CRD summary
This review assessed risks and benefits of patent foramen ovale closure before neurosurgery in the sitting position. The authors concluded that closure should be considered where use of the sitting position had major advantages for the outcome, but that this conclusion may be limited due to reliance on observational data. Given the review’s limitations, the degree of caution appears appropriate.

Authors’ objectives
To assess the risks of neurosurgery in the sitting position and the risks and benefits of patent foramen ovale (PFO) closure before neurosurgery in the sitting position.

Searching
MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched from inception to November 2007 for relevant studies published in any language. Search terms were reported. Additional studies were identified through bibliographies of reviews and retrieved studies, plus handsearches of relevant journals from a six-month publication period. The authors stated that papers in multiple languages were searched, but provided no details.

Study selection
Cohort studies that included 10 or more patients who underwent either percutaneous PFO closure for any reason with at least three months follow-up or neurosurgery in the sitting position with assessment of venous air embolism (VAE) or paradoxical air embolism (PAE) were eligible for inclusion. Where both PFO and atrial septal defect closures were reported, studies were included if they reported data separately for PFO. Studies were excluded if they were studies of paediatric patients, experimental or animal studies, case studies, expert opinion, duplicate publications or studies with unclear methods.

Both prospective and retrospective studies were identified. Studies evaluated a range of PFO closure devices, predominantly in secondary prevention of paradoxical embolism in patients with at least one documented thromboembolic event. Remaining indications were mostly migraine and diving. Mean ages of patients ranged from 30 to 57 years. Patients who underwent posterior fossa and cervical procedures were included in the neurosurgical studies.

Two reviewers independently assessed studies for eligibility.

Assessment of study quality
The authors stated that quality was independently assessed by two reviewers, with disagreements resolved by a third. No details of the quality assessment were presented.

Data extraction
Data were independently extracted by two reviewers. Data were extracted on procedural success rates, major and minor peri-procedural complication rates and residual shunt rates.

Methods of synthesis
The authors stated that studies were pooled in a meta-analysis if there was no heterogeneity of definitions or methodologies.

Results of the review
Neurosurgery in the sitting position:

Twenty-eight non-randomised studies were included (n=4,806); 15 were prospective. Rates of venous air embolism
were 39% (95% CI 31 to 47) for posterior fossa surgery and 12% (95% CI 7 to 20) for cervical surgery. Clinical and transoesophageal endocardiography detected paradoxical air embolism rates ranged from 0 to 14%.

**PFO:**

Thirty-three non-randomised studies were included in the review (n=5,416); 19 were prospective and 14 were retrospective.

The pooled success rate across all 33 studies was 99.2% (95% CI 98.5 to 99.6). The pooled minor peri-procedural complication rate was 3.5% (95% CI 2.7 to 4.5; 29 studies). The pooled major complication rate was 1.4% (95% CI 1.1 to 1.9; 30 studies). Thirty-one studies reported residual shunt rates (range 0% to 50%) from immediately after closure to a mean follow-up of 19 months.

Subgroup analysis (15 studies) of most common and current PFO closure devices (early clinical experience excluded) indicated a pooled success rate of 99% (95% CI to 99 to 99.7). Thirteen studies reported minor (4%, 95% CI 2.4 to 5.6) and major (1%, 95% CI 0.7 to 1.8) peri-procedural complication rates.

**Authors’ conclusions**
The authors recommended screening for PFO and consideration of PFO closure in cases where use of the sitting position for neurosurgery had major advantages for the outcome. They considered that these conclusions may be limited due to a lack of level A evidence and use of data from observational cohort studies.

**CRD commentary**
The review question was broadly defined in terms of the interventions and study designs of interest. Several sources were searched to identify all the relevant evidence. Attempts were made to minimise errors and bias in the selection of studies and extraction of data. The authors stated that similar efforts were made in the assessment of study validity, although there appeared to be no attempt to incorporate variation in validity in the results of the review. The authors give very little information on how the statistical pooling of studies was undertaken. Taken together with the observational nature of the evidence, the pooled success and complication rates were not reliable. Consequently, the authors’ caution in making firm conclusions is appropriate.

**Implications of the review for practice and research**

**Practice:** The authors stated that PFO closure should be considered, particularly in cases where PFO is the only concern and the sitting position confered a significantly lower surgical risk. They recommended antithrombotic therapy after PFO closure to prevent device thrombus formation. Ideally PFO closure should take place at least two to four before surgery; in an emergency it may be conducted immediately before surgery or using the horizontal plane.

**Research:** The authors stated that their recommendations required prospective evaluation in well-designed studies.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.