Case 12 David Howell

Posterior Tibial Tendinopathy and Hyaluronic Acid Injections

A 58 year old lady initially presented in June 2019 with worsening posterior medial ankle pain. There had been no history of trauma.

Her job involved mainly standing and usually she would walk 30 minutes to work, which she was now unable to do.

She had tried resting, including time off work, icing and elevating and anti-inflammatories, but was still symptomatic.

Past medical history included hypertension, hypothyroidism and previous obesity. Over the preceding year, through sensible eating and exercise, she had lost over 5 stone in weight, and now had a healthy BMI of 23. She took an angiotensin receptor blocker for her blood pressure, levothyroxine for her hypothyroidism and had no known allergies.

Examination findings showed a normal range of motion through her ankle joint. She did overpronate, more so on her symptomatic side. She had a slight lateral deviation of her heel, a flattened arch and 'too many toes' sign.



Image from <u>https://orthoinfo.aaos.org/en/diseases--</u> conditions/adult-acquired-flatfoot/ (2/11/2020 at 1045)

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She had weakness on single leg heel raise (could manage 2) and was tender along the course of the posterior tibial tendon (PTT). There was some soft tissue swelling, but no redness or warmth. On heel raise she could produce a longitudinal arch (Hubscher manoeuvre), indicating a flexible flatfoot.

The Achilles tendon was non-tender through its course to insertion.

With a history of polymyalgia rheumatica (PMR) and hypothyroidism, bloods were checked, which showed normal inflammatory markers and also normal thyroid function. She also had no other symptoms of PMR.

X-rays showed no evidence of arthritis in either her tibiotalar or subtalar joint.

A clinical diagnosis of posterior tibial tendinopathy dysfunction was made.

We initially tried conservative management, including initial rest with a boot when weightbearing for 2 weeks, then a progressive loading programme through the local physiotherapy department. She also started to use an orthotic, with a medial arch support.

She initially improved and returned to work however, a holiday involving a lot of walking caused a recurrence of her symptoms.

She was seen by the lower limb orthopaedic surgeon, who suggested a prolonged 6 week period when weight bearing in a boot, followed by a repeated loading programme. Again, her symptoms settled to a degree, but she still was symptomatic after long periods at work on her feet.

She walked with a slow, antalgic gait, and her pain was 4/10 on the visual analogue scale. COVID-19 did hamper her access to appropriate heath care professionals and further discussions regarding treatment options. She was very keen to avoid surgical intervention.

Review in October 2020 continued to show the above clinical signs.

Ultrasound examination showed a normal anterior joint, with no effusion. Her extensor tendons were all normal. Lateral ankle examination was also normal.

The Achilles tendon (AT) showed a normal fibrillar pattern, and no activity with power doppler (PD). There was slight cortical irregularity at its insertion, but no tenderness on sonopalpation, and no activity with PD.

The medial ankle ligament complex was all normal, including on dynamic testing.

The PTT did show some loss of its normal fibrillar pattern along its course posterior to the medial malleolus, along with thickening (7mm versus 5mm on the asymptomatic side). There was surrounding fluid, greater than on the asymptomatic side, with slight activity on PD. Flexor digitorum longus, and flexor hallucis longus were normal.

The diagnosis was stage 2 disease.

Background

'Flatfeet' is the common term used for either 'adult acquired flatfoot deformity' (AAFD) or 'posterior tibial tendon insufficiency' (PTTI). It can affect 5-15% of the population and can be either congenital or acquired. 7-15% can be symptomatic and present to a health care professional. (Ling and Lui, 2013)

It has a wide clinical spectrum, which can progress from a tendinosis of the PTT through to a complete tear (PTTI). AAFD is caused by both PTTI (a dynamic stabiliser) and failure of the static stabilisers (bone and ligaments). The spring ligament complex (calcaneal-navicular ligament) is the most commonly compromised static stabiliser. (Vulcano et al, 2013)

This causes the 'flatfoot' with:

'plantar sag and forefoot adduction through the talonavicular and subtalar joints, which leads to plantar and medial migration of the talar head causing the arch to flatten and the foot to displace under the talus. Involvement and failure of the interosseous ligament between the calcaneus and talus can cause the heel valgus.' (Vulcano et al, 2013)

The condition is associated with a pre-existing flat foot, female sex, diabetes, high impact sports, raised BMI and hypertension. (Vulcano et al, 2013) There are also associations with previous trauma and inflammatory arthropathies and tendon rupture with local steroid injections. (Geideman and Johnson, 2000)

