**Table 2. Critical appraisal tool for reviewing analgesia studies involving subjects incapable of self-reporting pain**

CRITICAL APPRAISAL TOOL FOR REVIEWING ANALGESIA STUDIES (CATRAS) INVOLVING SUBJECTS INCAPABLE OF SELF-REPORTING PAIN

How should this critical appraisal tool be used?

This critical appraisal tool has been designed for use in systematic reviews and meta-analyses which critically evaluate published analgesia studies conducted in human and non-human species. The CATRAS will also enable detailed evaluation of conflicting or confounding information within the published literature concerning analgesic efficacy of drugs. The comprehensive criteria within the domains of the CATRAS could also be used as a template for designing high quality pain studies. Users of the CATRAS are advised to consider the fact that the CATRAS does not assess outcomes of patient safety.

Are additional resources required when using the CATRAS?

Yes. To assess the quality of the pain assessment tool (PAT) used within the analgesia study being reviewed; domain 3 of the CATRAS requires the investigator to review the original or revised literature describing the development, refinement or validation of the PAT.

How should an analgesia study which uses more than one pain assessment tool be graded?

If several PATs are used within one publication, the study should be broken down into several studies (i.e. one per PAT) and an overall CATRAS assessment performed for each PAT. The level of evidence and methodological soundness domain scores will remain the same.

**Table 2 (*continued*)**

STEP 1

Domain 1: Level of Evidence (LOE)

The LOE for an individual study is assigned according to the study-type and its inherent likelihood to exclude bias. The LOE for a specific published study selected for review is determined using criteria incorporated into this domain.

STEP 2

Domain 2: Methodological Soundness

The LOE of an individual study must be established prior to assessment of its methodological soundness as the soundness of methodologies utilized in a particular study selected for review is analysed using criteria that are dependent on the LOE.

STEP 3

Domain 3: Grading of the pain assessment tool (PAT)

Pain assessment tools utilized in each reviewed publication are analysed against criteria in this domain. This step must be completed based on review of the original or revised literature describing the development, refinement or validation of the PAT. The literature must satisfy reviewers that the PAT being graded was designed for assessment of pain in the same context as it is being utilised in the study being evaluated by CATRAS (i.e. the same species and the same type of pain).

**Table 2 (*continued*)**

CRITICAL APPRAISAL TOOL FOR REVIEWING ANALGESIA STUDIES (CATRAS) INVOLVING SUBJECTS INCAPABLE OF SELF-REPORTING PAIN – Scoring Sheet

Name of Reviewer: Review Date:

Title:

Author/s:

Year of Publication:

Publication/Journal Title:

Volume: Issue: Page/s:

PICO question:

**Table 2 (*continued*)**

STEP 1. Domain 1: Level of Evidence (LOE)

1. Determine the *Level of Evidence* (LOE 1 to 6), which most accurately describes the *Study Characteristics* of the published study being reviewed.

|  |  |  |
| --- | --- | --- |
| **Study Characteristics** | **LOE** | **LOE****score** |
| **Randomised negative or positive controlled trials (RCTs)**, or meta-analyses of RCTs in the target species:Clinical studies that prospectively collect data and randomly allocate the subjects to intervention or control groups; or meta-analyses of these studies. | 1 | 3 |
| **Prospective clinical studies in the target species using concurrent controls** (i.e., controls recruited at the same time as experimental subjects) **without randomisation**. These studies can be:1. Interventional clinical: Include subjects that are allocated to intervention or control groups concurrently, but in a non-random fashion OR2. Observational clinical: Include cohort and case control studies. | 2 | 2.5 |
| **Experimental laboratory study in the target species**:These could include, but are not limited to randomised, blinded, and controlled studies.  | 3 | 2 |
| **Clinical retrospective studies in the target species**: The study and control groups have been selected from a previous period in time (historical controls). | 4 | 1.5 |
| **Case series and case reports in the target species**: A single group of subjects exposed to the intervention (or factor under study), but without a control group.  | 5 | 1 |
| **Studies, experimental or clinical, that are not directly related to the specific target species or target population**. These could be different species/populations, including experimental models in non-target species. | 6 | 0.5 |
| **Results*****Record the LOE and the LOE score corresponding to the study you are evaluating.***  |  |  |
| **LOE domain score (%)** ***Divide the study LOE score by 0.03*** |  |  |
| The **domain score (%)** achieved for Domain 1 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 2. |

**Table 2 (*continued*)**

STEP 2. Domain 2: Methodological Soundness

|  |  |
| --- | --- |
| LOE*Transcribe assigned LOE from step 1* |  |

1. Assignment of Methodological Soundness category (A to E) as follows (Please check the box next to your answer):
	* Studies categorized as LOE 1 in STEP 1 *go to* [A] [ ]
	* Studies categorized as LOE 2 in STEP 1 *go to* [B] [ ]
	* Studies categorized as LOE 3 in STEP 1 *go to* [C] [ ]
	* Studies categorized as LOE 4 in STEP 1 *go to* [D] [ ]
	* Studies categorized as LOE 5 in STEP 1 *go to* [E] [ ]
	* Studies categorized as LOE 6 in STEP 1 should have their methodological soundness assessed according to their Study Characteristics:
		+ *Randomised Control Trials* should go to [A]
		+ *Prospective clinical studies using concurrent controls* *without randomization* *go to* [B]
		+ *Experimental laboratory studies* *go to* [C]
		+ *Clinical retrospective studies go to* [D]
		+ *Case series and case reports* *go to* [E]

