

# Bismuth iodoform paraffin paste hypersensitivity reactions in mastoid cavities following isolation of mucosal lining: a series of 587 patients

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## Abstract

*Aim:* (1) To assess hypersensitivity to bismuth iodoform paraffin paste impregnated ribbon gauze following its use in packing canal wall down mastoidectomy cavities; (2) to determine if isolation of the skin and mucosa from the pack, using thin Silastic sheeting and Cortisporin ointment, reduces hypersensitivity reactions, compared with a previous series; and (3) to review the literature and to determine if bismuth iodoform paraffin paste hypersensitivity precludes the consumption of seafood (due to its high iodine content).

*Materials and methods:* All patients undergoing canal wall down mastoidectomy with intra-operative bismuth iodoform paraffin paste packing between 1985 and 2009 were identified and reviewed.

*Results:* Of 587 patients identified, the overall bismuth iodoform paraffin paste reaction rate was 1 per cent. All reactions were in patients undergoing revision mastoidectomy procedures, giving a reaction rate for revision procedures of 2.4 per cent.

*Conclusion:* Reactions are an uncommon event following post-operative mastoid cavity packing using bismuth iodoform paraffin paste. Reaction rates may be lowered by preparing the cavity with Silastic sheeting and Cortisporin ointment prior to packing, thus isolating the skin and mucosal surfaces. Development of such a reaction does not preclude the consumption of seafood.

**Key words:** Mastoidectomy; Cholesteatoma; Dressings; Hypersensitivity; Complications

## Introduction

Ear packing is usually undertaken in two different circumstances: post-operatively (after raising a tympanomeatal flap or following the creation of a mastoid cavity), or in the treatment of severe acute otitis externa.

After raising a tympanomeatal flap, the function of the pack is to ensure apposition of the elevated portion of the external canal skin onto the bony canal; this prevents haematoma formation and permits healing of the flap in the correct anatomical position. Following the creation of a mastoid cavity, packing ensures the graft (i.e. temporalis fascia, perichondrium or cartilage) is in contact with the bony cavity wall, thus minimising haematoma formation.

When treating acute otitis externa, ear packing is utilised when the external canal is completely closed, preventing topical antibiotic medications from entering the deep meatus. In this situation, the oedematous ear canal can be packed with antibiotic-impregnated gauze, which permits continuous topical treatment of the infected canal. The introduction of Pope wicks

(Medtronic Xomed, Minneapolis, Minnesota, USA) has decreased the use of gauze packing in the acute setting. These compressed foam aural tampons act as a hygroscopic agent and vehicle carrier for antibiotic drops, which can then act topically on the inflamed, infected canal.

Many materials and medications have been used for post-operative packing of ears. These packs are regularly kept in situ for two to four weeks, depending on local protocols, and therefore require an antiseptic quality to ensure they do not become a nidus for infection. Post-operative infections may both damage the graft material and lead to operative failure.<sup>1</sup>

Bismuth iodoform paraffin paste (BIPP) has traditionally been used for post-operative aural packing.<sup>2</sup> This paste is applied to ribbon gauze, either manually or, more often, as supplied by the manufacturer. Its antiseptic properties are thought to be related to both bismuth and iodoform (CHI<sub>3</sub>), with the paraffin component producing a workable, soft consistency. Iodoform is proposed to exert its antiseptic effects by the slow release of iodine on contact with oxygen in

blood or the atmosphere.<sup>3</sup> Bismuth is thought to yield dilute nitric acid on hydrolysis, which potentiates the antiseptic activity of iodine.<sup>3</sup>

Curiously, *in vivo* studies have demonstrated minimal change in the growth of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Escherichia coli* on exposure to BIPP, and have not detected any release of free iodine from BIPP over a four-week period.<sup>4</sup> However, despite its precise mechanism of action being unknown, when used empirically BIPP helps keep cavities clean and promotes granulation tissue, which may conversely be counterproductive.<sup>5–7</sup>

Although BIPP-impregnated ribbon gauze is an excellent packing material, it is not without its potential problems. Reactions to BIPP, involving a type IV hypersensitivity reaction to iodoform, occur in a proportion of patients who are exposed to BIPP packing. The incidence of these reactions is between 0.4<sup>8</sup> and 5.9 per cent,<sup>1</sup> 2 per cent on primary exposure, and up to 10.9 per cent on repeat exposure.<sup>1</sup>

A BIPP reaction is more common where prior exposure to BIPP has occurred; patch testing has been reported to reveal a 1 per cent reaction rate in patients not previously exposed, compared with 12 per cent following exposure.<sup>9</sup> Bennett and colleagues<sup>9</sup> patch testing also revealed that all patients who had a reaction and underwent further testing were allergic to iodoform (100 per cent) but not bismuth (0 per cent).

