NICE National Institute for Health and Care Excellence

Surveillance report 2016 – Headaches in over 12s: diagnosis and management (2012) NICE guideline CG150

Surveillance report

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Contents

Surveillance decision

We will not update the guideline at this time.

Reason for the decision

We found 44 new studies through surveillance of this guideline.

This included new evidence on assessment, diagnosis, and management of primary headaches that supports current recommendations. We asked topic experts whether this new evidence would affect current recommendations on NICE guideline CG150. Generally, the topic experts thought that an update was not needed.

None of the new evidence considered in surveillance of this guideline was thought to have an effect on current recommendations.

Other clinical areas

We also found new evidence that was not thought to have an effect on current NICE guideline CG150. This evidence related to the use of occipital nerve block in people with chronic or episodic migraine (with or without aura) and the use of non-invasive nerve stimulators in people with chronic or episodic migraine (with or without aura) or cluster headache.

Equalities

One topic expert highlighted an equality issue in people with severe and profound intellectual disability: 'people with severe and profound intellectual disability or communication disorder cannot give a clear history of or complain of headache.' The NICE guidelines on learning disabilities note the challenges of identifying physical health in this population and make recommendations.

Overall decision

After considering all the new evidence and views of topic experts, we decided that no update is necessary for this guideline.

See how we made the decision for further information.

Commentary on selected new evidence

With advice from topic experts we selected one study for further commentary.

Management

We selected a systematic review (SR) by Chen YF et al. (2015) for full commentary because this study assesses the clinical evidence available on occipital nerve stimulation (ONS) for chronic migraine. The use of neurostimulation in primary headaches is one of the areas highlighted by topic experts as relevant but not included in the current version of NICE guideline CG150. The SR by Chen YF et al. was published after a NICE interventional procedure (NICE IPG452) in this area which offers guidance on the use of ONS for intractable chronic migraine. NICE IPG452 was published in 2013 and recommends that 'this procedure should only be used with special arrangements for clinical governance, consent audit or research'.

What the guideline recommends

NICE guideline CG150 does not include a question about the clinical effectiveness of invasive nerve stimulators in chronic migraine.

Chen YF et al. (2015) – Occipital nerve stimulation in migraine

Methods

The SR by Chen YF et al. (2015) evaluated the benefits and harms of ONS in patients with chronic migraine. This is an update of a SR which assessed a broader question about invasive peripheral nerve stimulation in patients with refractory pain. The previous SR was used in the development of NICE interventional procedures in this area.

Searches were conducted in at least three databases including The Cochrane Library, MEDLINE and EMBASE. The search strategies were available in a separated document. Trials registers were also reviewed. The searches were also supplemented by reviewing the references of relevant articles identified and other websites (Medicines and Healthcare Products Regulatory Agency and Food and Drug Administration).Two authors independently selected studies for inclusion. They included RCTs or controlled studies, or uncontrolled case series with more than 10 people included. One reviewer did the data extraction and the risk of bias assessment using the Cochrane Collaboration's Risk of bias tool. A second reviewer checked the quality of the data extracted. The certainty in the evidence for key outcomes was assessed using GRADE criteria.

The authors performed a meta-analysis of different effectiveness outcomes recommended by the International Headache Society. Only results from RCTs were used to evaluate the effectiveness of the interventions. They also assessed the homogeneity of the results using I^2 and visual inspection of forest plots. Original investigators or sponsors of studies with missing data were contacted but not response was received. Global estimators of the effect for adverse events were not calculated given the heterogeneity of the methods used in the included studies.

Results

A total of 12 studies were included: three RCTs (range of included participants 67 to 157), two crossover studies (8 participants and 30 participants) and seven case series (range of included participants 10 to 25). Regarding the controlled trials, one study included people with migraine (with or with aura) or chronic migraine (people with medication overuse were a pre-specified group), three studies people with chronic migraine (in two studies it was unclear if people with medication overuse were included) and one study people with chronic migraine or medication overuse headache. Three studies were conducted in USA or Canada (industry sponsored), one in Italy and one in Germany. Five case series were conducted in USA or Canada, one in Italy, and one in UK and Italy (two centres).

The RCTs lasted 12 weeks and they were followed by an uncontrolled open-label period of one to three years. One crossover study had an intervention period (ONS switch on) of one month followed by another month of no intervention (ONS switch off – but with the possibility to switch on if needed). Then, all patients switched on their devices and were followed for 10 months. The other crossover trial had three periods of one week each: in one period people received stimulations to reduce the pain (supra threshold stimulation), in the second they received stimulation just under the threshold of perception (subthreshold stimulation) and in the third one, no intervention.

There were low or unclear risks of bias in the included studies, except for the high risk of attrition bias and reporting bias in one study and the high risk of performance and detection bias in another one. For one of the RCT included, only the information contained in an abstract was available, so most of sources of bias were considered unclear. None of the crossover studies included had a washout period between the different interventions assessed and they did not assessed or discussed the carry over effects of the intervention assessed.

