BDA evidence summary

NTI-tss - in pain management

This evidence summary aims to locate and summarise evidence on the use of the Nociceptive Trigeminal Inhibition Tension Suppression System (NTI-tss device) in pain management. It does not include detailed descriptions of the studies cited nor does it include information that was not presented in the literature.

The Curious about website encourages dental professionals to raise issues where a review of the available evidence would provide a useful resource for other dental professionals. Where there is a lack of evidence, the topic is considered for research and an award is made available.

These activities are sponsored by the Shirley Glasstone Hughes Fund, a restricted fund within the BDA Trust Fund. The focus of the fund is research into primary care dentistry and aims to generate a body of relevant research for practising dentists.

Contents

Key findings

- The NTI-tss device may be successfully used to manage bruxism and temporomandibular disorders TMDs in certain circumstances.
- No conclusion was reached regarding headache due to the poor quality of available publications.

Review question

This evidence summary was prepared in response to the following question: What is the evidence to support the use of the Nociceptive Trigeminal Inhibition Tension Suppression System (NTI-tss device) in pain management?

The case for action

The NTI-tss device

The NTI-tss is a pre-fabricated semi-customisable intraoral anterior bite stop. It is designed to cover at least one maxillary or mandibular incisor but most often covers two maxillary or mandibular central incisors.[1;2] The device aims to reduce trigeminally-innervated muscular activity and the US Federal Drug Administration (FDA) has approved the device for:[3]

- The prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches
- The prevention of bruxism and temporomandibular joint (TMJ) syndrome.

In the UK, the device is marketed as the most clinically effective, FDA-approved treatment for temporomandibular disorder (TMD), bruxism and medically diagnosed migraines.[4] The indications are listed as:

All cases requiring a disconnection of the occlusion and/or relaxation of the masticatory musculature such as:

- The prevention of symptoms associated with bruxism
- The treatment of certain types of TMD
- The prevention of occlusal trauma – for example protection of restorations and implants in cases of severe bruxism
- The prevention and treatment of chronic tension-type headache and migraine pain.

Despite questions over its safety,[5] the device is reported to have gained popularity as a result of its high clinical success rates in the treatment of migraines and other conditions associated with the trigeminal nerve system.[6]

Indications

Bruxism and Temporomandibular disorder

Bruxism

The causes of bruxism are multifactorial with psychosocial and pathophysiological factors thought to contribute.[7] Symptoms include jaw pain and headache[8] with possible effects being muscle hypertrophy, damaged dentition, dental implant failure,[9] and periodontial tissue damage.[10] The disorder can also threaten the integrity of the structures of the masticatory system.[11;12] and, in theory, the repetitive overloading of the TMJ and muscles may lead to TMDs.[10]

Overall between 8 and 31.4 per cent of people have some sort of bruxism with the disorder being more common when awake (between 22.1 and 31 per cent) than when asleep (12.8 per cent (± 3.1 per cent)).[13] There is no definitive treatment for the disorder but preventive measures include:[14-16]

- Oral devices
- Local injections of botulinum toxin (BTX type A)
- Relaxation techniques
- Physiotherapy
- Drug therapy

Temporomandibular disorder

Temporomandibular disorder (TMD) is a multifactorial process caused by muscle hyper or para function, traumatic injuries, hormonal influences or articular changes.[17] Symptoms include jaw, myofacial and muscle pain and a decreased range of mandibular motion.[17] TMD is one of the two most prevalent causes

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of chronic orofacial pain with an estimated cost in the USA of US$32 billion a year. TMDs have a substantial negative impact on oral health-related quality of life[18] and when myofaical pain is combined with migraine there is major impairment to daily life.[19]

Dental management of TMD often involves occlusal splints and occlusal adjustment. The stabilisation splint and the anterior repositioning splint are the most commonly used designs.[20;21]An historic estimate (1990) suggests that, in the US, dental splints for bruxism and TMD account for 2.91 per cent of dental care spend ($990 million).[22]

Migraine and chronic tension-type headache pain

The most common primary headache disorders[1] are tension-type headache, migraine and cluster headache. Diagnosis can be difficult; many people with headache do not have an accurate diagnosis of headache type. The disorder can have a significant impact on the person and their family or carers.[24] Current NICE and SIGN guidelines for headache recommend triptan, NSAIDs, aspirin or paracetamol as treatment for acute headaches, propranolol as a prophylactic measure and suggest acupuncture as a further prophylactic.[24;25] SIGN guidance considers acrylic splints for patients with migraine but does not recommend occlusal adjustment for treatment of patients with headache associated with temporomandibular disorders.[25]

Migraine

The cardinal sign of migraine is pain and this can be accompanied by symptoms including unusual sensitivity to light and/or sound or nausea and/or vomiting.[24;25] Episodes usually last four to 72 hours in adults. In the UK, it affects approximately six million people aged between 16 and 65. Every working day, over 100,000 people are absent from school or work because of the disorder[25] and this results an estimated cost of £2 billion a year.[25]The problem is often undiagnosed and undertreated and up to 50 per cent of patients are misdiagnosed.[25] Cure is not a realistic aim for migraine sufferers and the suggested objective should be control of symptoms to minimise the effect of the illness on a patient's life and lifestyle.[26]

Explanations for some migraine symptoms have been suggested with trigeminovascular system (TGVS) activation thought to be responsible for the pain itself[27] How the TGVS is triggered remains controversial though local disturbance of the brain function, known as 'cortical spreading depression', has been suggested in some cases (migraine with aura).[28]