In addition to BIPP reactions, encephalopathy has been described when BIPP is applied to dura mater for extended periods of time (i.e. up to four months), presumably due to bismuth toxicity.<sup>10</sup>

Treatment of a BIPP pack hypersensitivity reaction requires removal of both the pack and of any remaining BIPP paste in the ear, followed by topical steroid medication. Reactions to BIPP typically occur within a week of insertion. In such cases, pack removal is required at a critical point in the healing process. Bismuth iodoform paraffin paste reactions may not only impinge on the operative result,<sup>1</sup> but can be extremely painful, itchy and may cause a rash.

Other medications are available with which to impregnate ribbon gauze. Two of the most popular alternatives are Terra-Cortril ointment (Pfizer, New York, USA) and Tri-Adcortyl ointment (E R Squibb, Uxbridge, UK). These, however, contain oxy-tetracycline and neomycin, respectively, which also have the propensity to create allergic reactions; in addition, high-concentration neomycin is ototoxic.

The aims of this study were: (1) to determine the BIPP reaction rate, when packing mastoid cavities, in a patient series collected by the senior author (JAR); and (2) to assess whether a novel method of packing the cavity reduced the incidence of BIPP reactions.

## Materials and methods

All patients who had undergone intra-operative packing of a mastoid cavity with BIPP ribbon gauze between 1985 and 2009 were identified using the senior

author's (JAR) mastoid database, in which all complication and outcome data had been recorded. Reactions to BIPP had been noted within the database at the time of pack removal and during the post-operative course.

The method of preparing a mastoid cavity for BIPP insertion used at the University Hospital Network, Toronto, involved using thin Silastic sheeting (Dow Coming, Midland, Michigan, USA) to completely line the canal, neotympanum and mastoid cavity. Cortisporin ointment (bacitracin, hydrocortisone, neomycin and polymyxin B (King Pharmaceuticals, Bristol, Tennessee, USA)) was applied onto the sheeting, covering the gaps between the individual Silastic sheets. Following closure of the post-aural incision, BIPP-coated ribbon gauze was inserted down the meatus, which had also been lined with Silastic sheeting. The BIPP ribbon gauze was loosely packed onto the Cortisporin ointment and Silastic sheeting.

The BIPP ribbon gauze used at Toronto General Hospital was prepared in house with bismuth subnitrate powder 7.5660 g per unit of 30 g (252.2 mg/g), iodoform purified powder 15 g per unit of 30 g (500 mg/g), and mineral oil 7.433 ml. This was applied to ribbon gauze in the operating theatre by the scrub nurse. There was no Ray-tec™ band within the ribbon gauze. The commercially available BIPP contained bismuth subnitrate powder 25 per cent weight for weight (w/w), iodoform 50 per cent w/w and liquid paraffin 25 per cent w/w (Orion Laboratories, Balcatta, Western Australia, Australia).

The BIPP packing was left in situ for two weeks and removed in the out-patient clinic. After cleaning of the cavity, Lotriderm ointment (clotrimazole 1 per cent and betamethasone (base) 0.05 per cent; Schering-Plough, Kenilworth, New Jersey, USA) was applied to the healing edges of the cavity at regular intervals until the cavity was completely healed.

## Results and analysis

Between 1985 and 2009, 587 patients underwent canal wall down mastoid surgery for chronic suppurative otitis media (usually cholesteatoma) and received BIPP packing to aid post-operative healing. There were 341 (58 per cent) primary procedures and 246 (42 per cent) revision procedures. Eighty-eight per cent of the revision procedures were performed on patients whose primary mastoid operation had been performed in a different institution, and the packing material used in the primary procedure was often unknown.

Six patients developed a BIPP reaction following intra-operative packing (1 per cent). All of these patients had undergone a revision mastoidectomy procedure, giving a BIPP reaction rate for revision surgery of 2.4 per cent. A further two BIPP reactions developed in the course of cavity maintenance of one patient, when BIPP was used in the out-patient setting with no Silastic sheeting or Cortisporin ointment.