ONS was associated with a reduction of the days with prolonged moderate or severe headaches compared with controls (mean difference 2.59, 95% confidence interval [95%CI] 0.91 to 4.27, 3 studies, I^2 0%) but not with an improvement of the reported responder rates (relative risk [RR] 2.07,

95% CI 0.50 to 8.55, 2 studies, I^2 51%). The certainty of the evidence for these outcomes was considered moderate and low, respectively. Other effectiveness outcomes were summarised narratively given the heterogeneity in the variables measured or the incomplete data reporting. Only three studies contributed data to this narrative description, two of them were considered at high risk of bias. In one study ONS was associated with a mean reduction in headaches days per month at 3 months compared with sham and medication management. In another study ONS switched on reduced the median headaches days per week at 1 month compared with ONS switched off (crossover study). ONS was also associated with a reduction in overall pain intensity at 3 months compared with sham or medication management (one study), with a reduction of the patient-reported percentage headache pain relief at three months compared with sham (one study), and in the median of headache severity at 1 month compared with ONS switched off (one study). Results related to the reduction of MIDAS scores and utilisation of acute medication were poorly reported and varied between the studies.

Long-term outcomes were assessed in RCTs that followed-up the participants after the initial randomisation phase and in case series. Participants from RCT received the intervention (no comparison group available). In summary, at one year of follow up most of the people continued to use the device and the efficacy seemed to be preserved in the short term, but data from case series reported a drop around 40%–50% in the use of the device after this period of time.

Adverse events were mainly related to the insertion procedure or device related. Lead migration or dislodgement was frequent and the rates of infection varied from 4% to 30% among the studies. The certainty of the evidence was considered low. Different studies between RCT and case series reported serious adverse events that required hospitalisation: four implant site infections, three lead migrations, one post-operative nausea, one post-operative pain, two psychiatric complications. One study reported 40 serious adverse events at one year of follow-up from a total of 209 adverse events recorded. These 209 adverse events were related to the device itself (for example battery issues, device malfunction, etc.), to a response to the device (for example allergic reaction, skin erosion, pain, swelling, etc.), and to the stimulation (for example muscle spasms, cramping, nausea or vomiting, etc.). One other trial was stopped early due to adverse events in six of the nine participants of the study. Long-term outcomes reported were related to change of the skin at the implant site (one) and on case of reduction/loss of musculoskeletal control (one).

Strengths and limitations

Strengths

- It is a moderate quality SR relevant to NICE guideline CG150. They did a comprehensive literature research and a duplicate selection of the included studies. One reviewer did the data extraction and quality assessment of the included studies. A second reviewer assessed the quality of the data extracted.
- They used appropriate methods for combining the results and the heterogeneity of the results was assessed. Most of the results were reported narratively given the considerable variation in the results among the studies included.
- An assessment of the certainty in the evidence was conducted for the main outcomes included. Authors discussed how the quality of the evidence identified impacted on their conclusions.

Limitations

- The definition of chronic migraine varied between the studies included and in some of the included studies it was unclear if they included or not patients with medication overuse.
- It is unclear if subgroup analysis or sensitivity analyses were intended to determine the causes of heterogeneity. In one of the pooled estimates the I^2 was 0% and in other one 51%. No further analyses were performed.
- Authors reported most of the results narratively given the heterogeneity in the methods and formats of the outcomes assessed in the included studies.
- Authors also highlighted that most of the results were incomplete and poorly described in the studies. Positive results in the reduction in prolonged moderate/severe headaches came from three RCTs sponsored by the manufacturers. This fact could include a risk of publication and reporting bias. Long-term outcomes predominantly come from case series.

Impact on guideline

The intervention assessed in the SR was considered relevant to NICE guideline CG150. In the SR, authors included RCTs and case series studies in people with chronic migraine which were refractory to multiple treatments. Studies varied in their population, methods and outcomes assessed. ONS seems to reduce prolonged moderate/severe headaches but the impact in other relevant outcomes was not relevant or varied across the studies included. The long-term effectiveness (more than 1 year) and in subgroups (people with or without medication overuse) is unclear. The adverse events reported were more related to the implantation procedure or the device rather than the intervention itself, however they were frequent and in some cases requiring management in hospital settings. Authors concluded that despite new RCTs in the area, there is insufficient evidence in terms of benefits and harms of ONS to recommend its use in this

population. It is considered that the evidence identified in both interventions assessed is limited in quality and quantity and therefore unlikely to impact on NICE guideline CG150.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 4 years after the publication of headaches in over 12s: diagnosis and management (2012) NICE guideline CG150.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

Previous surveillance update decisions for the guideline are on our website.

New evidence

We found 28 new studies in a search for RCT and SRs published between 26 March 2014 and 18 May 2016. A further 2 studies were identified through post-publication communications.

Evidence identified in previous Evidence Update and surveillance 2 years after publication of the guideline was also considered. This included 14 studies identified by search.

From all sources, 44 studies were considered to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of new evidence from surveillance and references for all new evidence considered.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication.

Stakeholders commented on the decision not to update the guideline. Overall, 7 stakeholders commented. See appendix B for stakeholders' comments and our responses.

Seven stakeholders commented on the proposal not to update the guideline. Three agreed or had no comments on the decision and four disagreed. Of the four who disagreed, one provided comments which were unclear and one did not provide details as to why they did not agree with the proposal not to update. One stakeholder requested an additional reference to TA260 which is currently linked to within the recommendations and the pathway. The final stakeholder queried one conclusion of the surveillance report around verum acupuncture for migraines, however the evidence identified in the surveillance review was for cluster headaches and therefore support current guideline recommendations. No new ongoing or published studies were identified by the consultees. One stakeholder disagreed with the decision to remove the research recommendation relating to pizotifen from the NICE version of the guideline and NICE research database; therefore this recommendation will be retained. One stakeholder disagreed with the proposal to remove four research recommendations and commented on the scope of the guideline and equality issues but did not give a clear reason as to their disagreement.

See ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

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