RECOMMENDATION

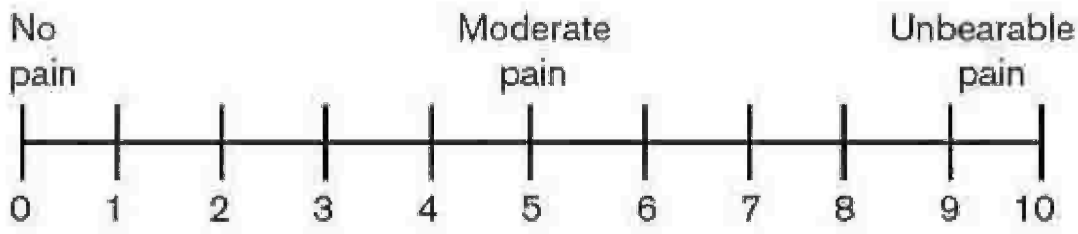
It is recommended to perform a case series study extending for 6-12 months on the pain relieving effect, tolerability and side effects of diacerein in OA patients.

ANNEXES

Annex (1)

Pain Visual Analogue Scale (VAS) (170)

0 - 10 VAS



Description

Purpose: The pain VAS is a unidimensional measure of pain intensity, which has been widely used in diverse adult populations, including those with rheumatic diseases.

Content: The pain VAS is a continuous scale comprised of a horizontal (HVAS) or vertical (VVAS) line, usually 10 centimeters (100 mm) in length, anchored by 2 verbal descriptors, one for each symptom extreme. Instructions, time period for reporting, and verbal descriptor anchors have varied widely in the literature depending on intended use of the scale.

Number of items: The pain VAS is a single-item scale.

Response options/scale: For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 100 [100-mm scale]). To avoid clustering of scores around a preferred numeric value, numbers or verbal descriptors at intermediate points are not recommended.

Recall period for items: Varies, but most commonly respondents are asked to report "current" pain intensity or pain intensity "in the last 24 hours."

Practical Application:

How to obtain: The pain VAS is available in the public domain at no cost. Graphic formats for the VAS may be obtained from Scott & Huskisson or online: http://www.amda.com/tools/library/whitepapers/hospiceinltc/appendix-a.pdf.

Method of administration: The pain VAS is selfcompleted by the respondent. The respondent is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity.

Scoring: Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–100.

Score interpretation: A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in postsurgical patients (knee replacement, hysterectomy, or laparoscopic myomectomy) who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0–4 mm), mild pain (5–44mm), moderate pain (45–74 mm), and severe pain (75–100 mm). Normative values are not available.

Respondent burden: The VAS takes <1 minute to complete.

Administrative burden: The VAS is administered as a paper and pencil measure. As a result, it cannot be administered verbally or by phone. No training is required other than the ability to use a ruler to measure distance to determine a score. Caution is required when photocopying the scale as this may change the length of the 10-cm line. As slightly lower scores have been reported on the HVAS compared to the VVAS, the same alignment of scale should be used consistently within the same patient.

Translations/adaptations: Minimal translation difficulties have led to an unknown number of cross-cultural adaptations.

Psychometric Information

Method of development: The pain VAS originated from continuous visual analog scales developed in the field of psychology to measure well-being. Woodforde and Merskey first reported use of the VAS pain scale with the descriptor extremes "no pain at all" and "my pain is as bad as it could possibly be" in patients with a variety of conditions. Subsequently, others reported use of the scale to measure pain in rheumatology patients receiving pharmacologic pain therapy. While variable anchor pain descriptors have been used, there does not appear to be any rationale for selecting one set of descriptors over another.

Acceptability: The pain VAS requires little training to administer and score and has been found to be acceptable to patients. However, older patients with cognitive impairment may have difficulty understanding and therefore completing the scale. Supervision during completion may minimize these errors.

Reliability: Test–retest reliability has been shown to be good, but higher among literate ($r = 0.94$, $P < 0.001$) than illiterate patients ($r = 0.71$, $P < 0.001$) before and after attending a rheumatology outpatient clinic.

Validity: In the absence of a gold standard for pain, criterion validity cannot be evaluated. For construct validity, in patients with a variety of rheumatic diseases, the pain VAS has been shown to be highly correlated with a 5-point verbal descriptive scale ("nil," "mild," "moderate," "severe," and "very severe") and a numeric rating scale (with response options from "no pain" to "unbearable pain"), with correlations ranging from 0.71–0.78 and 0.62–0.91, respectively). The correlation between vertical and horizontal orientations of the VAS is 0.99.

Ability to detect change: In patients with chronic inflammatory or degenerative joint pain, the pain VAS has demonstrated sensitivity to changes in pain assessed hourly for a maximum of 4 hours and weekly for up to 4 weeks following analgesic therapy ($P < 0.001$). In patients with rheumatoid arthritis, the minimal clinically significant change has been estimated as 1.1 points on an 11-point scale (or 11 points on a 100-point scale). A minimum clinically important difference of 1.37 cm has been determined for a 10-cm pain VAS in patients with rotator cuff disease evaluated after 6 weeks of nonoperative treatment.

