taking this group of drugs orally.

Prevention

Prevention is key. Ideally, all patients about to receive intravenous bisphosphonate therapy should have a full dental assessment with necessary treatment prior to commencing therapy and all dental treatment completed.

It is thought that the incidence of ONJ is low within 6 months of the commencement of bisphosphonate therapy and thus patients who have just started this therapy should have a thorough dental assessment and treatment if this was not carried out prophylactically.

Routine treatment of patients receiving bisphosphonates

The following are recommended in the routine dental management of patients receiving bisphosphonates:

- Maintenance of oral hygiene.
- Routine restorative dentistry should avoid soft tissue injury.
- Perform routine scalings but avoid soft tissue injury.
- Inspect and adjust removable prostheses for potential soft tissue injury.
- Treat dental infections aggressively but avoid surgery, if possible.
- Endodontics is preferable to extraction. Coronectomy with root canal therapy may be an option.
- Only grossly mobile teeth should be considered for extraction. An atraumatic technique is essential. Primary closure of wounds may be helpful. The use of prophylactic and post-operative antibiotics (preferably amoxicillin or clindamycin) should be used. Patients should be followed-up till healing is complete.

Treatment of patients with bisphosphonate-induced ONJ

Restorative dentistry

Routine restorative care should be provided under local anaesthesia. It is probably wise to use a vasoconstrictor-free solution.

Periodontal treatment

Scaling can be performed but damage to soft tissue should be avoided.

Endodontics

Teeth with pulpal involvement should be treated endodontically.

Extractions

Only grossly mobile teeth should be considered for extraction. An atraumatic technique is essential. Primary closure of wounds may be helpful. The use of prophylactic and post-operative antibiotics (preferably amoxicillin or clindamycin) should be used. Chlorhexidine rinses should be advised pre- and post-operatively. Patients to be followed up until healing is complete.

Implantology

Implants should generally be avoided in patients receiving bisphosphonates.

Management of affected bone

Surgery should be minimised and only sharp bony edges removed.

Chlorhexidine rinses should be used four times a day. Topical application of chlorhexidine gel may be helpful.

Antibiotics should be prescribed if there is evidence of infection around the exposed bone. Amoxicillin (500 mg four times a day initially followed by twice a day for maintenance) is useful. Clindamycin is the alternative if allergic to penicillin (150-300 mg four times daily) but limit to no more than 2-week course.

Antifungals may be required.

Dentures can be worn but must be adjusted to avoid soft tissue trauma and may be soft-lined.

Further reading

American Association of Oral and Maxillofacial Surgeons. Position paper on bisphosphonate-related osteonecrosis of the jaw - 2009 update.

Carters VM, et al (2008) Bisphosphonate use and the risk of adverse jaw outcomes - a medical claims study of 714,217 people. *JADA* **139**, 23-30.

Grbic GT et al (2008) Incidence of osteonecrosis of the jaw in women with post-menopausal osteoporosis in the health outcomes and reduced incidence with zoledronic acid once yearly pivotal fracture trial. *JADA* **139**, 32-40.