Autonomic responses to ultrasound-guided percutaneous needle electrolysis of the patellar tendon in healthy male footballers

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ABSTRACT

Background Ultrasound (US)-guided percutaneous needle electrolysis (PNE) is a novel minimally invasive approach, which involves the application of a galvanic current via an acupuncture needle. As in any procedure involving needling, vagal reactions have been reported during PNE.

Objective To examine for changes in autonomic activity during the US-guided PNE technique on healthy patellar tendons by measurement and analysis of heart rate variability (HRV).

Methods Twenty-two male footballers were randomly allocated to: a control group (11 players), for whom HRV was recorded for 10 min, both at rest and during an exhaustive US examination of the patellar tendon and adjacent structures; and an experimental group (11 players), for whom HRV was recorded for 10 min, both at rest and during application of US-guided PNE on the patellar tendon. The following HRV parameters were assessed: mean NN interval, mean heart rate, time domain parameters (SDNN, rMSSD, pNN50), diameters of the Poincaré plot (SD1, SD2), stress score, and sympathetic/parasympathetic ratio.

Results There were no differences between groups in any baseline measurements, nor were there any significant differences between control group measurements (baseline vs intervention). The experimental group exhibited statistically significant increases in SDNN/SD1 (p=0.02/p=0.03) and SD2 (p=0.03), indicating increased parasympathetic and decreased sympathetic activity, respectively.

Conclusions US-guided PNE was associated with an autonomic imbalance characterised by greater parasympathetic activity, which could potentially result in a vasovagal reaction. Care should be taken to monitor for adverse reactions during US-guided PNE and simple HRV indicators may have a role in early detection.

INTRODUCTION

Techniques involving puncture of the skin are common in physiotherapy. These procedures may use a mechanical stimulus, as in acupuncture or dry needling,[1 2] or apply electrical current as in electroacupuncture,[3] stimulation of myofascial trigger points[4] or electrostimulation using galvanic current.[5 6]

Currently, a technique called percutaneous needle electrolysis (PNE) is also being used. Ultrasound (US)-guided PNE is a novel minimally invasive approach that involves the application of a galvanic current through an acupuncture needle.[5 6] This technique has mainly been applied to treat tendinopathies.[6–9] Much like acupuncture,[10–13] this technique is believed to influence mechanotransduction in tendons.[5 6] Tendinopathies are one of the biggest challenges in the clinical setting today.[14]

Similar to any other procedure in which needling is applied,[15 16] mild vagal reactions such as paleness, sweating, piloerection, and coldness in the skin are common during the US-guided PNE technique in clinical practice. Moreover, visceral effects (eg, nausea±vomiting, pupil dilation) may appear, especially in association with stronger stimulation, a greater number of needles, and/or a longer retention time. Occasionally, vasovagal reactions may occur, which are clinical phenomena mediated by the vagus nerve and characterised by lightheadedness and malaise. Exceptionally, vasovagal reactions may result in brief and reversible loss of consciousness (vasovagal syncope).

Heart rate variability (HRV) is a useful tool to analyse imbalances between

sympathetic and parasympathetic activity.[17] HRV has been validated as an accurate tool to assess the status of the autonomic nervous system (both sympathetic and parasympathetic components) under various conditions.[18–21] Given that vasovagal reactions involve an autonomic imbalance characterised by a predominance of parasympathetic activity, HRV may be a useful tool to detect these reactions. The HRV methods most commonly used for this purpose are based on the time domain[17] and the Poincaré plot.[22] For the time domain, there are several parameters that, according to the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology,[17] provide information about parasympathetic activity such as the standard deviation of the RR intervals (SDNN), the square root of the mean of the sum of the squares of the differences between the adjacent RR intervals (rMSSD), and the number of adjacent RR interval (RRI) pairs that differ by >50 ms in the full register, divided by the total number of RRIs and expressed as a percentage (pNN50). By contrast, the Poincaré plot reflects HRV fluctuations.[23] Physiologically, the transverse axis (SD1) is a measurement of the short-term changes in RRIs and is considered an indicator of parasympathetic activity.[24] The physiological meaning of the longitudinal axis (SD2) is not as clear but it is thought that it reflects the long-term changes in RRIs and it is considered an inverse indicator of sympathetic activity.[25] Naranjo *et al*[26] recently defined two new indices to facilitate the physiological interpretation of the Poincaré plot: the stress score (SS) and the sympathetic-parasympathetic ratio (S/PS), respectively. The SS is expressed as the inverse of the diameter SD2 multiplied by 1000 and it is considered to be directly proportional to sympathetic activity at the sinus node. The S/PS ratio is expressed as the quotient of SS and SD1 and it is considered to reflect autonomic balance—that is, the relationship between sympathetic and parasympathetic activity.

