Eiscreme und Kopfschmerzen

Sie arbeiten auf einer HNO-Abteilung als Krankenschwester. Gerade haben Sie wieder ein Kind, dem die Gaumenmandeln operativ entfernt wurden, ermahnt, nicht zu schnell das Eis herunterzuschlingen, das Sie ihm zum »Kühlen von innen« gegeben hatten. Nun hinterfragen Sie Ihren Rat und recherchieren fix in PubMed – eigentlich sollte es doch über alles eine Studie geben…

Sie finden die Untersuchung von Kaczorowski & Kaczorowski (2002); werden Sie Ihren kleinen Patienten weiterhin empfehlen, ihr Eis nicht zu schnell zu essen?

- Lesen Sie die Studie:

- Beurteilen Sie die Studie anhand des Beurteilungsbogens.

- Beantworten Sie die Frage aus dem Szenario.
people than expected would need further investigation, dietary restriction would undoubtedly be beneficial when screening this particular population.

We thank Neil Macauley, department of biochemistry, for analysing the Haemoccult tests.

Contributors: NH and RH helped to conceive and design the study and revised the paper. SF wrote and edited the paper and analysed the data. AT collected data and helped to revise the paper. NH is guarantor for the study.

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Competing interests: NH is extremely fond of black pudding.


Cold stimulus headache, also known as ice cream headache, is a common problem and is reported to occur in about a third of a randomly selected population. It was further suggested that the ice cream headache could be induced only in hot weather. A Medline search from 1966 to August 2002 with the MeSH terms and combination operators “ice cream,” “headache,” and “randomized controlled trial” to identify English language trials in this area produced no results.

In order to fill this important knowledge gap, we compared the effect of two ice cream eating regimens on the incidence of ice cream induced headaches in a prospective randomised manner. The study was carried out during the winter to test whether this phenomenon was restricted to hot weather only.

Participants, methods, and results

All 145 students at Dalewood Middle School in Hamilton (Canada) in classes 63, 81, 82, 83, 84, and 85 were eligible to participate and were approached by the principal author after permission was received from the school’s teachers. They were told the purpose of the study and the potential risks and benefits and were asked to provide verbal consent.

The sample size calculation was performed assuming a 10% incidence of ice cream headache with cautious ice cream eating and that a 20% absolute increase in incidence between eating regimens would justify mum’s nagging. To detect this level of difference with 80% power would require 71 participants in each arm of the trial.

Participants were randomised via a concealed (face down) distribution of scrambled, stapled baseline and exit questionnaires marked with a red or green dot in the upper left corner. All participants were instructed to complete a baseline questionnaire recording age, sex, headache history, and lifetime prevalence of ice cream headache. Participants who received green dot questionnaires were given 100 ml of ice cream and were told to eat it in >30 seconds. They were further instructed to have about half their ice cream left after 30 seconds and then to continue at their own pace.

Participants who received red dot questionnaires were given 100 ml of ice cream but were instructed to eat it in <5 seconds. The temperature of the ice cream was not formally regulated throughout the study. There were six eating sessions between December 2001 and January 2002 that included 21 to 28 participants, and each session compared both eating regimens.

The primary outcome measure was the incidence and duration of ice cream headache assessed via self reported questionnaires completed 5–10 minutes after eating the ice cream. All statistical tests were conducted on an intention to treat basis and were two tailed (P<0.05).

All 145 students from six classes who were approached provided verbal consent. There were no refusals and no loss to follow up. The table shows the baseline characteristics of the two groups.

Twenty (27%) of 73 students in the accelerated eating group reported ice cream headache compared with 9 (13%) of 72 students in the cautious eating group (relative risk 2.2 (95% confidence interval 1.03 to 4.94), number needed to harm 6.71 (3.79 to 200.48)). Of the 29 headaches reported, 17 (59%) occurred in <5 seconds. The lifetime prevalence of ice cream headache among the participants was 115/145 (79% (73% to 86%)).

Comment

The main weaknesses of our study were lack of blinding and the use of self reporting to ascertain the main outcome measure. Nevertheless, these findings...
confirm that cold stimulation of the palate induced by gobbling up ice cream more than doubles the likelihood of developing ice cream headache among middle school students. In contrast to previous studies, our results suggest that ice cream headache can be induced in cold weather even in subjects who eat their ice cream at a slow pace. The lifetime prevalence of ice cream headache was also considerably higher than what was previously reported. We thank Ms A Charters, Mr P Sallewsky, and Ms N Diacon, who are teachers at Dalewood Middle School, as well as the students who participated in the study (classes 63, 81, 82, 83, 84, and 85). We also thank Isabelle Cottencourt, mother and wife respectively, of the investigators. Presented at the 2002 Bay Area Science and Engineering Fair (BASEF), April 3-6, 2002, Mohawk College, Hamilton, ON, Canada Funding: This work was supported by an unrestricted grant from mum and dad.

Competing interests: None declared.

### Kritische Beurteilung einer Interventionsstudie

#### Quelle:

Forschungsfrage: 

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### Glaubwürdigkeit

1. **Wie wurden die Teilnehmer rekrutiert und den Untersuchungsgruppen zugeteilt?**

   - Rekrutierung? Randomisierung? Zuteilung?

2. **Wie viele Patienten, die anfangs in die Studie aufgenommen wurden, waren am Ende noch dabei?**

   - Wurden die Ausfallraten begründet, z. B. Unfall, Tod, Verletzung des Protokolls? Follow-up > 80%?

3. **Waren die Teilnehmer, das Personal und die Untersucher verblindet?**

   - Wenn nein: wäre eine Verblindung möglich und ethisch vertretbar gewesen?

4. **Waren die Untersuchungsgruppen zu Beginn der Studie ähnlich?**

   - Geschlecht, Alter, Krankheitsstadium, Bildung, Beruf?

5. **Wurden die Untersuchungsgruppen – abgesehen von der Intervention – gleich behandelt?**

   - Unwahrscheinlich, dass andere Faktoren die Ergebnisse beeinflusst haben?

6. **Wurden alle Teilnehmer in der per Randomisierung zugeteilten Gruppe bewertet?**

   - Wechselte kein Teilnehmer die Gruppe? Intention-to-Treat-Analyse?

7. **War die Größe der Stichprobe ausreichend gewählt, um einen Effekt nachweisen zu können?**

   - Fallzahlberechnung? Signifikante Effekte?

8. **Stehen die Ergebnisse im Einklang mit anderen Untersuchungen auf diesem Gebiet?**

### Aussagekraft

9. **Wie ausgeprägt war der Behandlungseffekt?**

   - z. B. RR, RRR, ARR, NNT? Median, Mittelwert?

10. **Sind die unterschiedlichen Ergebnisse nicht nur auf einen Zufall zurückzuführen?**

   - p-Wert?

11. **Wie präzise sind die Ergebnisse?**

   - Konfidenzintervalle?

### Anwendbarkeit

12. **Sind die Ergebnisse auf meine Patienten übertragbar?**

   - Ähnliche Patienten, ähnliche Umgebung?

13. **Wurden alle für mich wichtigen Ergebnisse betrachtet?**

   - Nebenwirkungen? Compliance?

14. **Ist der Nutzen die möglichen Risiken und Kosten wert?**

   - Kostenanalyse?

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**Bewertung der Glaubwürdigkeit (Bias-Vermeidung):**

$1 - 2 - 3 - 4 - 5 - 6$