

Teething products may be harmful to health

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Key points

Reports 14 teething products without evidence of effectiveness are licensed for use in the UK.

Nine of these 14 products are potentially harmful, containing one or more of sucrose, alcohol or lidocaine.

Suggests clear guidance on the management of teething which steers parents away from potentially harmful products is needed.

Abstract

Introduction An internet search identified teething powders licensed in the UK containing sucrose and alcohol.

Aims To identify current UK guidance on teething and potentially harmful ingredients in teething products.

Methods Internet searches identified UK national guidance on teething and evidence on teething interventions. The Medicines and Healthcare products Regulatory Agency was asked to provide information on the sugar and alcohol content of UK-licensed teething products. The internet search also highlighted concerns about 2% lidocaine teething product use in the USA. Information on lidocaine content was extracted from product information leaflets.

Results A clinical knowledge summary notes the lack of evidence of effectiveness of teething powders, granules, pills or gels. Of 14 licensed teething products, two contain sucrose, six contain alcohol and six contain lidocaine, all potentially harmful ingredients. There is an opportunity to develop some new UK guidance drawing on extant teething guidance and the clinical knowledge summary.

Conclusions Despite a lack of evidence of effectiveness for teething products, of the 14 licensed products in the UK, nine contain one or more of sucrose, alcohol or lidocaine. There is an opportunity to develop new guidance to steer health professionals and the public away from these potentially harmful products.

Introduction

'Designed to smile', the Welsh programme to reduce decay in children, is changing to encompass health visitors and dental practices in the prevention of tooth decay between ages zero and three. The increase in interactions between dental teams and health visitors has led to an increase in requests for advice on teething. When this increase in requests for advice on teething was reported to the author, he recalled a product seen for sale some years ago. The product was homeopathic teething powder, with sucrose as the sole ingredient.

A rapid search of the internet identified two teething powders for sale on UK websites containing sugar and a number of teething gels containing alcohol. The search also

identified Medicines and Healthcare products Regulatory Authority (MHRA) advice to avoid unlicensed homeopathic teething powder because of the risk of serious side effects.¹ The MHRA advice references a clinical knowledge summary on teething that indicated both teething powders and gels lack evidence of effectiveness.² The advice gives consumers details on teething products currently licensed for use in the UK.

The problem with development of early childhood dental decay is the delivery of care to the very young child; this care frequently requires a general anaesthetic. Milk teeth are susceptible to decay because the enamel and dentine have less mineral content than permanent teeth. When free sugar in the mouth is fermented into acid, the teeth lose mineral content and the decay process commences.³ The best way to prevent decay is to avoid consumption of free sugars, especially between meals. The use of sucrose as a teething product is unwise both in terms of the short-term risk of acid attack on the teeth and in terms of a child developing a sweet tooth. This applies whether the teething product is

one applied by the parent to the affected site, or is a teething biscuit or rusk.

While sugar in teething products may harm the teeth and contribute to developing a likeness for sweet things, alcohol is associated with other issues. Consumption of relatively low doses of alcohol by infants through breast milk is associated with arousing, rather than sedating, infants and is also associated with an increased propensity for crying and poor sleeping.^{4,5} Moderate exposure of infants to alcohol has been related to an impaired motor development and risk of hypoglycaemia.^{6,7} Evidence from animal studies suggest that there is potential for post-natal exposure to alcohol to impact upon brain development.⁸

Aims

Given the lack of evidence of effectiveness of teething preparations and the potential harm associated with giving sugar or alcohol to a teething child, an investigation of teething powders and gels available in the UK, and licensed by the MHRA, was undertaken to identify those containing sugar or alcohol.

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Method

Contact was made with the MHRA by email asking for details of all powder and gel products licensed for teething (including homeopathic and herbal products), and whether the licensed products include sugar or alcohol in the ingredients. In addition, through a separate email, the MHRA were asked how, in principle, any concern about products containing potentially harmful ingredients should be formally raised using the example that at least two of five licensed homeopathic products contained sugar. Teething product information sheets were reviewed to identify other ingredients of potential interest and the advice they provide on frequency of use.

Results

MHRA provided the details on the ingredients of teething powders and gels by email response on the following day. Teething powders are licensed either as homeopathic or herbal products, whereas teething gels, with the sole exception of Nelson's Teetha Teething Gel, all hold full product licences (Table 1).

