

research



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ORIGINAL RESEARCH Cluster randomised clinical trial

Intraosseous versus intravenous vascular access in upper extremity among adults with out-of-hospital cardiac arrest

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Study question What is the effect of intraosseous versus intravenous access among adults with out-of-hospital cardiac arrest?

Methods This pragmatic randomised clinical trial included adults (20-80 years) with non-traumatic out-of-hospital cardiac arrest. Biweekly randomised clusters of four participating advanced life support

ambulance teams were assigned to either intravenous or intraosseous access in the upper extremity. The primary outcome was survival of patients to hospital discharge. Secondary outcomes included pre-hospital return of spontaneous circulation, sustained return of spontaneous circulation (≤ 2 hours), and survival with favourable neurological outcomes (cerebral performance category score ≤ 2) at hospital discharge.

Study answer and limitations Of 1771 adults with out-of-hospital cardiac arrest, 1732 (741 in the intraosseous group and 991 in the intravenous group) were included in the primary analysis (median age 65.0 years; 1234 (71.2%) men). The rate of survival to hospital

discharge was 10.7% (79/741) for intraosseous access and 10.3% (102/991) for intravenous access; this difference was not significant (odds ratio 1.04, 95% confidence interval 0.76 to 1.42; $P=0.81$). The exclusion of adults aged >80 years might affect generalisability.

What this study adds The intraosseous route is a reasonable alternative to the intravenous route for resuscitation of adults with out-of-hospital cardiac arrest.

Funding, competing interests, and data sharing See full paper on [bmj.com](https://www.bmj.com) for funding. No competing interests declared. Data will be available to other researchers on request, with information shared after approval by the corresponding author.

Study registration [ClinicalTrials.gov](https://www.clinicaltrials.gov) NCT04135547.

Primary and secondary outcomes. Values are numbers (percentages) unless stated otherwise

Outcome	Total (n=1732)	Intraosseous (n=741)	Intravenous (n=991)	Odds ratio* (95% CI); P value
Primary				
Survival to hospital discharge	181 (10.5)	79 (10.7)	102 (10.3)	1.04 (0.76 to 1.42); 0.81
Secondary				
Pre-hospital return of spontaneous circulation	169 (9.8)	80 (10.8)	89 (9.0)	1.23 (0.89 to 1.69); 0.21
Sustained return of spontaneous circulation	562 (32.4)	233 (31.4)	329 (33.2)	0.92 (0.75 to 1.13); 0.44
Survival with favourable neurological outcomes (CPC ≤ 2)	136 (7.9)	63 (8.5)	73 (7.4)	1.17 (0.82 to 1.66); 0.39

CI=confidence interval; CPC=cerebral performance category.

*Unadjusted, with intravenous serving as reference.

Spinal surgery for stenosis and spondylolisthesis

ORIGINAL RESEARCH Five year follow-up of a randomised, multicentre, non-inferiority trial

Decompression alone or with fusion for degenerative lumbar spondylolisthesis (Nordsten-DS)

Kgomotso EL, Hellum C, Fagerland MW, et al

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Study question Does decompression alone perform as well as decompression with instrumented fusion for patients with intolerable leg and back pain due to lumbar spinal stenosis and a concomitant degenerative spondylolisthesis?

Methods This Norwegian multicentre trial included 267 participants with a mean age of 66 years, comprising 68% women, who had symptomatic spinal stenosis and a single level spondylolisthesis. Participants were randomly assigned to surgery with either decompression (n=134) or decompression with additional instrumented fusion (screws, rods, and bone grafts) (n=133). The primary outcome was a $\geq 30\%$ reduction in pain related functional impairment from before surgery to five year follow-up, as assessed by the Oswestry disability index, in the modified intention-to-treat analysis. Such improvement is considered a threshold for obtaining a clinically meaningful improvement of spinal stenosis surgery. The predefined non-inferiority margin was -15% . Adverse events assessed during follow-up included reoperation rates on the index level or adjacent lumbar levels.