Chronic type-tension headache

Tension-type headache is the most common primary headache disorder with a lifetime prevalence in the general population ranging between 30 and 78 per cent.[25;29] A sub form of tension-type headache is chronic tension-type headache,[29] which by definition occurs on average at least 15 days per month for more than three months and lasts hours to days or is unremitting. The condition is a serious disease that results in a greatly decreased quality of life and high disability. The exact mechanism of chronic tension-type headache is not known but it is thought that central pain mechanisms play an important role[29] and that muscle tension contributes in some patients.[8] Most treatment strategies are ineffective for this condition and due to this, and the loss in quality of life, and the chronic nature of the disorder, it has a high societal burden.[30]

The evidence

Evidence suggests that the NTI-tss device may be successfully used to manage bruxism and TMDs in certain circumstances.[2;31;32] Contradictory results were reported when the NTI-tss device was compared with alternative appliances as were several complications and side effects for the NTI-tss.[31;32] No conclusion could be reached specifically regarding the NTI-tss device in pain management. The systematic review by Stapelmann and Türp was the subject of a summary review that concluded that a cautious approach should be taken to the device due to the scarcity of clinical data.[34]

Bruxism and TMD

Stapelmann and Türp concluded that NTI-tss device may be successfully used to manage bruxism and TMDs but only if the patient is willing to maintain contact and follow advice.[2] Evidence suggested tension suppression (reduced electromyography (EMG) activity) but there was no clinical correlation. Adverse events, mostly affecting single teeth or the occlusion, were reported for patients employing the device and as the NTI-tss was not more effective than the comparator(s) it was suggested that only limited indication is warranted:[2]

- A patient with acute and intense temporomandibular pain who requires emergency therapy for the rapid incorporation of an oral appliance to increase the vertical dimension of the jaws.
- For reducing the EMG activity of jaw closing muscles during jaw clenching or tooth grinding.

The subsequent RCTs,[31;32] do not offer evidence to warrant amending the conclusion reached by

1 "Primary" refers to a lack of clear underlying causative pathology, trauma, or systemic disease.[23]

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Stapelmann and Türp.[2] The first of the subsequent trials demonstrated counselling to change habits and behaviourto be effective in the management of masticatory myofascial pain though simultaneous use of an occlusal stabilisation splint (OSS) or NTI-tss device, especially the OSS, produced an earlier improvement.[31] Possible adverse effects for the NTI-tss device, including tooth sensitivity, were recorded. The second study demonstrated that both the NTI-tss and occlusal stabilisation splints can reduce the bruxism index and concluded that the NTI-tss device had a more predictable therapeutic effect effect.[32]

Headache

No conclusion was reached with regards specifically to headache due to the poor quality of publications.[2]

Methods

Search strategy

A systematic review was located that examined the available data on the efficacy and/or effectiveness of the NTI-tss device with regards to bruxism, TMD and headache.[2] This systematic review was current for literature published up until December 31 2007.

As a consequence only relevant studies published since the systematic review were sought (2008 – 2014). Six of the nine search strategies used in the identified review were repeated (Cochrane, PubMed, TRIP, Quintessenz Verlag, MEDPILOT.DE and Google Scholar). The following additional databases were searched with equivalent strategies and no language restrictions:

- LILACS
- MEDLINE (Ovid)
- SciELO
- WHOLIS

Databases not searched were:

- The database of the Deutscher Ärzte-Verlag
- BIREME
- Web of Science (Cited reference search)

Grey literature was searched and a snowballing strategy was employed once publications relating to the questions were located.

As a systematic review (SR) covering randomised controlled trials (RCTs) was used as the baseline for this summary papers were included if they met the following criteria:

- Were SRs or RCTs
- Examined the NTI-tss device and pain management or TMD in any population and setting
- Compared the NTI-tss device to any device used for the same indications
- Had defined outcomes.

Studies were excluded if they:

- Did not examine the device in pain management or TMD
- Had unclear outcomes
- Contained data of interest that could not be extracted.

Results

Over 300 journal publications (non-deduplicated) were returned through searches and following sifting by the author three were judged to be relevant. Of the relevant publications one was a systematic review[2] and the remaining two papers randomised controlled trials (RCTs).[31;32]

The systematic review examining the NTI-tss device as a therapy for bruxism, TMDs and headache[2] covered five RCTs with all but one trial investigating TMD or bruxism. The remaining trial examined the device in tension-type headache and migraine.

All of the located publications suffered from limitations. Though well conducted, the systematic review covered studies with small sample sizes, which may have induced a statistical type II error[2], and methodological heterogeneity for example inclusion criterion and the comparator differed between studies. The studies conducted by Conti *et al*[31](Jadad score 4) and Liu *et*

2 An error that can lead to the null hypothesis being accepted in error

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al[32] (Jadad score 3) are both short-term studies, of three months and four weeks respectively, involving small study populations and could have led to a statistical type II error. The study by Liu *et al*[32] was a cross-over trial (two week wash out) raising the possibility of carry-over and period effects.[33] A further complication was the translation of this publication from Chinese to English. Whilst this was achieved, it was carried out using an automatic translation system so may not be completely accurate. In keeping with the original systematic review, the two more recent RCTs were graded using the Jadad scoring system. More information on this can be found in Appendix one.

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Appendix 1

Jadad scale

Jadad *et al*[35] described a method for assessing the quality of controlled clinical trials. The basic Jadad Score is based on the answers to the five questions below with the maximum score being five.[36]

Item	Points available	Description
Randomisation	2	1 point if randomisation mentioned
		1 point if method is appropriate
		1 point deducted if method inappropriate
Blinding	2	1 point if blinding is mentioned
		1 point if method is appropriate
		1 point deducted if method inappropriate
All patients accounted for	1	The fate of all patients is given

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