PP130 The Effectiveness Of Extracorporeal Shock Wave Therapy For Plantar Fasciitis: A Systematic Review And Meta-analysis

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Introduction: Extracorporeal shock wave therapy (ESWT) has been used since the 1990s to treat various musculoskeletal disorders, but there is considerable controversy regarding the effectiveness of ESWT. Our aim was to conduct a systematic review of randomized controlled trials (RCT) to investigate the effectiveness of ESWT for plantar fasciitis.
Methods: A comprehensive search was conducted via electronic databases including MEDLINE, Embase, the Cochrane Controlled trials register, and 5 Korean databases from inception date to April 2022. Two review authors independently assessed studies for inclusion and risk of bias, and extracted study data. Major outcomes were pain relief, function, and quality of life.
Results: We identified a total of 48 RCTs comparing ESWT with corticosteroid injection (n=14), conventional therapies (n=19), and sham control (n=21). Most studies included participants with chronic heel pain diagnosed as plantar fasciitis. All trials were susceptible to bias. In terms of pain results, ESWT showed no significant difference when compared with the steroid injection group and the conventional therapy group, and significant pain relief was confirmed only compared to the sham control group (Mean Difference -1.71; 95% confidence interval [CI] -2.44,-0.98; I2=70%;). Functional outcomes were significantly improved in the ESWT group compared to the steroid injection group (standardized mean difference 0.45; 95% CI 0.27,0.63; I2=0%) and the sham control group (SMD 0.84, 95% CI 0.23,1.45; I2=91%), but no significant difference was found when compared to the conventional therapy group.
Conclusions: Based upon the currently available low certainty evidence because of wide clinical diversity and varying treatment protocols of included trials, ESWT is associated with improved function and may be associated with pain reduction in plantar fasciitis. Further evidence is needed from well-designed studies with a standard dose and treatment protocol.

PP131 Health Technology Assessment Agencies' Expectations Regarding Patient Experience Data in Europe

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Introduction: Health technology assessment (HTA) agencies are increasingly embracing patient experience data (PED) to support reimbursement decisions. This study aimed to describe the European Network for HTA (EUnetHTA) and HTA agencies expectations regarding PED to support reimbursement in France, Germany, Italy, Spain and the UK.
Methods: Published HTA guidance documents were reviewed to identify recommendations related to clinical outcomes assessment (COA) (including disease-specificity, validation, analyses, endpoints and interpretation) and other forms of PED (e.g., patient preference information) in HTA decision-making. Insights from guidance documents were supplemented with a review of literature and published HTA cases and interviews with key opinion leaders (KOLs) focused on current and future states.
Results: The German and French guidance documents include PED recommendations focused on relevant COA and health-related quality of life data, without detailing preferred COA measures. However, key differences were noted between these two countries in the methodological approaches regarding responder definitions, acceptable missing data threshold and multiplicity analyses. These differences were reinforced by the case studies and the KOLs. UK's sources also focused on COA, in general proposing specific use of the EQ-5D to derive utility values for modelling, but included limited details on other PED-related elements. The Italian and Spanish guidance documents do not detail COA or other PED expectations, but the Italian KOL described that COA is considered if submitted. The currently developed EUnetHTA21 guidelines include PED-related information that bear the signature of certain individual HTA bodies. Globally, there is limited interest in PED beyond COA across the agencies.
Conclusions: The level of expectations with regards to PED varies across EUnetHTA and several European HTA agencies. Interest in PED derived from non-COA sources is limited across the countries. Knowing each agency's expectations with regards to PED is key when submitting HTA evidence dossiers and should be considered early in clinical trial design to integrate market access perspectives and optimize drug development. Global harmonization would help advancing PED measurement standards.

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