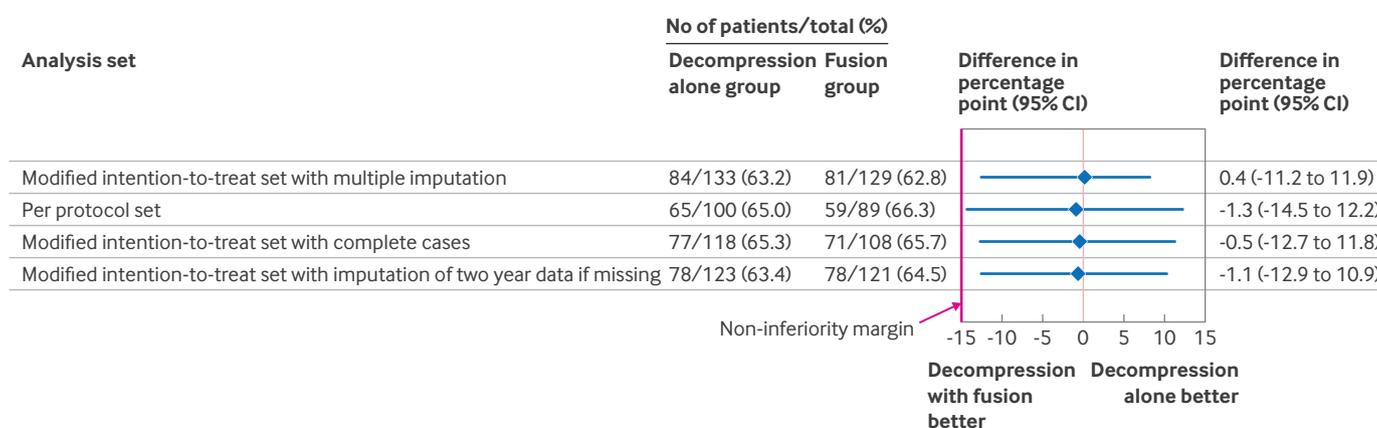
Study answer and limitations Five years after surgery, 63% of participants in both groups obtained at least a 30% reduction in the disability index (84/133 in the decompression alone group and 81/129 in the fusion group, 0.4 percentage points (95% confidence interval (CI) -11.2 to 11.9)), and no difference was reported in reoperation rates. The CIs were higher than the predefined non-inferiority margin of -15% . However, the results cannot be generalised to patients with degenerative scoliosis, severe foraminal stenosis, spondylolisthesis at multiple levels, or previous surgery.



A. NOORBESIPALAMY

What this study adds In participants with degenerative spondylolisthesis, decompression alone was non-inferior to decompression with instrumented fusion five years after primary surgery. Proportions of subsequent surgeries at the index level or adjacent lumbar levels did not differ between the groups.

Funding, competing interests, and data sharing Norwegian health authorities funded the trial but were not involved in trial design, data collection or analysis, interpretation of the results, or manuscript drafting. No competing interests declared. The NORDSTEN scientific board grants access to the data after a research protocol review.



Primary outcome. No of patients/total no (%) refers to the proportion of patients with 30% or more reduction in Oswestry disability index in each specified analysis. The between group differences is in percentage points and the corresponding 95% CIs. For patients in the modified intention-to-treat set with imputation of missing five year data, the missing values were replaced by multiple imputation. CI=confidence interval

Controversy continues about the best surgical option for patients with symptomatic lumbar spinal stenosis and concomitant degenerative spondylolisthesis. At the centre of this controversy is a debate on the efficacy of decompression alone versus decompression with fusion. In this context, durability has been defined as maintenance of clinical benefit without the need for additional intervention.¹ The potential benefit of fusion surgery in terms of durability should be weighed against the risks of future reoperations because of adjacent segment disease. Previous randomised controlled trials and observational register studies did little to settle the controversy because the results were inconsistent.²⁻¹⁰ Three previous randomised controlled trials (two from Scandinavia and one from Japan) reported findings favouring decompression without fusion,²⁻⁴ whereas one randomised controlled trial from the US reported findings favouring decompression with fusion.⁵ Specifically, the US randomised controlled trial reported significantly higher reoperation rates for patients managed with decompression without fusion.⁵