Critical Appraisal of Overall Value to the

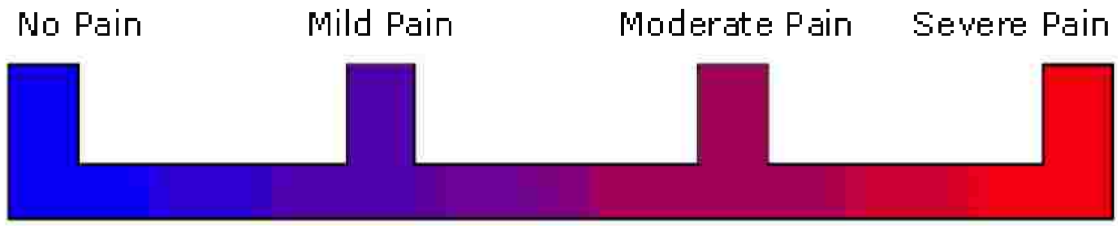
Rheumatology Community

Strengths/caveats and cautions/clinical and research

Usability: The VAS is widely used due to its simplicity and adaptability to a broad range of populations and settings. Its acceptability as a generic pain measure was demonstrated in the early 1970s. Limitations to the use of the pain VAS include the following: older patients may have difficulty completing the pain VAS due to cognitive impairments or motor skill issues, scoring is more complicated than that for the Numeric Rating Scale for pain (described below), and it cannot be administered by telephone, limiting its usefulness in research.

Annex (2)

Pain Verbal Rating Scale (VRS) [171]



The VRS comprises a list of adjectives used to denote increasing pain intensities. The most common words used being: no pain; mild pain; moderate pain; and severe or intense pain. For ease of recording these adjectives are assigned numbers. These rank numbers can lead to the misapprehension that intervals between each descriptor are equal, but this is not the case and could be a source of error. The VRS is ordinal. There is no published evidence about the distribution of data obtained from the VRS. In most cases, data collected using a VRS can only be analysed using non-parametric statistics.

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الملخص العربى

الهدف من البحث هو دراسة تأثير عقار دياسيرين على آلام الركبة وشدتها ومستوى مادة أنترليوكين-١ بيتا في السائل الزلالي للركبة وكذلك في الدم في مرضى الفصال العظمي للركبة.

وقد أجريت هذه الدراسة على ستين مريضا يعانون من الفصال العظمي لمفصل الركبة بالإضافة إلى ستة أشخاص كمجموعة ضابطة. وقد تم تقسيم حالات الفصال العظمي إلى ثلاث مجموعات:

المجموعة الأولى من المرضى يعالجون بواسطة دياسيرين لمدة شهرين بجرعة ٥٠ مجم كبسولة مرتين يوميا.

المجموعة الثانية من المرضى يعالجون بواسطة ديكلوفيناك صوديوم لمدة شهرين بجرعة ٧٥ مجم قرص مرة واحدة يوميا.

المجموعة الثالثة من المرضى يعالجون بواسطة الدوائين السابقين معا وبنفس الجرعات لمدة شهرين.

وقد تم تقييم شدة الألم وزمن المسافة التي يستطيع أن يمشيها المريض وتقدير نسبة تركيز مادة انترليوكين-١ بيتا، قبل وبعد شهر، وبعد شهرين من إعطاء العلاج لمرضى كل مجموعة من المجموعات الثلاث.

وقد اتضح أن شدة الألم وزمن المسافة التى يستطيع أن يمشيها المريض قد تحسنت بدرجة كبيرة بعد شهرين من تناول عقار دياسيرين حيث أصبح زمن المسافة التى يستطيع أن يمشيها المريض أقل فى المجموعة الأولى بعد شهرين مقارنة بالمجموعة الثالثة، ولكن لم يستطع عشرة من المرضى من استكمال البحث لنهايته من مرضى المجموعة الثانية.

ولم يتغير مستوى أنترليوكين-١ بيتا بدرجة مهمة إحصائيا بعد العلاج بعقار دياسيرين فى المجموعة الأولى والمجموعة الثالثة.

وبالنسبة لمستوى أنترليوكين-١ بيتا فى الدم، لم يوجد تغير ذو أهمية إحصائية بين المجموعات الثلاث قبل العلاج إلا أن مستوى أنترليوكين-١ بيتا فى الدم قد انخفض بدرجة مهمة إحصائيا فى المجموعة الثانية مقارنة بالمجموعة الأولى والمجموعة الثالثة بعد شهرين من العلاج.

الخلاصة:

يمكن استعمال دياسيرين فى التحكم فى شدة الألم الناتج عن حالات مرض الفصال العظمي للركبة التى لا تتحمل استعمال مضادات الالتهابات الغير ستيرودية والتى تتحمل استعمال دياسيرين.

التوصية:

نوصى بدراسة تمتد لستة أشهر إلى سنة على تأثير تخفيف الألم وقوة التحمل والآثار الجانبية لدياسيرين فى مرضى الفصال العظمى للركبة.

دراسة إكلينيكية على تأثير دياسيرين على آلام الركبة وشدتها ومستوى أنترليوكين -١ فى السائل الزلالى للركبة فى مرضى الفصال العظمى للركبة

رسالة علمية

مقدمة لكلية الطب – جامعة الإسكندرية
إيفاءاً جزئياً لشروط للحصول على درجة

دكتوراه فى الطب الطبيعى والروماتيزم والتأهيل

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