## Discussion

Reactions to BIPP following ear surgery are uncommon, but may affect operative success.<sup>1</sup> The incidence of BIPP reactions varies in the literature, with reported incidences of 0.4 per cent in a series of 712 patients<sup>8</sup> and 5.9 per cent in a series of 185.<sup>1</sup> Farrell's<sup>8</sup> series of 712 patients, with a 0.4 per cent reaction rate, was published in a 'Letters to the editor' style report; in this series, BIPP packing was used for both mastoid and tympanoplasty procedures, and the data collection methodology, number of revision cases and packing technique were not detailed.

Previous exposure to BIPP increases the chance of a reaction, as demonstrated by Lim *et al.*<sup>1</sup> Their series demonstrated a primary reaction rate of 2 per cent, and an 11 per cent reaction rate for those previously exposed to BIPP. As far as we are aware, there has been no proposed alteration in technical operative methods to decrease the incidence of reactions.

Bennett *et al.*<sup>9</sup> have suggested pre-operative patch testing for all patients undergoing mastoid surgery in whom the intention is to pack the cavity with BIPP ribbon gauze. In their series, the BIPP reaction rate was 1 per cent for patients with no previous exposure and 12 per cent for patients who had previously had a BIPP pack, either aurally or nasally.

The rate of BIPP reactions in our series was lower than one would expect from the literature, especially in the case of revision surgery. We hypothesise that minimising BIPP exposure and contact time may reduce reactions. Furthermore, we propose that the use of Silastic sheeting plus Cortisporin ointment to cover the mucosal and epithelial linings of the ear canal, tympanic membrane and cavity effectively isolates the lining from the BIPP and therefore reduces the potential for a type IV hypersensitivity reaction.

- **Bismuth iodoform paraffin paste (BIPP) reactions may be due to a type IV hypersensitivity reaction to iodoform**
- **Overall post-operative ear packing BIPP reaction rates of 0.4–5.9 per cent have been reported**
- **Isolating the mucosal lining using Silastic sheeting and Cortisporin ointment, prior to BIPP packing, may reduce hypersensitivity reactions**
- **Using this method, we achieved a 1 per cent overall reaction rate (2.4 per cent in patients undergoing revision mastoid procedures)**
- **A BIPP reaction does not preclude seafood consumption**

The BIPP preparation used in our institution differed from that commercially available, with mineral oil being used rather than paraffin oil. Bennett *et al.*<sup>9</sup> demonstrated that the reaction in allergic patients is to

iodoform and not the other constituents of BIPP. Therefore, we anticipate that our substitution of mineral oil for paraffin oil did not lead to our low rate of reactions. However, the resulting preparation was more solid and hence less likely to penetrate the gaps between the Cortomycin and Silastic sheeting.

It has previously been suggested that patients may be allergic to the Ray-tec<sup>TM</sup> band included within ribbon gauze. However, this is thought to be unlikely, as the reaction does not take the form of a linear inflammation, as one would expect if the Ray-tec<sup>TM</sup> strip was the cause.<sup>9</sup>

Dietary sources of iodine include fish, seafood and iodised salts. Otolaryngologists may be concerned that patients with a BIPP allergy will also be allergic to fish or seafood, and vice versa. Eighty-five per cent of patients with shellfish sensitivity have a positive skin-prick test to shrimp extract. The responsible seafood antigen is at least partially characterised as the fish equivalent of the muscle protein tropomyosin.<sup>11</sup> No evidence exists that the iodine content of seafood is related to these reactions.<sup>12</sup>

Bennett *et al.*<sup>9</sup> demonstrated that the predominant reaction in those with a BIPP reaction was to iodoform, rather than iodine. Hence, it is unlikely that individuals who are allergic to BIPP are also allergic to seafood, and vice versa.

## Conclusions

Reactions to BIPP are an uncommon event following its use in post-operative packing of the mastoid cavity. However, when reactions do occur they cause pain and discomfort for the patient and may have a detrimental effect on the operative result. We believe the low incidence of BIPP reactions in our series, 1 per cent overall and 2.4 per cent in patients undergoing revision mastoid procedures, was due to the use of Silastic sheeting and Cortisporin ointment in the newly formed cavity. This isolates the skin and mucosal surfaces, prior to the insertion of the BIPP pack and, we hypothesise, lowers the risk of a BIPP reaction. A hypersensitivity reaction to BIPP does not preclude the consumption of seafood.

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Dr C Coulson takes responsibility for the integrity of the  
content of the paper  
Competing interests: None declared

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