

REVIEW

Protamine Reduces Bleeding Complications without Increasing the Risk of Stroke after Carotid Endarterectomy: A Meta-analysis

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WHAT THIS PAPER ADDS

Heparin reversal with protamine is controversial, with some surgeons advocating the routine use of protamine to minimise bleeding complications, whereas others avoid heparin reversal to minimise the risk of stroke. This meta-analysis summarises the available data from one randomised and six non-randomised studies, reporting on about 10,000 patients. The results of the meta-analysis indicate that heparin reversal with protamine significantly reduces the risk of wound haematoma by 64%, without increasing the risk of post-operative stroke. Appropriately powered randomised controlled trials are needed to verify these findings.

Objectives: The aim was to evaluate the safety and efficacy of heparin reversal with protamine after completion of carotid endarterectomy (CEA), summarising the available data from both randomised and non-randomised studies.

Methods: The study was a meta-analysis. Pooled odds ratios (ORs) with 95% confidence intervals (95% CIs) were calculated for the outcomes of stroke and wound haematoma among patients receiving or not receiving protamine after CEA. Meta-regression analysis was performed to examine whether the documented differences were modified by potentially meaningful patient related or procedure related predictors, namely publication year, general anesthesia used, number of patients treated, mean age (years), males, neurological symptoms, use of patch, and use of shunt.

Results: Seven studies were included in the meta-analysis reporting on 3,817 patients receiving protamine after CEA and 6,070 patients not receiving protamine for heparin reversal. Only one study was randomised. A statistically significant reduction in wound haematoma requiring re-operation was recorded after heparin reversal with protamine in patients undergoing CEA (OR, 0.42, 95% CI, 0.22–0.80, $p = .008$). In contrast, no significant difference was observed in stroke rates between groups of patients that received and did not receive protamine (OR, 0.71, 95% CI, 0.49–1.03, $p = .07$). Meta-regression analysis did not reveal any significant effect mediated by the modifiers examined.

Conclusion: On the basis of the available data, heparin reversal with protamine seems to reduce the risk of wound haematoma, without increasing the risk of procedural stroke. However, taking into account the limitations of the analysis, further studies are needed to increase the level of evidence provided by the current meta-analysis.

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Article history: Received 28 October 2015, Accepted 31 May 2016, Available online 4 July 2016

Keywords: Carotid endarterectomy, Heparin, Protamine, Stroke, Haematoma, Meta-analysis

INTRODUCTION

It is common surgical practice to discontinue antithrombotic drugs (antiplatelets and anticoagulants) before

an elective surgical procedure to minimise peri-operative bleeding. Carotid endarterectomy (CEA) represents an exception to this rule, with the current European Society for Vascular Surgery (ESVS) and Society for Vascular Surgery (SVS) guidelines recommending that aspirin at a dose of 75–325 mg daily should be given before, during, and following CEA.^{1,2} Administration of heparin before carotid clamping is also routine, but its subsequent reversal with protamine remains controversial. Some surgeons advocate the routine use of protamine to

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<http://dx.doi.org/10.1016/j.ejvs.2016.05.033>

minimise bleeding complications, whereas some others avoid heparin reversal to minimise the risk of stroke through thrombus formation on the endarterectomised surface of the artery.

The aim of this meta-analysis was to evaluate the safety and efficacy of heparin reversal with protamine after CEA by summarising the available data from both randomised and non-randomised studies.

METHODS

Data collection

The current meta-analysis was conducted in accordance with the recommendations of the Meta-analysis of Observational Studies in Epidemiology (MOOSE) group.³ A combined computerised and manual systematic database search of the medical literature was performed, and publications were retrieved from electronic search engines (Medline, Embase, Scopus, Google Scholar, Ovid, and the Cochrane Library). All reference lists were searched for further relevant studies.

