Qutenza Patch - Our Early Experience

Abstract:

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Abstract
Qutenza is a high potency capsaicin topical patch which has been recommended for the treatment of peripheral neuropathic pain. The aim of this study was to assess our selected patients' response to Qutenza application. All patients had their dynamic pain score recorded prior to application and were asked to fill in a standardised questionnaire for three months post application. Patients were also asked to document any changes to the character of their pain, changes in sleep, activities of daily living and mood as well as any changes to their medication usage. 21 patients had Qutenza applied in a 5 month period. 17 patients completed the questionnaire in a 5 month period. We found that the mean overall reduction in pain score at 3 months was 32.7%. 8 of our patients (47%) reported improved sleep, activities of daily living and mood. 6 patients (35%) reported a reduction in medication use, while 7 (41%) reported an improvement in the character of their pain.

Introduction
Capsaicin is the compound in chilli peppers that makes them taste â hotâ . The active ingredient in hot pepper was first isolated more than a century ago. In 1997, scientists at the University of California in San Francisco discovered a gene for the capsaicin receptor, called the vanilloid receptor[1]. Qutenza is a high-potency capsaicin (8%) topical patch which has been recommended for the treatment of non-diabetic peripheral neuropathic pain including post herpetic neuralgia and human immunodeficiency virus (HIV) â associated neuropathy[2-4]. Qutenza is a cutaneous patch containing 179mg of capsaicin per 280cm2 patch equivalent to 8 % by weight. Other agents used in the treatment of peripheral neuropathic pain include anticonvulsants such as gabapentin or pregablin, anti-depressants such as amitriptyline or duloxetine and lignocaine 5% topical patch. Opioids and low concentration capsaicin products are recommended as second or third line agents for the treatment of neuropathic pain[5]. It is usual in chronic pain practice to use a combination of these agents because of the resistant and debilitating nature of neuropathic pain, however the evidence for this practice is lacking. The European Federation of Neurological Societies does however recommend a combination therapy approach when monotherapy is insufficient. Combination therapy however should employ medications with differing mechanisms of action[5].

Although lower concentrations of capsaicin (0.025% to 0.1%) have been available for many years, Qutenza is the first high concentration (8%) formulation available. It decreases pain by reducing transient receptor potential vanilloid 1(TRPV1) expression[6] and by decreasing the density of epidermal nerve fibres in the application area[7]. The TRPV1 receptor is a ligand-gated ion channel receptor expressed on nociceptor neurons on the skin[2,8]. Capsaicin is an agonist at the TRPV1 receptor and when applied initially, causes an increased sensation of pain[9], followed by a decreased sensitivity to pain which is attributed to the reduction in TRPV1 expression. Capsaicinâ s second mechanism of action is thought to be neurolytic i.e. to reduce the density of epidermal nerve fibres. Reinnervation has been shown to occur over time[8]. Systemic absorption from Qutenza is low, with only a third of patients after a 60 minute application showing detectable plasma capsaicin levels, the mean elimination half-life was shown to be 1.64 hours[9]. Metabolites were not detected in patients in pharmacokinetic studies[9]. The most common adverse drug reactions are application site erythema 63(%) and application site pain 42(%)[10].

Methods
Between February and June 2011 twenty one patients were referred for application of a Qutenza patch from our hospitalâ s chronic pain outpatient clinic. All patients would get assessed by either the Consultant in charge or the Pain Registrar. Symptoms and signs of neuropathic pain were evaluated including a history of sharp, shooting, electric like pain, paraesthesia, allodynia, hyperalgesia and hyperpathnia. All of the patients recruited would have been trailed with the conventional neuropathic pain therapies prior to selection for our study. Patients would not be referred if their painful area was on their face or soles of the feet/hands or they were diabetic.

The patch application process took place in a dedicated minor operation theatre. The patients selected for treatment had their dynamic pain score recorded prior to application and were asked to fill in a standardised â Pain Diaryâ for three months post application. Patients were asked to document any changes to the character of their pain, sleep pattern, activities of daily living and mood as well as any changes to their medication usage. Patients were given a patient information leaflet prior to admission and the procedure was explained and any concerns or questions answered. Informed consent was obtained prior to application of the patch. The Qutenza application procedure usually took approximately 2.5 â 3 hours from admission to discharge. The area for treatment was mapped out by the pain nurse in charge and a local anaesthetic cream (EMLA) was applied for one hour after which the Qutenza patch was applied for a further hour. It was explained to the patients prior to application of Qutenza that the patch may cause pain; they were encouraged to wear it for as long as possible but that it could be removed if the pain became intolerable. Following the procedure patients were discharged home with their â Pain Diaryâ and contacted on the first day post procedure, at one week and at three months.

Results
21 patients had Qutenza applied between the end of February and beginning of June 2011. 17 were contactable by phone at 3 months and their diary information obtained (M = 8, F = 9). Six patients had no response to the treatment at all. The overall mean reduction in dynamic pain score of the 17 patients was 38% at one month, 35.7% at 2 months and 32.7% at 3 months. 41% of our patients reported an improvement in the character of their pain and 35% reported a reduction in medication use at 3 months. 47% reported an improvement in sleep pattern, improved activity levels and an improved mood. We then divided the 17 patients into responders and non-responders. (See table 1 and 2) On closer examination 11 of these patients were chronic post-surgical pain with a neuropathic component, of this group 6 of these were responders 55%. Of the remaining 6 patients (i.e. the non-surgical peripheral neuropathic pain group) there was an 83% response rate. No patients with central neuropathic pain were included in our study. All of our patients experienced pain while the patch was applied but only one patient failed to tolerate the patch for the full hour. 88% of our patients experienced erythema post application of Qutenza and in all cases this had disappeared after 24 hours. No other complications were noted.

Discussion
The main body of evidence for the use of Qutenza for chronic pain in the literature exists for non-diabetic painful neuropathy, particularly for the conditions post herpetic neuralgia[2] and HIV associated neuropathy[3]. The results from these studies are broadly in line with our study results i.e. a mean reduction in numeric pain scores of approximately 30(%); however our study used patients of mixed presentations which suggest a broader range of neuropathic pain indications. Although pain reduction is often the focus of patients presenting to pain clinics, quality of life improvements are as important if not more important goals as often chronic pain patients will never be 100% pain free, therefore improvements in sleep, function and mood are important factors to be noted.

Broadly speaking pain can be classified into three types i.e. nociceptive, neuropathic and mixed (both nociceptive and neuropathic). On review of our results the responder group probably had a higher degree of neuropathic pain compared to the non-responder group; this may offer an explanation for the non-responders. This also suggests that diagnosis and patient selection are key in order to maximise the benefit of this new therapy. The advantages of Qutenza over conventional medical management for these conditions include low systemic absorption, less drug interactions and a once tri monthly dosing pattern. As with any new intervention, continuous evaluation must be observed to assess efficacy and complications. Initial results show that with careful patient selection, a reduction of dynamic pain scores and improvements in quality of life markers can be achieved using Qutenza for the treatment of peripheral neuropathic pain. Continued monitoring of this new treatment is however warranted.

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