Forced convective head cooling device reduces human cross-sectional brain temperature measured by magnetic resonance: a non-randomized healthy volunteer pilot study

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Background. This pilot study in five healthy adult humans forms the pre-clinical assessment of the effect of a forced convective head cooling device on intracranial temperature, measured non-invasively by magnetic resonance spectroscopy (MRS).

Methods. After a 10 min baseline with no cooling, subjects received 30 min of head cooling followed by 30 min of head and neck cooling via a hood and neck collar delivering 14.5°C air at 42.5 litre s⁻¹. Over baseline and at the end of both cooling periods, MRS was performed, using chemical shift imaging, to measure brain temperature simultaneously across a single slice of brain at the level of the basal ganglia. Oesophageal temperature was measured continuously using a fluoroptic thermometer.

Results. MRS brain temperature was calculated for baseline and the last 10 min of each cooling period. The net brain temperature reduction with head cooling was 0.45°C (SD 0.23°C, P=0.01, 95% CI 0.17–0.74°C) and with head and neck cooling was 0.37°C (SD 0.30°C, P=0.049, 95% CI 0.00–0.74°C). The equivalent net reductions in oesophageal temperature were 0.16°C (SD 0.04°C) and 0.36°C (SD 0.12°C). Baseline-corrected brain temperature gradients from outer through intermediate to core voxels were not significant for either head cooling (P=0.43) or head and neck cooling (P=0.07), indicating that there was not a significant reduction in cooling with progressive depth into the brain.

Conclusions. Convective head cooling reduced MRS brain temperature and core brain was cooled.

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The aim of our brain cooling research is to find a simple, non-invasive method of direct brain cooling which can reduce elevated brain temperature after injury. We previously found head fanning with ambient air reduced brain temperature in brain-injured patients by 0.26°C (P<0.001, 95% CI 0.17–0.34°C).1 This was encouraging, being similar to the tympanic temperature decrease of 0.27°C achieved in this study.2

1Declaration of interest. KCI Research and Development Facility, Ferndown, UK was approached by B.A.H. and P.J.D.A. and agreed to assist with the study. KCI developed and provided the cooling device, paid for the MRS scans, fluoroptic thermometry, and volunteers’ expenses, and gave an unrestricted grant to cover part-time salary for B.A.H. They were not involved in the analysis and interpretation of data or the decision to submit the manuscript for publication.
which has been argued may reduce the relative risk of poor outcome after ischaemic stroke by 10–20%. We therefore developed a forced convective head cooling device to deliver cold air at higher flow rates.

Invasive brain temperature monitoring is inappropriate in healthy people and usually only a single point of measurement is possible. There are, however, methods of measuring intracranial temperature non-invasively and more globally using magnetic resonance imaging (MRI), of which magnetic resonance spectroscopy (MRS) appears the most promising. Brain temperature during conductive head cooling has been measured in healthy adults with single voxel MRS.

The aim of this study was therefore to assess the effect of a forced convective brain cooling device on brain temperature in healthy adult humans, using two-dimensional MRS to measure brain temperature non-invasively across the brain.

Methods

Permission for the study was obtained from Lothian NHS Research Ethics Committee and Lothian University Hospitals NHS Trust management (REC Ref. No. 04/S1102/27). The participants were adult volunteers who gave informed consent. Inclusion criteria were age ≥18 yr and no significant medical history; exclusion criteria were claustrophobia, pregnancy, and contraindications to MRI.

Study design and interventions

This was a non-randomized study to assess brain temperature, measured by MRS, during forced convective cooling.

After a 10 min baseline, subjects received 30 min of head cooling followed by 30 min of head and neck cooling. Brain temperature was measured at baseline and at the end of head cooling and of head and neck cooling. Oesophageal, forearm, and fingertip temperatures were monitored continuously. Foot warming was used to facilitate a greater reduction in core temperature before defences against cooling were activated.