Types of studies, search terms, eligibility and exclusion criteria

The search included randomised and non-randomised studies, editorials, systematic reviews, meta-analyses, short papers, letters to the editor, personal views, and special communications. Mesh terminology used for search purposes were “carotid” [All Fields] AND “endarterectomy” [All Fields] AND (“protamine” [All Fields] OR “heparin” [All Fields]). All studies were identified that evaluated differences in stroke and wound haematoma rates in patients with carotid stenosis that underwent carotid endarterectomy with or without reversal with protamine after heparin anticoagulation. Scientific papers published from January 1974 until September 2015 were reviewed. No restrictions regarding language of publication were applied. If multiple articles for a single study had been published (overlapping populations), the latest publication was used and supplemented, if necessary, with data from the earlier publications. If the required data for the meta-analysis were not readily available in the published article, the corresponding authors were contacted; indeed, the authors of one article

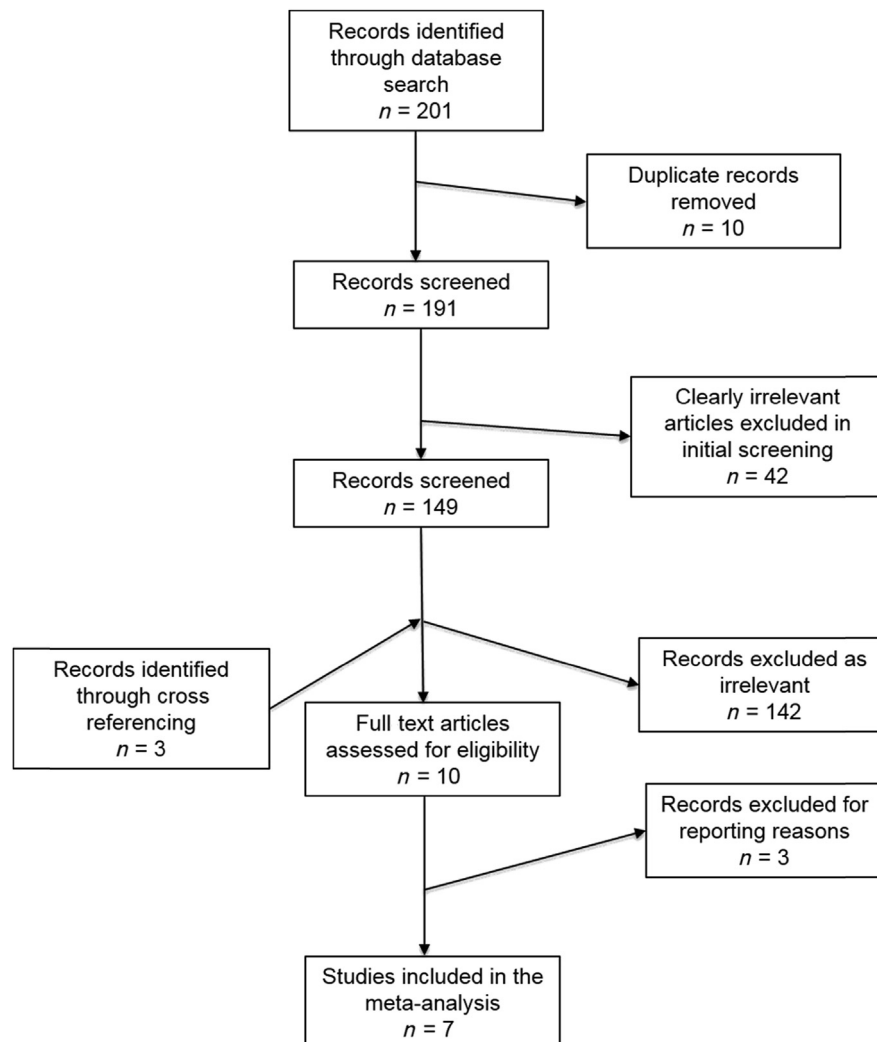


Figure 1. Flow chart presenting the selection of eligible studies.

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