There are 14 licensed teething products in the UK in powder, gel, granule, solution and pill formats (Table 1). Two of these products are covered by the same licence, and presumably are identical products. Of the 14 products, two contain sucrose. Half of the 14 products contained alcohol, with one homeopathic product containing both sucrose and alcohol.

A further response from the MHRA to the second email (which had asked how to raise concerns about homeopathic teething products) arrived 20 days after the query was raised. The email indicated that the MHRA would request the manufacturers of the two homeopathic teething powders containing sucrose to add to their product information sheet: 'May be harmful to the teeth.'

The review of the product information sheets identified information about frequency of use of the teething products. The product with sugar and alcohol, Weleda Chamomilla 3X granules, presented the greatest concern. The advice for use in children from birth to six years is for '1 salt spoonful given every 15 minutes until the condition improves for up to 6 doses'. It is unclear whether this means at most six times a day, or that up to six salt spoons can be given at each time the child is complaining of discomfort.

The review of product information sheets also identified the presence of lidocaine in all the teething gels with a full product licence.

Three of the products licensed for use in the UK contain lidocaine 0.33% w/w. The other three contain 0.5% (Bonjela Junior Gel), 0.6% (Boots Teething Gel 3 Months Plus) and 1.0% (Anbesol Teething Gel).

Discussion

Potential harms

From a dental perspective, frequent intake of sugar is the primary cause of tooth decay. Newly erupted teeth are particularly susceptible to decay until the enamel has had an opportunity to undergo post-eruption maturation.^{9,10} Frequent application of sucrose to newly-erupting deciduous teeth seems therefore unwise for the risk of decay to teeth.

At birth human brains are 30% of their adult size and continue to grow over the next five to six years. There is a considerable degree of development of brain and brain function between birth and age three. Alcohol is known to be harmful to the brains of children *in utero*. Experiments with rats suggest that, post-natally, alcohol continues to impact on brain development.⁸

Also of concern is the effect of alcohol on infant behaviour. The evidence, mainly from studies of alcohol in breast milk, suggests that infants exposed to alcohol have less sleep,^{4,5} cry more,⁴ and have impaired motor development,⁶ with decreased milk intake.¹¹ Risks of tooth decay may not be present for alcohol but the

behavioural impacts and possible developmental impacts of alcohol do suggest that products with alcohol should be avoided. There are teething products available containing neither sugar nor alcohol.

The other ingredient of concern identified from the product information sheets is lidocaine. In the United States there have been 22 serious adverse reactions, including deaths, associated with lidocaine 2% solution.¹² These events were associated with wrong dosing or accidental ingestion. All of the teething gels with a full product licence in the UK contain lidocaine. Risk of lidocaine overdose will be higher for the products with the greater concentration of lidocaine. It would seem wise to steer parents away from the use of lidocaine containing products and the higher strength products in particular, to minimise the risk of overdose. In December 2018, after the inquiries were made to the MHRA about lidocaine-containing products, the MHRA published new guidance that lidocaine-containing teething products would only be available under the supervision of a pharmacist and should be used only where other measures have not provided relief.¹³

A need for simple clear advice

The clinical knowledge summary highlighted a lack of evidence for effectiveness of any teething powder, gel or similar product.² While the absence of evidence of effectiveness is not the same as proof of ineffectiveness, it would

Table 1 Sugar, alcohol and lidocaine content of licensed teething products

Teething product licensed in the UK	Format	Licence type	Contains sucrose	Contains alcohol	Contains lidocaine
Ashton and Parsons' Infant Powders	Powder	Herbal	No	No	No
Boots Teething Pain Relief*	Granules	Homeopathic	No	No	No
Nelson's Teetha Teething Granules*	Granules	Homeopathic	No	No	No
Weleda Chamomilla 3X Granules	Granules	Homeopathic	Yes	Yes	No
Camilia Oral Solution	Solution	Homeopathic	No	No	No
Helios ABC 30C Pillules	Pill	Homeopathic	Yes	No	No
Nelson's Teetha Teething Gel	Gel	Homeopathic	No	Yes	No
Fennings Childrens Cooling Oral Powders	Powder	Full	No	No	No
Boots Teething Gel 3 Months Plus	Gel	Full	No	No	0.6%
Bonjela Teething Gel	Gel	Full	No	Yes	0.33%
Bonjela Junior Gel	Gel	Full	No	Yes	0.5%
Dentinox Teething Gel	Gel	Full	No	Yes	0.33%
Calgel Teething Gel	Gel	Full	No	Yes	0.33%
Anbesol Teething Gel	Gel	Full	No	Yes	1.0%

*Single licence for the two products

be prudent to avoid ineffective products which contain potentially harmful ingredients and for information targeted to health professionals and the public to guide accordingly.