The cooling device

The forced convective cooling device (KCI, Ferndown, Dorset, UK) delivered air through a hood, which left the face exposed, and a separate neck collar. The hood and collar were made of a double layer of nylon sheeting with holes punched in the inner layer through which the air flowed onto the head and neck. They were attached to the cooling machine by a Y connector and could be independently clamped off so that either head or neck cooling or both together could be delivered. The machine was sited in the scanner control room and the air ducted to the hood through 11.5 m of 8.5 cm diameter neoprene insulated tubing. The air temperature at the end of the tubing immediately before the hood was approximately 14.5 °C and the flow rate approximately 42.5 litre s⁻¹.

Temperature monitoring

Brain temperature

MRS is a well-established technique that uses an MRI scanner to detect certain naturally occurring brain metabolites. By interpreting the relative frequencies of a reference metabolite (N-acetyl aspartate; NAA) and water, it is possible to estimate tissue temperature with precision of approximately ±0.5 °C in 1 ml voxels.

Oesophageal temperature

Although brain temperature was of primary interest, oesophageal temperature was monitored by more conventional means with an MRI compatible fluoroptic temperature probe (Luxtron, Santa Clara, CA, USA), sheathed in a 10 fg enteral feeding tube, placed in the lower third of the oesophagus. The probes are too fine to be passed unsheathed. This thermometer is accurate to ±0.2 °C within 20 °C of the calibration point. Subjects rested for at least 30 min after passing the temperature probe in order to allow temperatures to stabilize and the sympathetic arousal the procedure may have induced to settle.

Defence against cooling

To delay the onset of defences against cooling, bilateral foot warming was used with an MRI compatible hot pack (Mueller Sports Medicine, Prairie du Sac, WI, USA) around each foot during the entire time in the scanner. Subjects wore thick socks, loose track suit type trousers, and tee shirts, and over this a waistcoat, opening down the back, made of heat reflecting material overlaid with polythene. The waistcoat was taped down around the base of subjects’ necks to prevent air blowing on their bodies. Once lying supine on the scanner bed, subjects were covered entirely by two layers of cotton cellulose blankets which were tucked down over their shoulders.

Defence against cooling was assessed by peripheral vasoconstriction and shivering score (none, moderate, and severe). Peripheral vasoconstriction was measured by forearm minus fingertip temperature using a fluoroptic skin temperature probe taped to one index finger opposite the nail bed and another on the radial side of the forearm midway between the wrist and the elbow. Vasoconstriction occurs before shivering.

Statistical design

Five volunteers were judged sufficient in the absence of suitable data on which to base a power calculation. The order of the cooling interventions was not randomized so that each intervention would have the same temporal interval from baseline for the purposes of comparison.
Determining the duration of the cooling periods

In our previous trial, it took less than 15 min for head fanning to begin reducing frontal lobe brain temperature.\(^1\) Thirty minutes each of head cooling and head and neck cooling were therefore judged sufficient to show a reduction in brain temperature. This also kept the total time in the scanner within reasonable limits for subjects to remain comfortable without moving their heads.

Data collection and analysis

MRS temperature

All MRI measurements were made on a 1.5 Tesla Signa scanner (GE Healthcare, Slough, UK) fitted with the standard head coil. Axial \(T_2\)-weighted fast spin echo images were acquired and used to position the spectroscopic imaging plane horizontally at the level of the basal ganglia. The manufacturer’s standard single-slice spectroscopic imaging sequence was used with point resolved spectroscopy (PRESS) excitation, echo time of 145 ms and repetition time of 1000 ms. The field of view was 32 cm with a phase-encoding grid of 24 × 24, and the slice thickness was 10 mm. Automatic shimming and chemical shift selective water suppression were applied. For each phase encoding, 512 complex data points were acquired with a sampling interval of 1 ms.