A meta-analysis aggregating the results of these four randomised controlled trials found no significant differences between the two treatment options in patient reported outcome measures, such as the Oswestry disability index or reoperation rates.⁶ Furthermore, two large studies of data from Scandinavia's national registers found no significant differences in

patient reported outcomes or reoperation rates after two years of follow-up when comparing decompression with or without fusion.^{7,8} By contrast, two studies analysing data from the US quality outcomes database found that decompression combined with fusion was associated with significantly better patient reported outcomes than decompression alone over two or five years,^{9,10} but no significant difference in reoperation rates.

Important findings

In a welcome addition to this evidence, Kgomotso and colleagues reported five year results from the Norwegian degenerative spondylolisthesis and spinal stenosis (Nordsten-DS) trial.¹¹ The findings are important because this trial evaluated surgery for spinal stenosis with concomitant degenerative spondylolisthesis over five years. The authors found that decompression with no fusion was not inferior to decompression with fusion with respect to patient reported outcomes and reoperation rates. The study primarily adds valuable data for patient reported outcomes: 84 (63%) of 133 patients in the decompression group and 81 (63%) of 129 patients in the fusion group met the primary outcome (a reduction in the Oswestry disability index of $\geq 30\%$ from baseline to five year follow-up). The difference between the groups was 0.4 percentage points (95% confidence interval -11.2 to 11.9). Confident evaluation of differences in reoperation rates may require longer follow-up because other evidence suggests that the distribution of reoperations for adjacent segment disease after a spinal fusion is bimodal, with peaks

in incidence after two and 10 years.¹² A longer follow-up may not add further value to patient reported outcomes; however, other health related events may occur during a longer follow-up that could affect these outcomes. An important limitation of Kgomotso and colleagues' study was that the patients were not masked to treatment assignment, which, for example, may affect patients' satisfaction with treatment. Furthermore, the study was not powered to compare differences in reoperation rates between the two treatment groups.

As Kgomotso and colleagues noted, only a few countries reported a change in surgical practice following earlier trials favouring decompression without fusion. In Sweden, for example, the rate of fusion surgery for patients with spinal stenosis and spondylolisthesis decreased from 75% in 2009 to less than 20% in 2018,¹³ whereas in the US, rates of decompression with fusion increased from 67% in 2016 to 90% in 2019.¹⁴ Changes to practice in countries such as the US may require the intervention of health leaders

This trial evaluated surgery for spinal stenosis with concomitant degenerative spondylolisthesis over five years



and policy makers in addition to new evidence.

Economic benefits

The health economic consequences of fusion surgery are important from a policy maker's perspective. Cost utility estimates are already available from a model based on data from the Nordsten-DS trial and reoperation rates reported by the aforementioned US randomised controlled trial,^{4,5} indicating that decompression with fusion is not cost effective compared with decompression alone in the surgical management of degenerative spondylolisthesis over a two year time horizon.¹⁵

Patient information and shared decision making are both undermined by the absence of consensus on how to surgically manage lumbar spinal stenosis with degenerative spondylolisthesis. While the US randomised controlled trial and quality outcomes database studies suggested that fusions can be beneficial for carefully selected patients, Kgomotso and colleagues' findings also indicated that decision makers could work towards reducing the global rate for fusion surgery, perhaps aiming for a Scandinavian level of less than 20%.⁵⁻¹⁰

In conclusion, Kgomotso and colleagues provided important five year evidence for the effectiveness of decompression without fusion with respect to patient reported outcomes. However, longer term studies are needed to finally settle the issue regarding differences in reoperation rates between decompression with or without fusion for spinal stenosis with degenerative spondylolisthesis.

