Subintimal angioplasty: meta-analytical evidence of clinical utility

Bown MJ, Bolia A, Sutton AJ

CRD summary
The authors concluded that subintimal angioplasty had good outcomes and should be considered as an alternative surgical bypass. The authors’ conclusions may not be reliable given potential methodological weaknesses of the review and primary studies and the risk of publication bias.

Authors’ objectives
To determine the effectiveness of subintimal angioplasty on rates of recanalisation of occluded vessels, patency rates over-time and limb salvage rates.

Searching
MEDLINE and EMBASE (both between 1950 to August 2008) were searched. Search terms were reported. Reference lists of retrieved articles were handsearched. Only full English-language publications were included.

Study selection
Studies that evaluated effectiveness of subintimal angioplasty on technical success, primary patency and limb salvage were eligible for inclusion. Only studies where details were reported of patients who underwent subintimal angioplasty were considered. Studies with no primary data or those considered multiple publications were excluded. The following studies were also excluded: case-series of less than 10 patients; studies with a highly selected subgroup of patients; and same centre studies where overlap in study duration was greater than six months. Articles were retained if one or more overlapping outcomes could be excluded.

Most of the studies assessed claudication and critical leg ischemia (CLI). Most of the lesions were located in the infrainguinal and femoro-popliteal regions. Study selection criteria were varied and included patients unfit for surgery and all patients who underwent subintimal angioplasty. Disease severities were varied and included claudication and CLI. Durations of follow-up were varied: primary patency (12 to 60 months); and limb salvage (six to 48 months). Stents were used in half of the studies. Outcomes reported included: immediate technical success rate of subintimal angioplasty; 12-month primary patency rate; and 12-month limb salvage rate.

The authors did not state how many reviewers assessed studies for inclusion.

Assessment of study quality
The authors did not state that they assessed study quality. However, information about quality measures such as study design, randomisation and study size were extracted and used in sensitivity analyses.

Data extraction
Data on total number of limbs treated, number of limbs saved or patent, study mid-dates (as a temporal reference point) and outcome measures (at 12 months and longest follow-up after subintimal angioplasty) were extracted on a per-limb basis. Data on quality measures and covariates (degree of limb ischaemia, use of adjunctive stents, patient selection criteria) were extracted. Data on primary patency and limb salvage rates were extracted on an intention-to-treat basis; number of limbs saved or patent at each time point was the numerator and number of limbs that underwent attempted subintimal angioplasty was the denominator. Data reported as percentages were converted back to numerators and denominators.

Data were extracted by a single reviewer in duplicate with a minimum two-month interval between extractions. Disagreements between data extracted at the two time points were resolved by consensus.

Methods of synthesis
Pooled rates and 95% confidence intervals (CIs) of technical success, 12-month primary patency and 12-month limb
salvage were calculated using random-effects meta-analysis. A weighted random-effects linear regression model was used to assess changes in the three primary outcomes over time. Sensitivity analysis was performed by calculating rates of primary patency and limb salvage at varying time-points (six to 60 months). Subgroup analysis was performed according to the degree of limb ischaemia, use of adjunctive stenting, selection criteria for patients to undergo subintimal angioplasty and anatomical location of lesions. Statistical heterogeneity was assessed using $X^2$ and $I^2$ statistics. Publication bias was assessed visually using funnel plots.

**Results of the review**

Thirty-seven studies were included (n=2,810 limbs): three prospective cohort studies; three prospective case note/registry reviews; one retrospective-prospective case note review; and 30 retrospective case note reviews.

Pooled rates for the effect of subintimal angioplasty on the primary outcome measures were: technical success (85.7%, 95% CI 83.3% to 87.7%; n=2,810 limbs, 36 studies, $I^2=54.0$%); 12-month primary patency (55.8%, 95% CI 47.9% to 63.4%; n=1,342 limbs, 19 studies, $I^2=86.0$%) and; 12-month limb salvage (89.3%, 95% CI 85.5% to 92.2%; n=1,322 limbs, 18 studies, $I^2=67.0$%).

**Regression analysis:** There was no significant change in the rates of technical success ($p=0.16$), 12-month primary patency ($p=0.75$) and 12-month limb salvage ($p=0.74$) over time.

**Subgroup analyses:** Degree of limb ischaemia, use of adjunctive stenting, selection criteria for patients to undergo subintimal angioplasty and anatomical locations of lesions did not significantly influence the effect of subintimal angioplasty on primary outcomes.

There was evidence for publication bias for the outcomes of technical success rate and 12-month limb salvage rate; however, there was little change in the pooled outcome estimates when analyses were restricted to studies with better outcomes.

**Authors’ conclusions**

Subintimal angioplasty had good outcomes and should be considered as an alternative to surgical bypass.

**CRD commentary**

The review addressed a clear question supported by appropriate eligibility criteria. Two relevant databases were searched. No attempts were made to search for unpublished studies and non-English papers were excluded; therefore, language and publication biases were likely (and were suggested by the authors’ own assessments). Some steps were taken to minimise risk of error and bias in data extraction, but not explicitly so with study selection. Study quality was not assessed; however, most studies were retrospective and likely to be of poor quality. Reliability of the pooling was unclear given both clinical and statistical differences between studies; however the authors carried out further analyses to try and investigate potential sources of heterogeneity. Given potential methodological weaknesses of the review and primary studies and the risk of publication bias, the authors’ conclusions may not be reliable.

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

**Practice:** The authors stated that subintimal angioplasty should be considered as an alternative to surgical bypass.

**Research:** The authors stated that further descriptive studies (to better define patients who undergo surgical, radiological and medical interventions for peripheral vascular disease) and randomised controlled trials on the effects of subintimal angioplasty on rates of limb salvage and quality of life were needed.

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