Analysis was carried out blinded to the time point for each subject. The method of analysis has been previously described\(^6\) and in brief was as follows. Imaging and spectroscopic data were transferred to a workstation for analysis. The spectroscopic data were processed with two-dimensional apodization and spatial Fourier transformation with interpolation resulting in 10 mm (1 ml) voxels. Zero-order phase correction was made using the residual water signal. Resulting spectra were modelled as Gaussian peaks using the AMARES algorithm\(^11\) within the MRUI package.\(^12\) For each spectrum, the ppm or Hz location of the water peak was set to 0 and the distance between the water peak and the NAA peak, as identified by the modelling software was recorded. The relationship between the distance from water to NAA and the temperature of the tissue is linear and was extrapolated from a previously conducted pilot study.\(^6\) The presence of cerebrospinal fluid (where there is no NAA) reduced the number of valid voxels at the centre of the brain and spectral distortions reduced the valid voxels around the periphery. Spectra were automatically discarded if fitted line widths were < 1 Hz or > 10 Hz, or if the metabolite peaks were more than 0.1 ppm offset from their expected values, or if the voxels lay on the edges of the PRESS excitation region. All spectra were also inspected visually and discarded if judged to be of poor quality, for example, having a badly elevated baseline or containing spurious peaks.

As with any thermometer, the accuracy of temperature readings depends on correct calibration. Calibration of a linear scale typically requires two parameters: the ‘scale factor’ and the ‘offset’. Temperatures for the remaining voxels were calculated using the equation \(T = 37 + 100 \left(\text{CSNA} - 2.035\right)\),\(^1\) where 100 is the ‘scale factor’ from the literature;\(^3\) \(\text{CSNA}\) is the measured chemical shift of NAA; 2.035, the group mean chemical shift of NAA measured in a group of healthy ‘reference’ volunteers; and 37°C, the ‘offset’, that is, the assumed group mean brain temperature of the volunteers.\(^5\) The ‘zero’ for the MRS temperature scale is thus set at 37°C, which is valid for assessing temperature change but may not be valid for measuring actual temperature. The actual mean brain temperature of the reference group (or of any human volunteers) is not known and may have been different from 37°C. This would affect the accuracy of absolute measurements but the method can still be applied to investigate temperature changes as we have done in this study. Approximately one-sixth of all voxels were automatically discarded because they yielded apparent temperatures outside the limits 32–40°C. These voxels were mainly around the edges of the brain.

The spectroscopic grid was overlaid on the corresponding axial \(T_2\)-weighted image, and voxels were classified by region, blinded to temperature values. The regions did not necessarily coincide with distinct vascular or physiological regions, but were chosen to explore possible temperature gradients while ensuring that there were sufficient valid voxels in each region. Voxels lying within the region formed by joining the tips of the lateral ventricles were designated ‘core’, voxels lying within approximately one voxel of the brain surface were defined as ‘outer’, and all other voxels were defined as ‘intermediate’ (Fig. 1). The resulting temperatures for the core, intermediate, and outer voxels for each subject were transferred to a Microsoft Office Excel spreadsheet (Excel 2003, Microsoft Corporation, Redmond, WA, USA).

Figure 1: Axial \(T_2\)-weighted image at the level of the basal ganglia, overlaid with the spectroscopic grid showing the region boundaries drawn in red, blue and green. Each numbered square on the grid corresponds to one voxel. Core voxels are within the green line, intermediate voxels between the green and blue lines, and outer voxels between the blue and red lines.
Oesophageal and forearm minus fingertip temperatures

Data collection was electronic, second by second and subsequently averaged over the final minute, and final 10 min of the baseline and the head and head and neck cooling periods.

Calculations and statistical analysis

The analysis plan was specified in advance. The mean temperatures of the core, intermediate, and outer voxels were calculated for each subject for the baseline and each cooling intervention. The overall brain temperature means were determined from these regional means. The formal tests for cooling effect were paired two-tailed \( t \)-tests of the baseline corrected MRS brain temperature, averaged over the means of the core, intermediate, and outer voxels, for all subjects for head cooling and head and neck cooling. The formal tests for temperature gradient were one-sample two-tailed \( t \)-tests comparing the slopes of each subject’s mean outer, intermediate, and core voxel temperatures for baseline corrected head cooling, head and neck cooling, and the mean of head plus head and neck cooling. With only five subjects, we could not test the assumption that the data were normally distributed; therefore, a Friedman non-parametric repeated measures analysis was also carried out.

The secondary analysis gives the mean baseline corrected oesophageal temperature differences with cooling for each subject for the last 10 min of each intervention, that is, over the equivalent time to the MRS brain temperature data acquisition.

Microsoft Office Excel and the Statistical Package for the Social Sciences (SPSS 12.0, SPSS Inc., Chicago, IL, USA) were used for organizing and analysing the data.

