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Injectable Collagenase versus Percutaneous Needle Fasciotomy for Dupuytren’s Contracture in Proximal Interphalangeal Joints: A Randomized Controlled Trial

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Authors: Simon Toftgaard Skov, MD, Therke Ibisgaard, MD, Per Søndergaard, MD, Jeppe Lange, MD, PhD

Center: Regional Hospital Silkeborg, Falkevej 1-3, 8600 Silkeborg, Denmark

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Relevance of the study:

The use of collagenase injections in the management of Dupuytren’s contracture has drastically increased after it became commercially available in 2009, but long term benefit still remains an Enigma. In literature, no prospective study is available which directly compares the results of Injectable Collagenase Clostridium Histolyticum (CCH) with other active treatment like Percutaneous Needle Fasciotomy (PNF). Although Dupuytren’s contracture is a benign fibro-proliferative condition, it is notoriously progressive and resistant in nature. This study provides 2 year follow up comparison which will be helpful to decide its actual clinical effectiveness.

Materials and methods:

- **Study Design:** Prospective, Non Blinded, Randomized Controlled Trial (RCT), Registered with Clinicaltrials.gov (NCT 01538017)
- **Study Population:** 50 patients (Mean age: 64 [58-70]), over the age of 18 years, with a clinical diagnosis of Dupuytren’s contracture, with a minimum 20degree Passive Extension Deficit (PED) of the proximal interphalangeal joint and a palpable cord
- **Study group (CCH):** Participants received an injection of 0.58mg collagenase (Xiapex; Pfizer Ltd.) into the affected cord and followed by next day manipulation and 4 month night time extension orthosis. (n=29 patients; Mean age: 62 [58-66])
- **Comparison group (PNF):** After 1 %lidocaine local anaesthesia, a 25-gauge needle was used to perforate the cord multiple times for approximately 10 to 15 minutes along with stretching the finger to rupture the cord and same orthosis protocol was followed. (n=21 patients; Mean age: 67 [64-70])
- **Follow-up:** 1 month, 1 year, and 2 years
- **Assessment:** The aim of primary assessment was to measure the incidence in which the PED was reduced by at least 50% from baseline. Secondary assessment included the mean change in proximal interphalangeal joint contracture, pulp-to-palm distance, table-top test, the incidence of passive extension deficit reduction to 5degree or less, the incidence of recurrence (return of PED of 20degree or more) and occurrence of adverse events/complications.
Results:

- The rate at which PED was reduced by at least 50% from baseline after 1 month did not significantly differ between the CHC (89%) and the PNF group (100%) (p=0.12).
- These rates decreased within both the groups at 1-year (34% and 52%, respectively) and 2 years (8% and 32%) but did not significantly differ (p=0.22 and 0.05, respectively).
- Recurrence rate did not significantly differ between the CHC and PNF group at 1 year (65% and 57%, respectively; p=0.56) and 2 years (83% and 68%, respectively; p=0.25).
- The rate of early complications like edema and local pain after 1 month were significantly higher in CHC (27/29) compared to PNF group (5/21)(both p<0.0001).

Limitations: small sample size, non-blinded, lack of standardization, possibility of inter observer bias

Conclusion: This study provides evidence that CCH is not superior to PNF in the treatment of isolated proximal interphalangeal joint Dupuytren’s contracture in terms of long term clinical outcome and it is associated with higher complication rate than PNF.

Take home message: Although both collagenase injection and percutaneous needle fasciotomy showed efficacy in the first month after treatment but they both were lacking in ability to maintain the clinical success in almost all patients after 1 year.

Level of evidence: Therapeutic level I

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Risk of aspirin continuation in spinal surgery: a systematic review and meta-analysis


AUTHORS:

Goes R, Muskens IS, Smith TR, Mekary RA, Broekman MLD, Moojen WA. Department of Neurosurgery, Haaglanden Medical Center, Lijnbaan 32, 2512VA The Hague, The Netherlands. Tel.: (31) 614057530.

