

Cost-effectiveness analysis of Platelet-Rich-Plasma versus standard of care (SoC) for the diabetic non-healing ulcer care

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Social and Economic Impact

Chronic non-healing ulcer is a major health problem and its prevalence in the world ranges from 1.9 to 13.1% (Rayner et al., 2009 Agale et al., 2013)

- Ulcers are associated with **older age, obesity and diabete**. The increasing of these two population characteristics will **lead to significant rises in prevalence**.
- Approximately 10–20% of individuals with diabetes mellitus develop a foot ulcer. Diabetic foot syndrome is diagnosed in 12–18% of patients with type 2 diabetes, and in 0.6–2% of patients with type 1 diabetes (Greer et al. 2012)

Diabetic chronic wounds **burden of disease is correlated to a high socioeconomic** impact in terms of both direct health-related costs and indirect costs.

- ✓ Diabetic wound has a significant **impact on quality of life causing pain** leading to social life limitations and loss of work productivity.
- ✓ Moreover become a substantial financial burden for the patient and the healthcare system (Siersma et al., 2013, Hopkins et al. 2018).
- ✓ An estimated 12% of individuals with diabetes foot ulcer require lower extremity amputation. "More than 85% of lower limb amputations are preceded by foot or ankle ulcers and diabetes is one of the major causes of non-traumatic amputations across the world" (Buckley et al., 2012, Greer et al. 2012)



Therapies

The goal of ulcer treatment is to obtain wound closure as expeditiously as possible.

Conventional treatment for non-healing ulcers includes wound cleaning, necrotic tissue debridement, prevention, diagnosis, and, if necessary, treatment of infection, mechanical off-loading, management of blood glucose levels and local ulcer care with dressing application.

It has been showed as **plasma growth factor (PGF)**, such as platelet derived growth factor (PDGF) significantly shortens treatment duration and leads to healing in approximately 80% of wounds.

An extensive review was performed by Picard et al. 2015. They carried out a PubMed and Cochrane search (1978–2015) including all studies assessing the clinical effect of PRP on the healing of diabetic chronic wounds. The screening retrieved 7,555 articles and 12 studies were included. On six randomized studies included, five found significant benefits for the use of PRP on diabetic chronic foot ulcers. The authors concluded stating that 87.5% of controlled studies found a significant benefit for the adjunction of PRP to treat chronic diabetic wounds. As PRP may be beneficial, they suggest using PRP on diabetic ulcers which remain unhealed after standard treatment.

Objective

The aim of this study is to perform cost-effectiveness analysis of intra-articular injections of Platelet-Rich-Plasma (produced with Regenkit) versus Standard of care (SoC) in the treatment diabetic wound.

Perspective: France National Health System (direct costs)

Time horizon: 3 month

Patients with non healing foot wound between ***grade 2A or 3A*** according to the classification of the *University of Texas*

Le creusot study



Monocentric Randomized Controlled study

96 patients screened

91 patients randomized (Intent to Treat subgroup)

86 patients completed the study (Per Protocol subgroup)

Diabetic patients, type 1 or 2, aged 18 years or older.

Neuropathic ulcers located on the plantar surface of the foot, grade 2A or 3A according to the classification of the University of Texas.

Surface area less than 5 cm² and depth greater than 5 mm, and whose infection and complications bone (osteitis, bone shock or bone sequestration) have been successfully treated before inclusion.

Le creusot study

Recap outcomes wound healing :



Percentage of wound healing at visit	Randomisation arm(N=86)		Statistics
	RegenKit (N=46)	Control (N=40)	
End of Treatment visit EoTV (6 weeks)	56,5 % (26)	20,0 % (8)	Khi2=11,938 p=0,001
Follow up visit 1 FUV1 (9 weeks)	71,1 % (32)	30,0 % (12)	Khi2=14,334 p=0,000
Follow up visit 2 FUV2 (12 weeks)	77,3% (34)	35,1% (13)	Khi2=14,652 p=0,000