Results

Three male and two female subjects, aged 31–48 yr, were recruited. Their BMI ranged from 21.6 to 28.5. Two subjects had long hair, which was left loose down their backs with the neck collar placed between their necks and hair. Two had short hair and one male pattern baldness. Although the MRS scans were not undertaken for diagnostic purposes, they were nevertheless routinely reported and were within normal limits.

One subject was scanned on the first day and two per day thereafter. The ambient temperature in the scanning room was 18.4°C for subject 1 and 20°C for subjects 2 to 5 (within recommended room temperature range for the UK). The head cooling had to be started again in subject 1 owing to the device becoming disconnected. This aborted head cooling period was not used in the analysis.

MRS brain temperature

Spectroscopic scanning took approximately 10 min for each measurement of brain temperature and was undertaken at baseline and during the final 10 min of each cooling intervention. All subjects yielded usable spectroscopic data. The MRS analysis yielded a mean of 69 valid voxels (range 54–90) per subject for the baseline, 54 (range 36–69) for head cooling, and 55 (range 33–73) for head and neck cooling. The mean number of valid voxels per subject in the outer region was 11 (range 2–23), intermediate 27 (range 14–40), and core 21 (range 13–32). Figure 2 shows a voxel temperature map for the same subject as in Figure 1.

In every subject, mean brain temperature over all voxels decreased relative to baseline with head cooling (Fig. 3A). The formal test for cooling, averaging MRS brain temperature over all voxels for all subjects, showed head cooling produced a baseline corrected reduction in mean brain temperature of 0.45°C (SD 0.23°C, range 0.16–0.77°C), which was statistically significant (\( P=0.01, 95\% \) CI 0.17–0.74°C). At the end of head and neck cooling, the baseline corrected reduction in mean brain temperature was 0.37°C (SD 0.30°C, range 0.01–0.66°C). This was on the borderline of significance at the 5% level (\( P=0.049, 95\% \) CI 0.00–0.74°C). These findings are supported by the results of an overall Friedman test (\( \chi^2 7.6, 2 \) df, \( P=0.02 \)).

Head cooling reduced mean brain temperature in the outer, intermediate, and core voxels relative to baseline, with the exception of subject 4 whose intermediate voxels were on average warmer with head cooling (Fig. 3B). The formal test for gradient was not significant at the 5% level (\( P=0.43, 95\% \) CI −0.15°C to 0.29°C) and neither was the Friedman test (\( \chi^2 1.2, 2 \) df, \( P=0.55 \)). This means, taking...
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Fig 3  Baseline corrected mean MRS temperature (°C) (a) with head cooling and head and neck cooling over all voxels for all subjects, (a) with head cooling over outer, intermediate, and core voxels for all subjects, (c) with head and neck cooling over outer, intermediate, and core voxels for all subjects. (d) Mean forearm minus fingertip temperature difference (°C) over final minute of baseline and each cooling intervention.
the five subjects together, cooling did not significantly reduce with progressive depth into the brain.

Head and neck cooling reduced mean brain temperature in the outer, intermediate, and core voxels relative to baseline, with the exception of the intermediate and core voxels in subject 4 and the core voxels in subject 2, which were on average warmer (Fig. 3c). The formal test for gradient was not significant at the 5% level ($P=0.07$, 95% CI $-0.03$°C to 0.58°C); neither was the Friedman test ($\chi^2 3.6, 2$ df, $P=0.17$). The formal test for gradient for the baseline corrected mean of head cooling plus head and neck cooling was on the borderline of significance at the 5% level ($P=0.049$, 95% CI 0.00–0.34°C). The Friedman test was not significant ($\chi^2 5.2, 2$ df, $P=0.07$).

**Oesophageal temperature**

Mean oesophageal temperature over baseline was 36.56°C (SD 0.36, range 36.16–37.02°C). Mean baseline corrected oesophageal temperature reductions over the final 10 min of each period (i.e. over equivalent times to MRS brain temperature measurement) were 0.16°C (SD 0.04°C, range 0.12–0.21°C) with head cooling and 0.36°C (SD 0.12°C, range 0.19–0.51°C) with head and neck cooling.