There are four recognised stages ranging from solely tendon involvement, through to bony involvement with degeneration of the tibio-talar joint. The initial classification system was devised by Jonson and Strom, who recognised three stages. A fourth stage was suggested by Myerson. (Myerson, 1997) Although several others have been developed, it is still widely recognised. (Ross et al, 2017) and (Abousayed et al, 2016)

Stage	Posterior Tibial Tendon and Foot Pathology	Clinical Findings	MRI Findings	Treatment Options ³⁻⁶
I	 PTT tenosynovitis Mild hindfoot deformity 	 Pain and swelling on the medial side of the ankle Mild weakness 	 Insertional tendinosis Tenosynovitis 	Immobilization Shoe modifications Medial arch supports NSAIDs Cryotherapy Stirrup brace Custom ankle foot orthoses PRP injection, shockwave Tenosynovectomy Arthoereisis
п	• PTT elongated and/or torn	 Possible pain along PTT Possible sinus tarsi pain Weak limb Inability to rise up on the forefoot and perform heel raise Mild deformity of hindfoot at midfoot pronation and forefoot abduction Pes planovalgus Loss of arch height (apropulsive gait) Medial column instability Varus forefoot Foot abduction Too many toes sign Flexible flatfoot (with stress maneuver) Inability to plantar flex and invert with foot past the midline Achiles contracture 	 Type I/II tear with tendinosis and/or tenosynovitis Talar fault and/or hindfoot valgus +/- Spring ligament abnormality 	 Arthoeresis Foot orthoses Stirrup brace AFO Shoe modifications: medial heel wedge, medial stabilizer medial outflare FDL transfer Kidner procedure Cotton osteotomy Tendo-Achilles lengthening Medial displacement calcaneal osteotomy Spring ligament reconstruction Lateral column lengthening Medial column fusion
ш	• PTT degeneration	 Fixed hindfoot valgus Sinus tarsi pain Rigid flatfoot (without stress maneuver) Inability to activate any inversion except that which occurs through the anterior tibial tendon 	 Type II/III tear with severe tendinosis and/or tenosynovitis Talar uncoverage Hindfoot valgus Spring ligament abnormality Tibiospring (superficial deltoid) ligament abnormality Early signs of talocalcaneal and/or calcaneofibular impingement Subtalar joint osteoarthritis 	 Custom bracing, if not surgical candidate Triple arthrodesis Lateral column lengthening
IV	 Incompetent deltoid ligament Degenerative changes of the hind- and midfoot joints 	Fixed hindfoot and tibiotalar valgus	Above findings with additional: Chronic superficial and deep deltoid sprain Tibiotalar and subtalar joint osteoarthritis Talocalcaneal and Calcaneofibular impingement	 Surgery for hindfoot valgus and associated deformity Deltoid reconstruction Tibiotalocalcaneal or pantalar fusion osteotomy

Image from Chhabra et al, (2011)

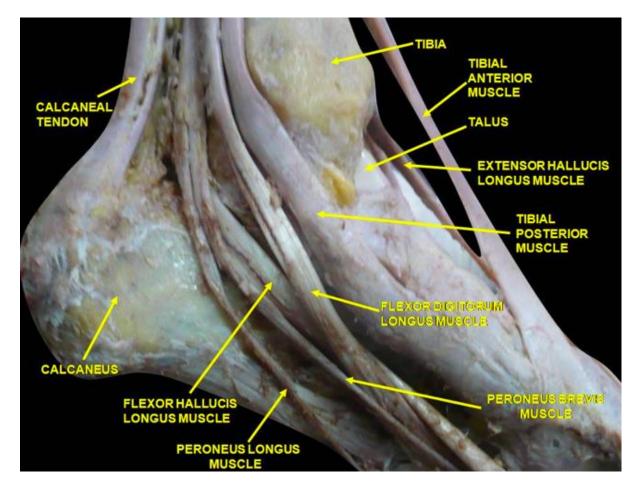
Alrolder et al, (2015) showed ultrasound to be 'slightly' more accurate than MR to identify tendinosis, complete and partial tears. Its use as a cost effective modality was recommended as a first line investigation. The spring ligament complex can also be visualised on ultrasound, including abnormalities such as thickening, loss of normal echogenicity and increased vascularity. (Mansour et al, 2008)

Hsu et al, (1997) suggested a tendon width of >6mm could be diagnostic of a tenosynovitis, and diagnostic confidence increased if combined with the 'target sign'(fluid around the tendon within the sheath).