The aim of this study was to assess the changes in sympathetic and parasympathetic activity (analysed through HRV) during US-guided PNE on the healthy patellar tendons of a group of male amateur football players. The purpose of this study was not to evaluate the technique therapeutically but rather to explore the possibility of vagal reactions during its use that might need to be taken into consideration for safe clinical practice.

METHODS

Participants

We studied a total of 22 members of an amateur male football club divided randomly into two groups, each comprising 11 players: a control group (CG) and an experimental group (EG). Exclusion criteria were: (1) pathology in the patellar tendon; (2) a Personal Psychological Apprehension Scale (PPAS) score >37.5[27]; (3) commonly accepted contraindications to PNE including chronic joint disease, surgery, prosthesis or osteosynthesis in the area of intervention, cardiac disease, neoplasia, coagulopathy, and use of certain drugs (fluoroquinoles, anticoagulants, corticosteroids or non-steroidal anti-inflammatories)[28]; (4) any contraindications to needling *per se* including unsurmountable fear of needles, history of adverse reaction to needling, immunocompromise, difficulty expressing feelings appropriately and/or allergy to metals[28]; and (5) epilepsy.

The local ethics committee at the University of Seville approved the study, which complied with all the principles set out in the Declaration of Helsinki. All subjects signed informed written consent forms to participate in this study.

Procedures

Firstly, all subjects filled in the PPAS, the general aim of which was to measure the psychological apprehension of the subjects during electrophysiotherapeutic treatment. This scale evaluates, by means of the opinion and self-positioning of the subjects, an individual's degree of apprehension to the application of an electrical current.[27] Subsequently, HRV was recorded in a seated position, in the early morning and after fasting overnight. HRV was recorded for the CG for 10 min, both at rest and during an exhaustive US examination of the patellar tendon and adjacent structures using a high resolution greyscale US machine (Logiq, GE Healthcare, Wisconsin, USA) with a linear probe (12 MHz) according to European Society of Musculoskeletal Radiology guidelines.[29] HRV was recorded for the EG for 10 min, both at rest and during application of US-guided PNE on the patellar tendon. The patellar tendon was selected because patellar tendinopathy it is one of the most commonly accepted indications for this technique,[7 8] although all study participants had healthy patellar tendons and did not suffer from any patellar pathology. The US-guided PNE technique was applied using a specifically developed medically certified (Directive 93/42/EEC) device (EPI Advanced Medicine, Barcelona, Spain), which produces modulated galvanic electricity through the negative electrode cathodic flow. This is applied using a modified electrosurgical scalpel that incorporates acupuncture needles (0.3 mm in diameter) of different lengths. The intensity can be adjusted by changing either the duration of stimulation or the output current (mA) of the device. Conversely, the polarity of the machine is fixed (ie, only cathodic flow is usable). During each procedure, all of which were performed by the same experienced operator, volunteers were seated to minimise the risk of any potential vagal reaction. Isopropyl alcohol was used to prepare the skin; povidone iodine was specifically avoided to prevent a tattoo effect of the cathodic flow. Finally, three US-guided precise applications at a fixed intensity of 3 mA were performed.