**Forearm minus fingertip temperature**

The forearm minus finger tip temperature differences averaged over the final minute of baseline, head cooling, and head and neck cooling are shown in Figure 3b. Generally, the difference increased as cooling continued, signifying increasing vasoconstriction. A difference of 0°C represents the onset of vasoconstriction and >4°C represents significant vasoconstriction.14

**Shivering**

All subjects said they felt cold by the end of the trial and subjects 1 and 2 had goosebumps. Only subject 5 experienced overt shivering, which occurred after neck cooling began and was scored as moderate.

**Discussion**

**The effect of the cooling device on temperature**

This study has shown that brain temperature can be reduced globally with forced convective head cooling. Head cooling produced a statistically significant mean overall MRS brain temperature reduction of 0.45°C within 30 min, including a reduction in core brain temperature (Fig. 3n). Head and neck cooling produced a mean reduction of 0.37°C.

The MRS temperature measurements were acquired during the last 10 min of each 30 min cooling intervention, and therefore approximate the true temperature 25 min into the intervention. This is because there is not a one-to-one geometrical relationship between the position of a voxel and the time at which its data are acquired during an MRI sequence. Rather, the data required for each voxel are built up slowly throughout the scan time and the most important information can be thought of as being acquired half way through a standard sort of sequence. Although subjects received each intervention for 30 min, the head cooling results may represent cooling for as little as 20 min because the MRS brain temperature data were being collected over the final 10 min of the intervention (centred on 25 min).

All subjects reduced their oesophageal temperature compared with baseline with both head cooling and head and neck cooling. Since considerable precautions were taken to prevent their bodies being directly cooled by the cold air, it is not unreasonable to conclude that a heat loss gradient had to occur from the head through the jugular veins, venous system, and lungs before it could affect oesophageal temperature measured behind the right atrium. This, together with the temperature reduction in core voxels and the lack of a significant temperature gradient with cooling, suggests that external convective cooling can affect deep brain temperature. These findings are contrary to mathematical modelling of external head cooling which estimates that this affects superficial brain areas only (up to 1.5 cm), and that varying external convection from still air through to infinity essentially makes no difference to cerebral heat exchange and thus to brain cooling in humans.15 16 However, modelling inevitably necessitates making a number of assumptions, although even allowing for this the latter conclusion does seem somewhat counterintuitive.

The mean brain temperature reduction with head and neck cooling (0.37°C) was of only borderline statistical significance and three subjects (2, 4, and 5) had a smaller brain temperature reduction compared with baseline than with head cooling (Fig. 3a). With few subjects, the possible reasons can only be speculative. Because head and neck cooling was delivered second, subjects could have been defending more strongly against cooling simply because they had been cooled for longer. Head and neck cooling, however, reduced oesophageal temperature more than head cooling in all subjects, despite producing an increase in vasoconstriction in all but subject 5 (Fig. 3n), who nevertheless shivered. This suggests head and neck cooling together may have relatively more effect on core trunk temperature and thus be less head selective than head cooling alone.

It is possible that neck cooling caused carotid vasodilation in these three subjects and this reduced its brain cooling effect. It has been shown that cooling induces vasodilation in isolated rabbit carotid artery preparations and, to a greater extent, heating induces vasoconstriction.17 These responses appear logical because carotid blood flow from the body to the brain would be reduced under...
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conditions of hyperthermia, which would attenuate brain heat gain and be in synergy with the brain cooling mechanisms of heat loss from the upper airways and through the skull.\textsuperscript{19} Conversely, under cold conditions the brain would receive rather more blood from the body to compensate for heat losses from the head. By the end of 30 minutes of head cooling, mean global brain temperature had reduced by 0.45°C and oesophageal temperature by only 0.16°C, which suggests body temperatures were relatively warmer in comparison to brain temperatures than at baseline (i.e. the brain–body temperature gradient narrowed because cooling affected brain temperatures to a greater extent than oesophageal temperatures). Therefore, if neck cooling did induce carotid vasodilation the consequent increase in flow of relatively warmer blood from the body may have reduced the rate of brain cooling. Although global brain temperature reduced more than oesophageal temperature with head cooling we cannot say whether it reduced below oesophageal temperature, that is, whether selective brain cooling occurred, because the methods of temperature measurement are not directly comparable. Although MRS temperature over 2 cm\textsuperscript{3} of parenchyma in pigs during whole body heating and cooling has been found to be highly correlated ($r=0.93$) with fluoroptic temperature measured in the centre of the same parenchymal volume,\textsuperscript{20} the limits of agreement have not been assessed.

