

Considered Judgement Form

Meeting date: 14 August 2007

Topic: Effectiveness of Autologous Platelet Rich Plasma (PRP) in Bone Healing

Background and Purpose: The Evidence Based Healthcare (EBH) group completed a brief report on Autologous Growth Factors (AGF) and bone healing in November 2002. The conclusion of the literature review at that point was that little evidence of effectiveness of AGF in bone healing was found. It was recommended to review the literature when new research in this area becomes available.

Dr Margaret Mackey asked the EBH researchers to carry out an updated evidence-based review. The new report supplements the EBH literature review completed in November 2002. The purpose of this report is to examine the evidence from the published clinical studies related to use of PRP in surgical procedures involving bone healing.

Platelet-derived growth factors are a subset of Autologous Growth Factors that thought to have healing properties. Growth factors contained in platelets are referred to as stimulants of cell replication, hence involved in stimulation of processes of osteoregeneration, osteointegration and wound healing. PRP is a normal autogenous blood clot that contains a highly concentrated number of platelets. The platelet concentration depends on the method of its preparation. Available commercial products have platelet concentration 4 to 10 times the usual baseline platelet count.

1. Effectiveness, Volume of Evidence, Applicability/Generalisability & Consistency/Clinical impact

Overall impression from the reviewed literature is that lack of robust scientific studies does not allow the reviewer to either verify or refute the ability of PRP to enhance osseous healing.

Further to the EBH brief report of November 2002, a few clinical studies have been found that would support effectiveness of autologous Platelet Rich Plasma in treatment of impaired bone fracture healing. A majority of the studies suggested that further clinical trials needed to be carried out in order to determine efficacy of platelet rich plasma in bone healing.

Several articles on systematic review of the studies on effectiveness of autologous platelet rich plasma in orthopaedic and dental surgery do not support PRP use. The consensus of these articles appears to be that the current use of PRP is not based on strong scientific evidence.

The authors of several studies made unequivocal conclusions on the benefit of autologous PRP use in oral surgery. However quality, size and validity of these studies do not appear to substantiate these conclusions. These studies do not demonstrate robust evidence of effectiveness. Reported effectiveness of treatment modality derived from low quality trials is likely to be biased.

The current concepts review on the role of growth factors in the repair of bone discussed the in vitro and animal studies on the role of platelet-derived growth factors (PDGF) in fracture healing and bone repair. The review concluded that such studies did not determine clearly effectiveness of the PDGF in osseous healing. Lieberman et al also discussed clinical applications of commercial products containing growth factors in

fracture healing and spinal fusion. In regard to fracture healing the authors summed up that the available preclinical data on PDGF in the treatment of non-union was insufficient to predict clinical effectiveness of growth factors applications. In respect to spinal fusion, the role of PDGF was unclear and required further analysis.

Orthopaedic surgery

Several case reports demonstrated accelerated bone healing with the use of PRP rich plasma. Augmentation with PRP reported as beneficial in cases of non-union and impaired fracture healing. However these reports are confined to case studies and case series, hence the level of evidence is not regarded as scientifically robust.

Spinal surgery

Few reports on the use of PRP have been identified. The conclusions of the reports are in conflict, and the overall impression is that superiority of the PRP use over conventional fusion has not been established.

Dental, periodontal and maxillofacial surgery

A few reports on the clinical benefits of autologous PRP augmentation need to be balanced against the reports on insufficient or absent clinical response from this treatment modality. The papers on systematic review of the existing studies do not appear to indicate endorsement for this therapy.

Safety considerations

No major safety concerns associated with use of PRP have been reported. As it is an autologous product, there are no concerns regarding blood-borne infections. Possible promotion of wound infections and the risks related to use of bovine thrombin that is added to the platelet concentrate to initiate clotting and activate platelets have been discussed in the literature. A suggestion that PRP may inhibit healing has been discussed but evidence in support this hypothesis appears to be limited to one study only.

2. Cost

3. Equity

4. Consistency with the intent of the AC Act

5. Possible Purchasing Options

List the possible purchasing options.

6. Evidence Statement

To sum up, the studies reported up to date provided no conclusive scientific evidence to determine that use of autologous PRP has significant benefits for osseous healing. Grading of evidence by SIGN scoring system suggests that a vast majority of studies are graded at a low level of evidence (3 or 2-), with a significant risk or moderate probability that the relationship is not causal.

Overall impression of the review of the existing publications is that evidence on the efficacy of autologous PRP use is contradictory, inconclusive and the quality and amount of evidence are not entirely convincing.

Although this therapeutic modality is deemed to be potentially promising, paucity of high quality evidence in a way of randomised controlled trials does not appear to conclusively support its use.

7. Purchasing Recommendations

What recommendation(s) does the advisory group draw from this evidence?

Suggested purchasing recommendations:

Current scientific evidence does not support purchasing of this treatment as an adjunct to orthopaedic, maxillofacial or dental procedures. ACC should not purchase until high quality evidence becomes available.

Additional information: Periodontal disease is not a condition covered by ACC unless under exceptional circumstances, i.e. under treatment injury provisions. The ACC Dental Policy and Clinical Advisor has confirmed that such claims are at present negligible.

It is therefore not currently necessary to consider autologous PRP for the treatment of periodontal disease.