Current resources on teething for health professionals in the UK available online include the clinical knowledge summary on teething² and the Scottish Dental Clinical Effectiveness Programme (SDCEP) advice on the management of acute dental problems.¹⁴ The clinical knowledge summary covers diagnosis of teething, a summary of the evidence base for interventions and advice on self-care. The SDCEP advice on teething is included as part of advice of management of pericoronitis and teething content. It focuses on the use of analgesics and is the only advice which includes some basic oral hygiene measures. The *Delivering better oral health* toolkit is usually the first port of call for dental team members for advice on prevention, but it does not currently include teething advice.¹⁵

For the public, NHS Choices for England¹⁶ and NHS Direct Wales¹⁷ both include the same advice on features of teething in their pregnancy guide. NHS Choices has additional content on 'tips for helping your teething baby' in a separate webpage not linked to the page on features of teething.¹⁶ Equivalent websites for Scotland and Northern Ireland do not include teething content. The Patient.info website has advice on symptoms and managing teething which does include cautions about lidocaine-containing teething gels.¹⁸

Overall there is a very mixed pattern of advice provision. The sources range in how comprehensive they are, and of the advice they provide. There is scope for the development of simple and consistent advice on identification and management of teething for both health professionals and the public across the UK which could then be used by all organisations. This advice needs to help with diagnosing teething, providing advice on evidence-based actions and steering users away from potentially harmful actions and products. It should be possible to do this drawing on the clinical knowledge summary and SDCEP advice, with awareness of the content of licensed teething products

Questions for licensing of products

The issues raised in this paper also reflect a wider concern of products being licensed for use across the UK when there is an absence of evidence for that use and the products contain potentially harmful ingredients. The MHRA website outlines the process for granting a product licence.

Before granting a licence the MHRA needs to know whether the medicine:

- Works well with minimal harm for most people who will be taking it
- Is acceptably safe.

A high level of side effects in a medicine used to treat a life-threatening condition, such as cancer, may be an acceptable trade off, but not in one used to treat a minor ailment, such as hay fever. In general, side effects are considered to be very common when they occur in at least one in ten cases and uncommon when they occur in between one in 100 and one in 1,000 cases. Side effects occurring in one in 10,000 cases are regarded as very rare.¹⁹

There are a number of issues with current teething products set against this process. There is no evidence that these teething products work at all. Does the use of an intervention or product for which there is no evidence of effectiveness count as treatment for a minor ailment? Can a product without evidence of effectiveness be regarded as one which works well? The inclusion of low levels of lidocaine, alcohol or sugar in teething products could be argued as presenting low risk of harm. Even so, when minimal harm is associated with lack of evidence of effectiveness, the key question is whether that combination means that a product is acceptably safe? This is particularly the case when there are alternative products not containing those ingredients, and therefore not associated with those risks.

In addition to protecting the public from products which are not acceptably safe, licensing arrangements should ensure that users are warned about the potential harms associated with those products not demonstrated to be effective. The addition of the warning that sugar-containing teething powders 'May be harmful to teeth' is welcomed, as is the limiting of lidocaine-containing products to 'provision under pharmacist supervision'. Parents should also be made aware when teething products contain alcohol.

Conclusions

There is an absence of evidence for the effectiveness of teething products. Most teething products licensed for use in the UK contain sucrose, alcohol and/or lidocaine, all of which have potential harms and side effects. Guidance on management of teething could help health professionals and parents to manage teething and avoid these products. The prudent approach would be to change licensing arrangements to avoid the use of harmful ingredients in licensed products without evidence of effectiveness.

Failing that, the harms and side effects associated with those ingredients should be highlighted to parents via the product information sheets and their interactions with health professionals.

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