Comparison with other studies of direct brain cooling by forced convection

There are two clinically feasible methods of non-invasive direct brain cooling: helmets containing frozen material or circulating cold fluid and forced convection of air. Our head cooling rate is similar to that with a circulating cooling helmet in brain-injured patients with parenchymal temperature monitoring.\textsuperscript{21} However, forced convection of air has potential advantages because it causes no pressure on the skull and utilizes all the methods of heat transfer to the environment.\textsuperscript{22} It is thus more likely to facilitate the normal mechanisms of heat loss through the skull, including the face, and also from the upper airways in self-ventilating subjects.\textsuperscript{19 23} Nevertheless, there are very few studies of forced convective methods of direct brain cooling.\textsuperscript{24}

Given the lower temperature and higher airflow of our device, it is perhaps unsurprising that the reduction of 0.45°C in brain temperature is greater than the 0.26°C reduction we previously demonstrated in a randomized, cross-over trial of bilateral head fanning of ambient air with electric fans in brain-injured adults ($n=12$).\textsuperscript{1} We are aware of no other trials of head cooling with a forced air device in humans with intracranial temperature measurement. A helmet delivering 13°C air at 16.7 litre s\textsuperscript{−1} was used on large, healthy dogs ($n=16$) with body temperature maintained at 38°C on normothermic cardiopulmonary bypass.\textsuperscript{25} Mean parenchymal temperature (1 and 2 cm below the dura) reduced by 1.35°C in 30 min. It is hard to explain why the cooling rate was so much greater in dogs than in our subjects, except that dogs’ heads are smaller. Anaesthesia will have reduced their defence against cooling, although maintenance of body temperature at normothermia is likely to have more than compensated for this and makes the cooling rates achieved more remarkable.

Limitations of the study

This is a small observational study designed to obtain data on the cooling device in healthy humans before investigating the clinical potential in brain injury. It has fulfilled its purpose, nevertheless there are some limitations.

Although spectroscopic imaging can measure brain temperatures on a regional basis, interpretation of the measurements in an absolute sense is confounded by large between subject variations in mean temperature and by within subject temperature ranges between single voxels. This does not exclude the use of the technique in studies such as this where individuals are acting as their own controls. Furthermore, within-subject ‘noise’ should make it more difficult to show the consistent overall cooling effect we have demonstrated here. Clinical utility will be limited by the precision of the technique, which is of the order of 0.5–1°C for 1 ml voxels imaged at 1.5 Tesla.\textsuperscript{6} Therefore, the measurements from several voxels must be combined to achieve significant results for small temperature changes from scan to scan. Nevertheless, much useful information can be obtained from modest group studies such as ours. The increasing availability of higher field scanners and phased array head coils will improve the precision and encourage wider use of temperature measurement in clinical research and management.

Spectral quality is likely to be affected by both $B_0$ (static magnetic field) and $B_1$ (radiofrequency) inhomogeneities, including the effect of potentially non-uniform water suppression. We used a spectral line width cut-off of 10 Hz to automatically reject poorly shimmed voxels but several visually poor spectra survived this check. It is likely that they would also have survived the methods recently used by others.\textsuperscript{26} In future work, we are planning to use ‘machine learning’ algorithms to assist with the automated quality control of spectra, which will be important when processing CSI data sets from large studies. Spectral quality in frontal and temporal regions will remain an issue, especially on scanners that have only first-order (gradient) shimming available.

Conclusions

This study provides the necessary basis for investigating the clinical potential of this device in brain-injured patients. It contributes new information about human responses to brain cooling by showing that forced
convective head cooling reduced brain temperature, measured by MRS, and that core brain was cooled.

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