Ultrasound can also visualise the tendon and may show hypoechoic thickening, loss of normal fascicular pattern and synovial thickening. Neovascularisation can also be demonstrated with power doppler. (Drakonakiet et al, 2016) Fluid alone around the tendon can be a common finding, (Lee et al, 2019) so must be interpreted along with other ultrasound and clinical findings.

It therefore seems reasonable, when reviewing the above table and evidence, that ultrasound +/-x-ray along with clinical examination can be used for diagnosis, especially in stages 1 and 2.

Conservative treatment has been shown to be successful for stage 1 and 2 disease (Alverez et al, 2016). Treatments include NSAIDs, orthotics, bracing and strengthening exercises. Vulcano et al, (2017) also suggested initial conservative management, regardless of disease stage.



Anatomy and Aetiology

Image taken from <u>https://brookbushinstitute.com/article/role-tibialis-posterior-fatigue-foot-kinematics-during-walking 2/11/20</u> @ 1150

The PTT originates from the proximal posterior tibia and fibula and interosseous membrane. Its distal tendinous part inserts into mainly the navicular tuberosity, but also the base of the medial, intermediate and lateral cuneiforms, and 2nd, 3rd and 4th metatarsals.

The direction of muscle force changes from vertical to horizontal as it passes posteriorly the inferiorly around the medial malleolus.

The PTT is at risk of poorer blood supply compared to other tendons due to its incomplete central mesotenon, in particular between the well vascularised musculotendinous junction and its insertion. It is in this area of hypo vascularity that pathology to the tendon is mostly seen, increasing in degrees of tendinopathy through to failure. Petersen et al, (1997) showed by immunohistochemical investigation that there was no laminin (reflecting vascularization) where the PTT glides round the bone, and this area therefore had no blood supply. This area was instead replaced by fibrocartilage. If the dynamic stability is lost, then it can affect the static stabilisers as described above, and lead to advancing pathology, including bony/joint involvement. (Ling and Lui, 2013)

Discussion

Review of the evidence using the University of East London's online library shows no specific evidence for the use of hyaluronic acid (HA) and PTT.

However, the patient had tried the majority of all other evidence based conservative approaches and was still symptomatic and very keen to try and avoid surgery. In our local area, currently all surgery is very delayed with COVID 19 and emergencies are being prioritised.

The use of HA had been recommended as a treatment option by the orthopaedic consultant she had also seen, who had had successful experiences in its use with similar cases, when injected under ultrasound guidance. As part of my training, I had also seen HA used for the same condition by the MSK Consultant Radiologist, along with HA for other tendinopathies. Other Sports Medicine Consultants and Specialist Physiotherapists I have worked with also had used this as a treatment modality.

Local steroid injection is an option, but must be used with extreme caution around a weight bearing tendon, due to the risk of rupture. Ikpeze et al, (2019) actually go a step further, and say local steroid is contraindicated, although the paper was written for management of elderly patients (although did include a study on over 40s).

Oloff and Lam, (2017) reviewed the evidence for plasma rich protein (PRP) and posterior tibial tendinopathy. They noted limited evidence with small study sizes, and could not recommend either way its use. Potential use was discussed with the patient, who felt it could be a future treatment option. Reviewing its benefits on other tendinopathy, Chen et al, (2017) showed a benefit with PRP and improvements in pain with lateral epicondylitis and rotator cuff injuries. Cruciani et al, (2019) did an 'umbrella review' of PRP and soft tissue injuries – they did fine the studies to be of low quality with risk bias, but with some evidence of benefit.

Other locally available treatments include topical glyceryl trinitrate. Several studies have shown its benefit in tendinopathy, both short and long-term, but none specifically for posterior tibial tendinopathy. (Paoloni et al, 2017)

Shockwave therapy is another treatment option again with limited evidence. However, recently Robinson et al, (2020) did show statistically significant improvements in a small study (10 patients) treated with radial shockwave and importantly with no adverse outcomes.

Lynen et al, (2017) compared 2 HA injections, given a week apart to focal shockwave treatment (3 treatments). They showed better outcomes in the HA group and also found it was better tolerated.

Unfortunately, in our area, there is no state funding for this treatment so the patient felt it wasn't an option for her and had confidence in the treatment suggested by the Orthopaedic Consultant.