RELEVANCE OF THE STUDY:

There is a progressive increase in the number of aging population and a corresponding increase in the number of degenerative spinal diseases warranting surgical intervention. However, with increasing age, many patients receive anti-platelet drugs (including aspirin) for co-existing cerebrovascular and ischemic cardiac diseases. Spine surgeons often face the challenge of operating on spinal pathologies in patients who have been administered anti-platelet drugs. In such instances, the continuation or discontinuation of aspirin before surgical procedures remains matter of debate among surgeons. Currently, there seems to be a lack of consensus about aspirin (dis)continuation before spinal interventions. The authors of this systematic review have evaluated available evidence about continuation of aspirin and compared peri- and postoperative blood loss and complication rates between patients who continued aspirin and those who discontinued aspirin perioperatively in spinal surgery.
MATERIAL AND METHODS

Study Design: Systematic review and meta-analysis of results

A systematic review of the current literature has been conducted by the authors to identify studies reporting outcomes of continuation versus discontinuation of low-dose aspirin in spinal surgery. PubMed, Embase, Cochrane, and Web of Science databases were searched. For the search strategy, the keywords “neurosurgery” which included spinal surgery and “aspirin” with synonyms were used. The review was limited to studies in humans and has been performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

The authors had used strict inclusion and exclusion criteria. Only literature in English and Dutch was reviewed. Case reports, congress abstracts, commentaries, and reviews were excluded. Studies were excluded when patients used other anticoagulants or a combination of anticoagulants; a control group was missing; or when patients did not undergo a neurosurgical procedure, cranial, or peripheral nerve surgery. Non-clinical studies (laboratory or in vitro studies) were also excluded.

RESULTS:

After removing duplicates, 1,457 unique articles were identified. After screening for titles and abstracts, 1,406 articles were excluded. Based on inclusion criteria, three case series were included, with a total of 370 patients.

- No significant differences in mean operating time were seen between the aspirin-continuing group (mean=201.8 minutes, 170 patients) and the aspirin discontinuing group (mean=178.4 minutes, 200 patients); (Pinteraction=0.78).
- No significant differences in mean perioperative blood loss were seen between the aspirin-continuing group (mean=553.9 milliliters) and the aspirin-discontinuing group (mean=538.7 milliliters); (Pinteraction=0.96).
- No significant differences in perioperative complications between aspirin continuation and discontinuation.
- Similar non-significant differences between the two groups were found for cardiac events, stroke, and surgical site infections.
CONCLUSION:

- Continuation of aspirin during neurosurgical procedures does not result in a higher rate of complications.
- Because of the limited number of included case series, further well-designed prospective trials are imperative to demonstrate potential benefit and safety.

LEVEL OF EVIDENCE: 1.

FUNDING: No funding was received for this study.

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Re-Displacement of Stable Distal Both-Bone Forearm Fractures In Children: A Randomised Controlled Multicentre Trial.


AUTHORS

Joost W. Colaris, Jan Hein Allema, L. Ulas Biter, Mark R. de Vries, Cees P. van de Ven, Rolf M. Bloem, Albert J.H. Kerver, Max Reijman, Jan A.N. Verhaar
Investigations performed at 4 hospitals in Netherland: Erasmus Medical Center (Rotterdam), HAGA Hospital (The Hague), Reinier de Graaf Hospital (Delft) and Saint Franciscus Hospital (Rotterdam).

RELEVANCE OF THE STUDY

- Distal forearm fractures are common in the pediatric age group, and management involves application of an above elbow cast (AEC) with or without percutaneous K-wire fixation.
- Re-displacement of these fractures may result in malunion which could lead to impaired forearm function.
- Previous studies comparing fracture re-displacement between these 2 groups (i.e. AEC alone vs AEC with percutaneous K-wire fixation) includes single and both bone forearm fractures. This study is the first randomized multicenter evaluation of displacement in only both bone forearm fractures.
- Objective of the study was to determine whether stabilizing K-wires could prevent re-displacement in a reduced and apparently stable, both bone distal forearm fractures in children.

MATERIAL AND METHODS

Study Design: Randomized Control Multi-center Trial

- The study included distal forearm fractures in children below the age of 16 years old, which was stable after closed manipulative reduction.
- 128 children with mean age of 8.8 years were included and randomly assigned to 2 groups;
  1. Group being treated with AEC alone (n=67)
  2. Group treated with 2 stabilizing K-wires and AEC (n=61)
- Unstable fractures after reduction, fractures older than 1 week and open fractures were excluded from the study.
- Outcome parameters
  - Primary: re-displacement of fracture
  - Secondary: limitation of forearm supination and pronation, cosmesis, upper limb function, radiological assessment and complication rate.
  - Outcomes were measured 1, 2, and 4 weeks and 6 months following the initial trauma (Mean follow-up 7.1 months)
RESULTS

- Group being treated with AEC alone showed significantly higher percentage of fracture re-displacement
- Significantly less limitation of forearm supination and pronation in the group with stabilizing K-wires
- More complications were noted in the group with stabilizing K-wires, mostly resulting from improper surgical technique.
- Radiological assessment revealed that the group treated with AEC alone showed increase in angulation during period between initial reduction and cast removal.
- There were no significant difference between the two groups in terms of upper limb function and cosmesis at 6 months post-treatment.