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Intake of sugar sweetened beverages among children and adolescents in 185 countries between 1990 and 2018

Lara-Castor L, Micha R, Cudhea F, et al; on behalf of the Global Dietary Database

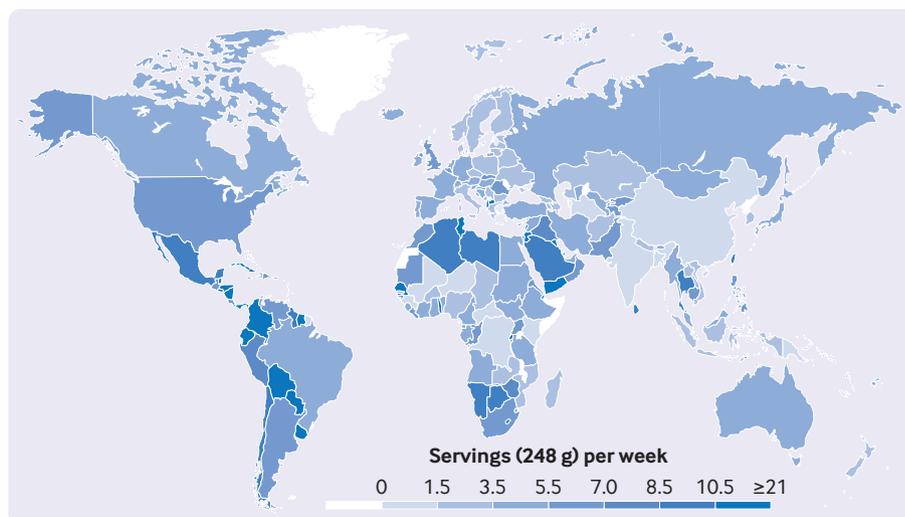
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Study question What were the global estimates for intakes of sugar sweetened beverages (SSBs) and trends over time in children and adolescents between 1990 and 2018, including by age, sex, parental education, and rural or urban residence?

Methods This study was based on a cross sectional analysis of new data on intakes of SSBs from the Global Dietary Database 2018 among children and adolescents aged 3-19 years between 1990 and 2018, jointly stratified at subnational level by age, sex, parental education, and rural or urban residence. The final Global Dietary Database model incorporated 1224 dietary surveys from 185 countries, with 89% representative at national or subnational level, thus covering about 99.0% of the global population in 2018. SSBs were defined as any beverages with added sugars and ≥ 209 kJ for each 237 g serving, including commercial or homemade beverages, soft drinks, energy drinks, fruit drinks, punch, lemonade, and aguas frescas. This definition excluded 100% fruit and vegetable juices, non-caloric artificially sweetened drinks, and sweetened milk. All included surveys used this definition.

Study answer and limitations In 2018, mean global SSB intake was 3.6 (one standardised serving=248 g) servings/week (1.3 (95%



National mean intakes of SSBs (standardised 248 g (8 oz) serving/week for this analysis) in children and adolescents aged 3-19 years across 185 countries in 2018. Values were truncated at 21 servings/week to better reflect the distribution of intakes globally. The figure was created using the *rworldmap* package (v1.3-6). SSB=sugar sweetened beverage

uncertainly interval 1.0 to 1.9) in south Asia to 9.1 (8.3 to 10.1) in Latin America and the Caribbean). SSB intakes were higher in older versus younger children and adolescents, those resident in urban versus rural areas, and those of parents with higher versus lower education. Between 1990 and 2018, mean global SSB intakes increased by 0.68 servings/week (22.9%), with the largest increases in sub-Saharan Africa (2.17 servings/week; 106%). Of 185 countries included in the analysis, 56 (30.3%) had a mean SSB intake of ≥ 7 servings/week, representing 238 million children and adolescents, or 10.4% of the global population of young people. Even with systematic searches for all relevant surveys, data for several countries (particularly lower income nations) and time periods were limited, highlighting the need for additional dietary collection and surveillance efforts in these nations.

What this study adds The study found that intakes of SSBs among children and adolescents aged 3-19 years in 185 countries increased by 23% from 1990 to 2018, parallel to the rise in prevalence of obesity among this population globally. SSB intakes showed large heterogeneity among children and adolescents worldwide and by age, parental education, and urbanicity.

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