Hyaluronic Acid

HA is present in synovial fluid of both joints and tendon sheaths. Studies have shown its use can improve tendon gliding resistance. (Taguchi et al, 2009) Osti et al, (2015) showed HA may 'improve tendon viability and proliferation.' There is an increase collagen type 1 (which is the predominant collagen in tendons, providing the main structural support). They also showed that HA didn't cause an increase in collagen type 3, which is seen in tendinopathy, so hypothesised this also maybe protective to tendons. Tuncay et al, (2002) also showed in animal studies on rats' tendons that there was a likely anti-inflammatory effect caused by HA, 'by inhibiting leucocyte function'.

Ultrasound guidance can ensure safe delivery of HA within the sheath, but not into the tendon. Wu et al, (2016) did show that intra-tendinous injection could cause tendon damage, with ongoing inflammation seen up to day 42.

Evidence for HA and tendinopathy is sparse, but growing. A Cochrane review suggested that currently there was not enough evidence to recommend its use in either Achilles or patellar tendinopathy. (Kearney et al, 2015)

However, ISAKOS 2015 showed a significant benefit of HA in patellar tendinopathy. This was compared to local steroid injection – this study arm was actually stopped early, as there was no benefit. They suggested the use of HA, after conservative measures had failed, and as an alternative prior to surgery.

OARSI 2016 compared steroid to HA alone or HA plus Botox for patella tendinopathy – again the HA and HA plus Botox showed favourable results, and also a safe treatment option.

Gorelick et al, (2015) showed using HA alone, or in combination with steroid was superior to steroid alone, especially from 6-12 months in lateral epicondylitis. In a separate paper, Gorelick et al, (2015) also showed benefit of HA in Achilles tendinopathy when compared to steroid or conservative measures with both function and pain.

Orlandi et al, (2015) looked at the addition of HA to steroid for de quervains tenosynovitis and showed benefit in terms of outcome and recurrence. Fogli et al, (2017) also showed HAs benefit for US guided peritendinous injections, including reducing tendon thickness and neovascularisation and described it as a 'safe' procedure. Fogli et al, (2017) also found that HA had the same effect on all tendinopathies in the study (Achilles, patella and lateral elbow).

Number of injections

Flores et al, (2017) in their prospective randomised trial comparing HA and physical therapy to physical therapy alone, showed significant benefit, and gave 2 injections a week apart. Of note, they also emphasised the importance of physical therapy, and it still being the 'gold standard treatment.'

Kumai et al, (2014) used just a single injection of HA and found this to be of benefit in tendinopathy, and safe at a volume of 2.5ml.

Frizziero et al, (2019) found 3 HA injections, given a week apart, showed benefit at 90 days for Achilles and mid portion patella tendinopathy.

There aren't any large RCTs comparing optimal dose or frequency of injections.

Local Anaesthetic (LA)

Honda et al, (2016) showed in both in vitro and in vivo the negative effects of LA (lidocaine) on tendons, including weakening and cell death of tenocytes. Also, from past experience of peritendinous injections (for example, de quervains tenosynovitis) the space is small for the injectate, so it seems pragmatic not to dilute the HA with LA, to ensure the full dose can be given.

Post Procedure Boot

The local orthopaedic consultant did recommend a boot to off-load the tendon after injection. This suggestion seems to be following previous experience of injections involving steroid around the tendon, (with increased risk of rupture) rather than HA. Frizziero et al, (2019) allowed patients in their study to weight bear, but avoid strenuous activity post procedure, with no adverse outcomes. However, I followed the advice of the Consultant.

Informed consent

The patient was requesting an HA injection, and that was her expectation. We had an initial consultation to discuss the procedure, and gain informed consent, after explaining the risks and limited evidence. She was aware of the risks of using steroid, and why we were avoiding its use.

However, it was also important that I felt it was a reasonable treatment option, and I could confidently justify the procedure. Evidence was based on HAs positive effects on other tendinopathies outlined above, with no published data specifically for posterior tibial tendinopathy. Folgi et al, (2017) stated the beneficial effect of HA was the same on the three tendons in their study.

I felt it was reasonable to use, given the request by a Consultant Orthopaedic colleague, and positive results from other MSK colleagues. She had failed conservative approaches, and was keen to avoid surgery. Side effects are very rare, and I felt the main side effect would be it didn't work, and would be unlikely to worsen her condition.

The prolonged period in a boot would help off-load her, followed by a structured loading program. She had had a treatment failure when using a boot then loading program previously, so if she did have benefit this time, one could hypothesise the addition of HA helped. Ostenil tendon specifies it's use if for tendinopathy, and the patient clearly had evidence of this, clinically and on ultrasound images. Its delivery was under ultrasound guidance, so the

risk of it being placed into the tendon was low. It was given in the dose of 40mg in 2ml. Product literature suggests 2 doses a week apart, which I followed.