CONCLUSION

K-wiring of apparently stable distal forearm both-bone fracture in children may reduce risk of fracture re-displacement and result in less limitation of forearm motion. Higher rate of complications seen in fractures treated with K-wires might be reduced with application of proper surgical technique.

REFERENCE


The Effect of a Single Early High-Dose Vitamin D Supplement on Fracture Union in Patients with Hypovitaminosis D

Authors

Investigation performed at Carolinas Medical Center, Charlotte, North Carolina, United States.
Relevance of the study:

- Vitamin D is intimately involved in the process of osteogenesis, remodelling and bone healing either directly or indirectly.
  - There is an increased prevalence of low vitamin D levels among healthy individuals with a reported incidence of 3% to 43% reaching in some studies up to 66% in orthopaedic trauma patients.
  - Vitamin D is implicated in non-union of long bone fractures in many studies implying that supplement of vitamin D may improve the rates of union.
  - There was a paucity of quality research on the effects of hypovitaminosis D on the union of long bone fractures.

- The aim of this study was to evaluate the effect of a single high dose vitamin D supplement in fracture union in patients with long bone fracture and low levels of vitamin D.

Materials and Methods:

Study design: Prospective, double blind, randomized, placebo controlled study.

- A total of 100 patients with hypovitaminosis D (<30ng/ml) with a long bone fracture of either tibia, femur or humerus presenting within two weeks of injury were selected for evaluation in this study conducted between July 2011 to August 2013.
- The patients having age lower than 18 years, pathological fracture, uncontrolled diabetes mellitus, any associated co-morbid condition that can affect the calcium, phosphate & vitamin D homeostasis or Gustilo-Anderson open type IIIB/C fractures were excluded from the study.
- The patients in treatment group (n=50) received a single dose of oral vitamin D supplement 100,000IU. or in control group (n=50) a placebo (Lactose anhydrous inside a gelatin capsule). Forty-three patients in each group completed the study.
The patients were evaluated at 2 weeks, 4 weeks, 3-4 months, 6 months and at one year in terms of clinical and radiological signs of fracture union, vitamin D toxicity or complications like infection, implant failure & non-union.

Results:
- A total of 14 patients, seven from each group were lost to follow up and were not included in final evaluation.
- There was no significant difference in demographic profile of patients in treatment or the control group.
- Union was achieved in 40/50 patients in the treatment group compared with 39/50 in the control group which is statistically insignificant.
- There were two cases of non-union in each group (p =1) which is again insignificant statistically. There was one case of fixation failure in each group and one case of infection in the control group.
- The authors also observed a higher prevalence (90%) of low vitamin D levels in patients with long bone fractures presenting to a level one trauma centre.

Conclusion: The results of this study conclude that,
- Low vitamin d levels (<30ng/ml) are frequently associated (90%) with long bone fractures
- There is no significant association between hypovitaminosis D and fracture non-union. 95% of fractures healed despite having low levels of vitamin D.
- A low vitamin D level per se doesn’t appear to be a cause of non-union.

Take home message:
A single high dose bolus of vitamin D given within two weeks of injury does not alter the rate of fracture non-union.

Level of Evidence: 1
Funding: Non Industry Funded.
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An Evidence-Based Evaluation on the Use of Platelet Rich Plasma in Orthopaedics – a Review of the Literature


Authors
Nasir Hussain, Herman Johal, Mohit Bhandari.