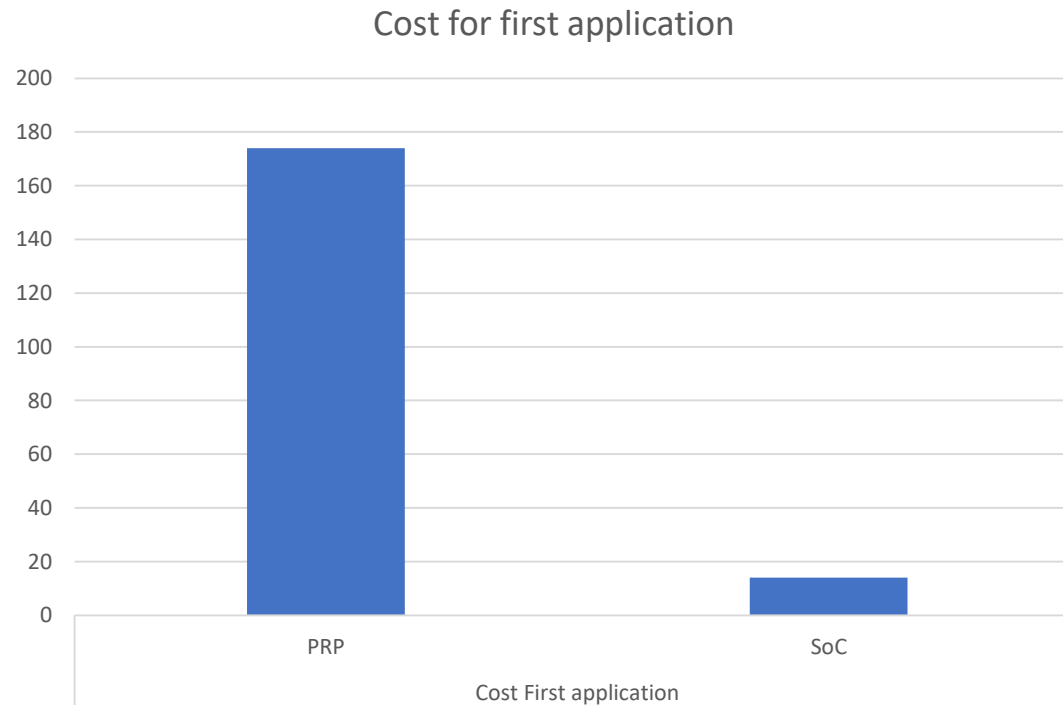


Data - Costs

Only direct costs have been included.

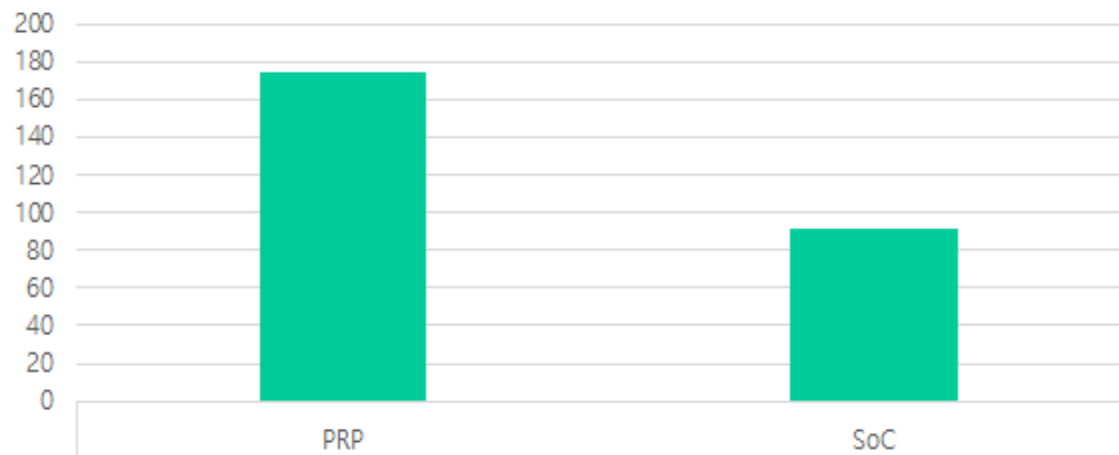
PRP is more costly because:

- Medical device
- Time consuming process

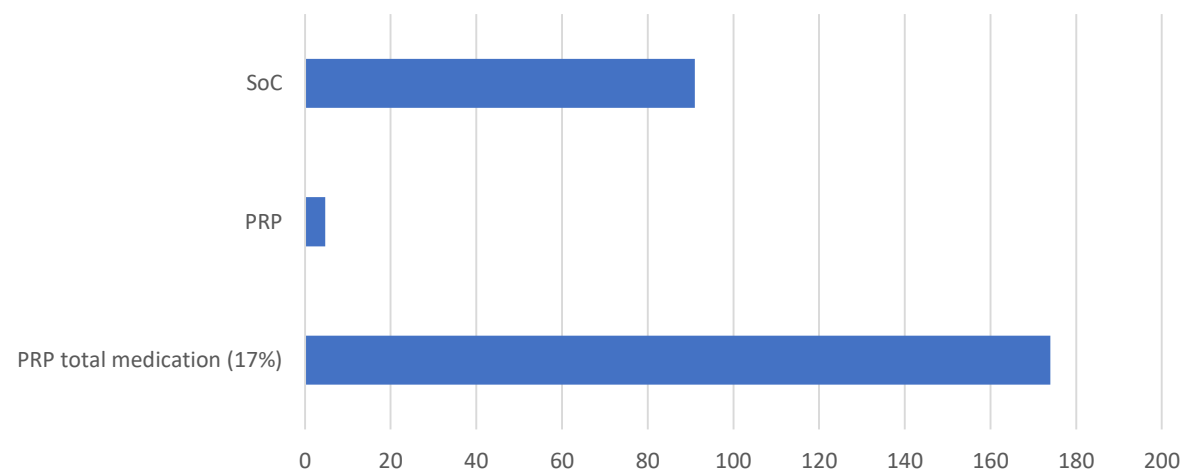


Data - Costs

Cost First week



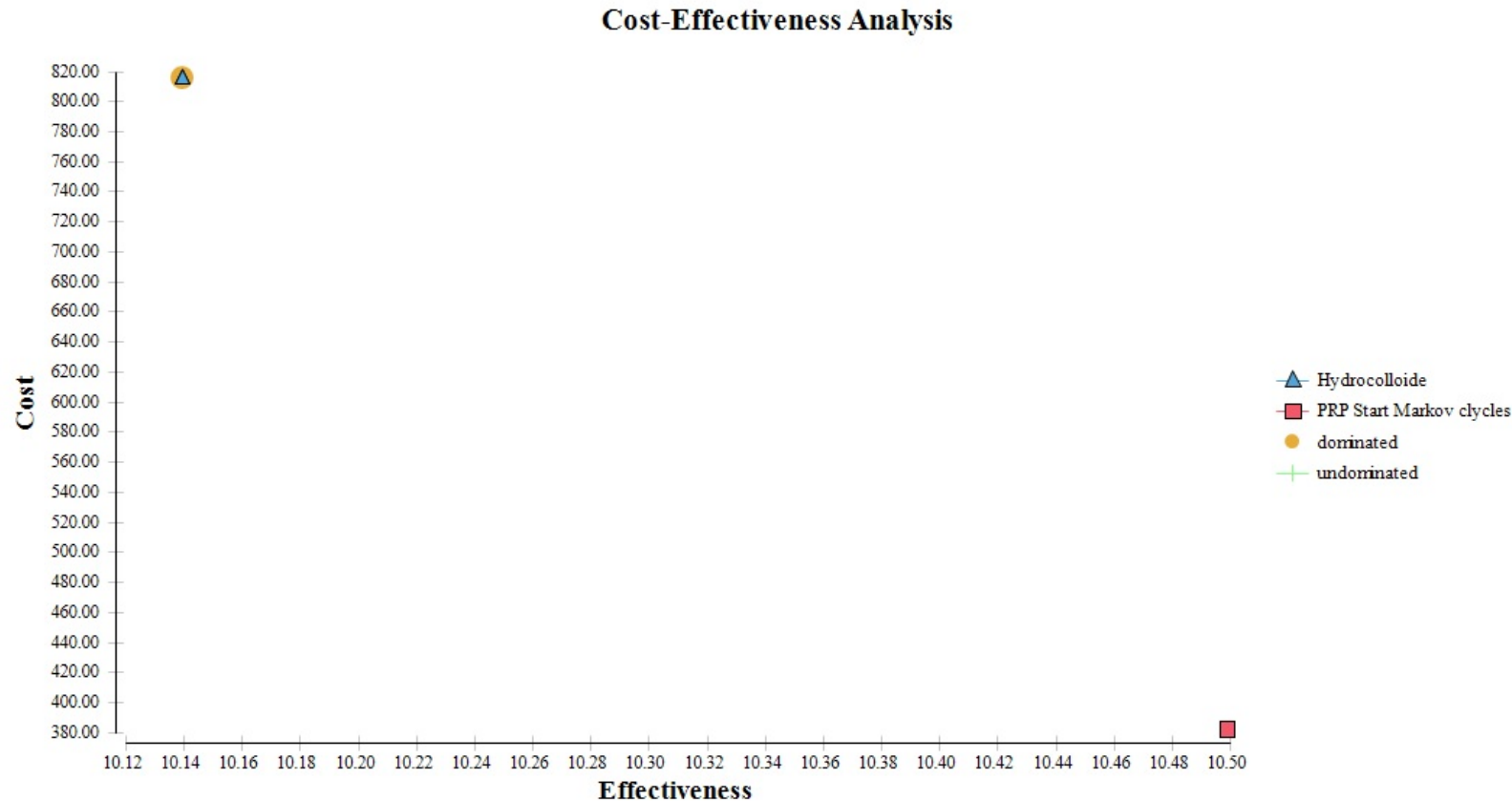
Cost Following weeks



Results

The average cost per QALY is respectively around € 80.44 for comparator and € 36.43 for PRP. The incremental effectiveness of PRP is 0.36 QALY with a decrease cost of 433 €.

The ICER of PRP introduction is - €1,205/ QALY that being lower than zero indicate the dominance of the new therapy.



Results

The main difference in costs is due to the daily nurse visits and medication for the comparator therapy, while for PRP therapy we have only one visit per week.

The PRP therapy cost is higher in the first week (175.4€), due to the expense for medical devices and nurse time, but decrease at few euros in the following weeks.

Only 17% of patients per week needed a new medication (on average a patient has 1.46 medication in 12 weeks).

Therefore the PRP branch need less nurse time and less use of materials resulting cost saving respect to the hydrocolloid. The PRP therapy is less costly thanks to fewer number of medication and higher probability of healing.

Limitations and future steps:

- Clinical study has not been published (yet)
- The comparison is between PRP and the SoC procedure used in French national setting.
- Run a probabilistic sensitive analysis
- Extension of trial results to one year based on assumptions on wound healing rates.