Measurement of HRV

The heart rate (HR) monitor Firstbeat Bodyguard (Firstbeat Technologies, Jyväskylä, Finland) was used to record HR data for 10 min in every session (at rest and during US or US-guided PNE). Data were downloaded from the devices to a computer using Firstbeat Uploader software (Firstbeat Technologies) and all the RRI series were imported into the software package Kubios (University of Eastern Finland, Kuopio, Finland), which was used to calculate the HRV parameters including mean NN interval, mean HR, SDNN, rMSSD, pNN50, SD1, SD2, SS, and S/PS ratio.

Statistical analysis

All variables are expressed as mean±SD. The normality of the data distribution was evaluated using the Shapiro-Wilk test. Data were first analysed using a two-factor repeated measures analysis of variance (ANOVA) with one between-group factor (CG vs EG) and one within-group factor (baseline vs intervention). The Games-Howell post-hoc test was used for multiple comparisons. Data were analysed with the Statistical Package for the Social Sciences (SPSS) V.21 (SPSS Inc, Chicago, Illinois, USA) and statistical significance was set at $p<0.05$.

RESULTS

There were no significant baseline differences in any demographic variables between the subjects in the CG and the EG, including age (22.7±4.47 vs 24.4 ±4.23 years, p=0.46), weight (75.4±12.20 vs 76.2 ±6.72 kg, p=0.85), height (177.1±6.61 vs 181.3 ±2.97 cm, p=0.21), and body mass index (24.0 ±2.83 vs 23.2±2.22, p=0.52). On the PPAS scale, the CG and EG scored 22.73±4.45 and 23.36±3.55, respectively (p=0.72).

Table 1 shows the mean±SD of the study variables (mean NN interval, mean HR, SDNN, rMSSD, pNN50, SD1, SD2, SS, and S/PS ratio) at rest (baseline measurement) and during US examination or application of the US-guided PNE technique in the CG and EG, respectively. There were no differences between the CG and the EG in baseline measurements of NN interval (896.2±171.85 vs 98.8±130.33 ms, p=0.97), HR (70.0±12.25 vs 69.0±9.37 bpm, p=0.85), SDNN (100.0±35.66 vs 89.0±42.78 ms, p=0.52), rMSSD (67.2±27.03 vs 57.5±21.65 ms, p=0.46), pNN50 (29.7±19.91% vs 24.5±16.50%, p=0.51), SD1 (47.6±26.22 vs 40.7±15.32, p=0.15), SD2 (131.3±45.97 vs 125.5±45.99, p=0.77), SS (8.5±3.00 vs 9.1±3.71, p=0.73), or S/PS ratio (0.28 ±0.25 vs 0.31±0.29, p=0.53).

There were no significant differences between the CG measurements taken at baseline and during the US examination (all $p>0.05$). By contrast, compared to baseline values, the EG exhibited statistically significant elevations in the following three HRV parameters during US-guided PNE: SDNN (139.8±31.90 vs 89.0 ±42.78, p=0.02), SD1 (67.4±25.67 vs 40.7±15.32, p=0.03), and SD2 (191.5±58.08 vs 125.5±45.99, p=0.03).

DISCUSSION

The main finding of this study was a significant increase in parasympathetic activity (in keeping with a potential vasovagal reaction) during application of the US-guided PNE technique on healthy patellar tendons of male football players, by means of simple HRV measurements. The relevance of this finding to clinical practice lies in the avoidance of clinically significant vasovagal reactions (including syncope); therefore it is important to advise physiotherapists that this invasive technique should be performed with

Table 1 Heart rate variability parameters before and after US examination or US-guided PNE