Central Michigan University College of Medicine, CMED Building, 1280 S. East Campus St., Mt. Pleasant, MI 48859, USA
Division of Orthopaedic Surgery, Department of Surgery, McMaster University & Centre for Evidence Based Orthopaedics, 293 Wellington Street North, Suite 110, Hamilton, Ontario L8L 8E7, Canada
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Relevance of the study:

- Platelets play a vital role in healing process by enhancing the angiogenesis and mitogenesis of healing capable cells by secretion of various growth factors like platelet derived growth factor (PDGF), vascular endothelial growth factor (VEGF), transforming growth factor beta (TGF-β).
- The platelet rich plasma contains 4-5 times more platelets than the autologous blood levels, it can be activated (if prepared with calcium chloride with or without thrombin) or deactivated & leucocyte rich or poor. 70% of cytokines are released within 10 minutes and 100% within an hour of activation.
- Platelet rich plasma has gained a momentum in the field of orthopaedics and ever since it has broadened in terms of indications. However, its effectiveness is not yet fully established and there is literature available for and against its efficacy.
- In respect of the growing popularity of PRP, cost considerations and uncertainty of its efficacy in variety of orthopaedic condition, the authors undertook this review to help clinicians in decision making in the light of current clinical evidence.
Study design: Review article.

Knee osteoarthritis:

- Knee osteoarthritis progresses gradually without adequate treatment due to inflammatory changes and limited regeneration potential of cartilage. Aging coupled with repetitive trauma leads to diminution of joint space and finally a restricted & painful joint.
- There are a number of randomized control studies, meta-analyses evaluating the efficacy of PRP in knee osteoarthritis with many showing improvement in pain scores and function at short term follow up.
- However, statistical pooling was limited due to wide variability in reporting and considerable risk of bias.
- American Academy of Orthopaedic Surgeons (AAOS) and National Institute for Health and Care Excellence (NICE) currently propose that the evidence is inconclusive in regard to the use of PRP for knee osteoarthritis.

Rotator cuff tears:

- The basic science evidence has shown that PRP has positive effects in tendinous injuries but the available clinical trials and meta-analyses reported inconsistent results.
- A recent Cochrane review of 19 randomized trials and a number of meta analyses revealed no added advantage of using PRP in rotator cuff tears. However, there was a statistical insignificant decrease in the incidence of re-tear.

Epicondylitis:

- PRP has gathered greatest attention in the treatment of lateral epicondylitis (Tennis Elbow) which affects about 2-3% of general population. It is also used in medial epicondylitis but the results are not so promising as in lateral epicondylitis.
- A recent review of meta-analysis of 10 RCT revealed that PRP significantly reduced the VAS pain scores compared to steroids.
- Functional outcome also improved with PRP compared to steroids and autologous blood however, on long term follow up this effect was maintained only in relation to steroids.
Patellar tendinopathy:
- Currently there is limited high quality data on the use of PRP in patellar tendinopathy which is a frequent cause of anterior knee pain among young athletes amounting to 14.2% of all sports related injuries.
- A recent meta-analysis did not reveal any significant improvement in VAS pain scores and Victoria institute of sports assessment questionnaire at 6 months follow up.

Achilles tendinopathy:
- A recent review of three RCTs revealed no significant improvement in ultra-sonographic scores and VISA scores in PRP group compared to control at one year follow up.
- There is weak strength of conclusions owing to lack of high quality evidence at present.

Hamstring injuries:
- They constitute about 29% of all sports related injuries and usually resolve within 3-6 weeks but the addition of PRP quickens recovery time.
- There is only one meta-analysis currently reviewing RCTs on the subject which revealed that addition of PRP with physiotherapy led to 3% greater return to play than control which was statistically insignificant. There was also no significant difference in pain scores in comparison with controls.

Anterior cruciate ligament repair:
- PRP has been used in ACL reconstruction to enhance the repair and earlier return to work.
- In a recent Cochrane review and a systematic review, it was found that there is no statistically significant difference in International Knee Documentation Committee (IKDC) functional outcome. However, statistical pooling was not done in either review due to heterogeneity of reporting outcomes. Five of the six studies revealed no significant difference in tunnel healing or widening with addition of PRP.

Conclusion:
- Based on the results of conflicting meta-analyses and scarcity of treatment guidelines for PRP by professional bodies. It is evident that PRP may be useful in treatment of lateral epicondylitis and knee osteoarthritis.
• There is inconclusive evidence regarding its use in rotator cuff repair, ACL repair, Achilles tendinopathy, patellar tendinopathy, hamstring injuries and medial epicondylitis.
• All future meta-analysis should focus on sub-group analysis as well.

Level of Evidence:

Funding: Nil