All of the above was explained, highlighting the limitation of evidence, and we were doing this based on evidence of HA in other tendinopathies. I specifically informed her that there was no evidence currently in the literature for treatment of posterior tibial tendinopathy. I also explained the small risk of infection, possible pain, and the rationale of not using LA. Although I cannot find any reported cases, there potentially is a chance of allergic reaction, and possible tendon rupture, which I explained, along with ostenil tendon being a medical device. She was also aware of how to use the boot post procedure, and had planned follow up with a physiotherapist, for a structured loading program. She was also given post procedure advice, and who and how to contact if any problems.

It is important to use a validated tool, before the procedure and to monitor response to treatment. This needs to be easy and quick to do in a clinical setting, and reproducible. It could provide a basis to publish a number of cases, either with positive or negative results. Budiman-Mak et al, (2013) showed the 'foot function index – revised' to be valid for PTT and easy to use. Ross et al, (2018) also showed a number of clinical tests that were reliable to assess function, including heal raise (maximum number). This again is easy to perform in a clinic. There are numerous other tests that could be used to assess outcomes, especially if one was designing a RCT.

Procedure

The patient was asked to lie comfortably in a supine position, with her knee flexed at 90 degrees. A pillow was placed under her ankle for support. Our standard clinical procedures were followed regarding infection control with both skin and probe preparation. The posterior tibial tendon was identified, along with the location of the neurovascular bundle. With the tendon in a transverse view, an in plane approach from the posterior side was used, and ostenil tendon delivered with clear needle visualisation. The procedure was repeated after a week. She wore the boot when weight bearing, from the 1st injection, and for 1 week after the 2^{nd} injection.

All of the above, including what was discussed, was documented in her notes.

Conclusion

It is clear that there is a huge lack of evidence specially for HA in posterior tibial tendinopathy and only limited evidence for its use in other tendinopathies. Although there is supporting clinical evidence for other tendinopathies, they are separate clinical entities, and we must be mindful of this. But, potentially it maybe a successful treatment and halt the need for surgical intervention in some cases. It does otherwise seem a large leap from conservative treatment to operation, with its own associated risks.

Many studies are also at risk of bias, with funding from the producing drug companies. Large, unbiased RCTs need to be carried out, on individual tendinopathies (both mid portion and insertional), with validated outcome measures. One needs to account for the different stages of tendinopathy we are treating and the effect on outcomes this may have. Any comparison arms would also need to be standardised, such as loading programs or orthotics used, for example. Assessing optimal dose and number and frequency of injections needs to be assessed, along with longer term outcomes.

The need for off-loading post procedure with HA for lower limb peri-tendinous injections also needs further studies.

Tendinopathy and tendon health is far from simple and often there will be ongoing factors at play – BMI, cholesterol, and genetics, which need to be accounted for.

Ideally, comparing it to a sham treatment would be of benefit, but this may not gain ethical approval. Comparing it to steroid, especially in a weight bearing tendon again would likely not be ethical, due to risk of harm. It could also be compared to other emerging treatments, such as PRP and again with shockwave (Lynen et al, 2017) (both focal and radial) but with perhaps 5 or 6 treatments, which often in clinical practice we use.

A simple and practical suggestion would be to develop an online national tool to record data, to help understanding of procedures and outcomes. If successful, this could be expanded on an international scale.

An online anonymised proforma could be quick to complete (with patient consent), for example in this case:

PTT Age Risk factors (e.g. BMI) Foot function index – revised score pre-procedure US findings – hypoechoic thickening/loss of normal fascicular pattern/synovial

Thickening/neovascularisation

Injection given and frequency

Loading program yes/no

Follow up foot function index - revised score

The British Society of Urogynaecology have an online Audit database to do exactly this – record surgical data to help understanding for future studies and maintain best practice. It is information we should be recording in the notes and could be easily transferable, and encouraged and set up by either The Faculty of Sport and Exercise Medicine or the British Association of Sport and Exercise Medicine.

With patient consent, email follow up could monitor longer term benefits.

My initial background is in General Practice, where my treatment has predominately always been evidence-based. Published, high quality evidence is lacking and clearly need to be put in to place, to keep up with the rapidly growing world of sports and musculoskeletal medicine, which seems to be more experimental and hearsay. We want to ensure we are doing best by are patients, and above all ensure we are doing no harm. Classifications in Brief: Johnson and Strom Classification of Adult-acquired Flatfoot Deformity. Clinical Orthopaedics ad Related Research. 2016

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