	Control group		Experimental group	
	Baseline	Intervention	Baseline	Intervention
NN interval (ms)	896.15±171.85	942.36±106.25	898.75±130.33	958.76±165.37
HR (bpm)	69.97±12.25	65.78±7.41	69.00±9.37	65.76±11.11
SDNN (ms)	99.95±35.66	118.70±42.97	89.02±42.78	139.82±31.90*
rMSSD (ms)	67.23±27.03	77.87±33.46	57.53±21.65	88.09±40.66
pNN50 (%)	29.69±19.91	34.51±17.68	24.52±16.50	32.31±15.21
SD1	47.57±26.22	55.10±23.68	40.71±15.32	67.35±25.67*
SD2	131.30±45.97	141.79±54.70	125.53±45.99	191.54±58.08*
SS	8.52±3.00	7.87±2.47	9.10±3.71	5.68±1.75
S/PS ratio	0.28±0.25	0.18±0.12	0.31±0.29	0.10±0.06

Data are mean±SD. Interventions in the control and experimental groups consisted of US examination and US-guided PNE, respectively.
*p<0.05 baseline versus intervention scores for experimental group only.
HR, heart rate; NN interval, normal RR interval (RRI); PNE, percutaneous needle electrolysis; pNN50, number of adjacent RRI pairs that differ by >50 ms in the full register, divided by the total number of RRIs and expressed as a percentage; rMSSD, square root of the mean of the sum of the squares of the differences between adjacent RRIs; S/PS ratio, quotient of SS and SD1; SD1, transverse axis of Poincaré plot; SD2, longitudinal axis of Poincaré plot; SDNN, SD of NN interval; SS, stress score (inverse of diameter SD2×1000); US, ultrasound.

due care and one must be fully prepared to attend to any adverse reaction.

Specifically, statistically significant increases were observed in two markers of parasympathetic activity, SDNN and SD1 ($p=0.02$ and $p=0.03$, respectively). In addition, a statistically significant increase in SD2 was demonstrated, which is indicative of *decreased* sympathetic activity. Overall this suggests that the application of the US-guided PNE technique causes an autonomic imbalance with a predominance in parasympathetic activity. In this particular study, it would appear that this autonomic imbalance was elicited by the needling technique *per se*, regardless of the participants' attitudes, which were generally positive. In fact, subjects in both the CG and the EG scored an average of 23 points on the PPAS, which is much less than the threshold of 37.5 that is considered to indicate apprehension.[27] Thus it appears unlikely that any study subject manifested a significant degree of apprehension to the needling or the electrical current that may otherwise have had an impact on the results. Consequently, the HRV changes were attributable to the physiotherapy technique used in the study, which is important to acknowledge in order to avoid serious vasovagal reactions such as syncope.

The analysis of HRV has been applied to several pathological conditions[19 30–32] in addition to sports performance.[18 33] In the field of physiotherapy, HRV is now being incorporated into evaluation of the physiological effect of different techniques. In this context, we identified papers on HRV involving therapeutic massage,[21 34–36] craniosacral therapy,[37] and acupuncture.[20 38–40] Some authors have reported an increase in HRV based on increased parasympathetic activity that has been translated into techniques designed to reduce physiological stress.[21 34 37] Other authors have reported increased sympathetic activity during acupuncture needling, which is generally followed by increased parasympathetic tone afterwards.[38–40] In this study, beginning with two groups of homogeneous subjects (CG and EG), we observed a trend towards increased parasympathetic activity and decreased sympathetic activity in both groups, although the changes were only statistically significant in the EG. In light of the fact that US-guided PNE is a needling technique, it is likely that subjects were experiencing an autonomic imbalance and this should be borne in mind during clinical treatment to avoid potentially serious adverse reactions such as vasovagal syncope.

In conclusion, application of the US-guided PNE technique caused a measurable increase in parasympathetic activity (detected by HRV). Accordingly, patients should be monitored for signs of adverse vasovagal reactions when performing this technique in clinical practice. Simple HRV indicators could potentially be used as markers for early detection of potential vasovagal reactions during application of the US-guided PNE technique; however, their potential use for this purpose requires further evaluation.

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Contributors BdlCT and MAC conceived the study, supervised its design and drafted the manuscript. BdlCT and PGB contributed to the execution of the study. JNO performed data management and statistical analysis. All authors read and approved the final version of the manuscript.

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Patient consent Obtained.

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Notes