**Table 2 (*continued*)**

|  |
| --- |
| **[A] Randomised Controlled Trials** |
| **Quality Items** | **Quality Items Met? (Yes/No)** |
| Was the assignment of patients to treatment randomised? (If NO, this study is not LOE 1, review the level of evidence) |  |
| Was the randomisation list concealed? |  |
| Were all subjects who entered the trial accounted for at its conclusion? |  |
| Were the subjectsanalysed in the groups to which they were randomized? |  |
| Were owners, investigators and evaluators "blinded" to which treatment was being received? |  |
| Aside from the experimental treatment, were the groups treated equally? |  |
| Were the groups similar at the start of the trial? |  |
| Is the relevance to the question being posed high (i.e. no confounding factors such as concomitant drug administration or intervention which could bias the relevance to the question, the study directly addresses the question)? |  |
| Is there a high likelihood that the administered drug (or intervention) will have clinically relevant analgesic effect? |  |
| Was conflict of interest stated?  |  |
| Was ethical/institutional review board approval of the study stated? |  |
| Was the statistical methodology (including sample size) of the study appropriate?If “NO” please justify: |  |
|  Number of quality items met |  |
| Quality of the study score (1, 2 or 3) *Score = 3 if the study is considered* ***Good*** *(number of quality item met: >8)**Score = 2 if the study is considered* ***Fair*** *(number of quality item met: 4 to 7)**Score = 1 if the study is considered* ***Poor*** *(number of quality item met: <4)* |  |
| **Methodological soundness domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 2 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 3. |

**Table 2 (*continued*)**

|  |
| --- |
| **[B] Clinical studies using concurrent controls without randomisation**  |
| **Quality Items** | **Quality Items Met? (Yes/No)** |
| Were comparison groups clearly defined? |  |
| Were outcomes measured in the same (preferably blinded) objective way in both groups? |  |
| Were known confounders identified and appropriately controlled for? |  |
| Was follow-up of subjects sufficiently long and complete? |  |
| Is the relevance to the question being posed high? |  |
| Is there a high likelihood that the administered drug (or intervention) will have clinically relevant analgesic effect? |  |
| Was conflict of interest stated?  |  |
| Was ethical/institutional review board approval of the study stated? |  |
| Was the statistical methodology (including sample size) of the study appropriate?If “NO” please justify: |  |
|  Number of quality items met |  |
| Quality of the study score (1, 2 or 3) *Score = 3 if the study is considered* ***Good*** *(number of quality item met: >6)**Score = 2 if the study is considered* ***Fair*** *(number of quality item met: 3 to 5)**Score = 1 if the study is considered* ***Poor*** *(number of quality item met: <3)* |  |
| **Methodological soundness domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 2 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 3. |

**Table 2 (*continued*)**

|  |
| --- |
| **[C] Experimental laboratory studies in target species**  |
| **Quality Items** | **Quality Items Met? (Yes/No)** |
| Is the study a randomised Controlled Trial (RCT)? |  |
| Is the study a randomised Trial (including RCT)? |  |
| Is the relevance to the question being posed high? |  |
| Is there a high likelihood that the administered drug (or intervention) will have clinically relevant analgesic effect? |  |
| Was conflict of interest stated?  |  |
| Was ethical/institutional review board approval of the study stated? |  |
| Was the statistical methodology (including sample size) of the study appropriate?If “NO” please justify: |  |
| Number of quality items met |  |
| Quality of the study score (1, 2 or 3) *Score = 3 if the study is considered* ***Good*** *(number of quality item met: >5)**Score = 2 if the study is considered* ***Fair*** *(number of quality item met: 3 to 4)**Score = 1 if the study is considered* ***Poor*** *(number of quality item met: <3)* |  |
| **Methodological soundness domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 2 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 3. |

**Table 2 (*continued*)**

|  |
| --- |
| **[D] Retrospective clinical studies using controls without randomisation**  |
| **Quality Items** | **Quality Items Met? (Yes/No)** |
| Were comparison groups clearly defined? |  |
| Were outcomes measured in the same objective way in both groups? |  |
| Were known confounders identified and appropriately controlled for? |  |
| Was follow-up of subjects sufficiently long available and complete? |  |
| Were criteria used to include subjects in or exclude subjects from the study clearly stated? |  |
| Is the relevance to the question being posed high? |  |
| Is there a high likelihood that the administered drug (or intervention) will have clinically relevant analgesic effect? |  |
| Was conflict of interest stated?  |  |
| Was ethical/institutional review board approval of the study stated? |  |
| Was the statistical methodology (including sample size) of the study appropriate?If “NO” please justify: |  |
|  Number of quality items met |  |
| Quality of the study score (1, 2 or 3) *Score = 3 if the study is considered* ***Good*** *(number of quality item met: >7)**Score = 2 if the study is considered* ***Fair*** *(number of quality item met: >4 to 6)**Score = 1 if the study is considered* ***Poor*** *(number of quality item met: <3)* |  |
| **Methodological soundness domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 2 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 3. |

**Table 2 (*continued*)**

|  |
| --- |
| **[E] Clinical studies without controls**  |
| **Quality Items** | **Quality Items Met? (Yes/No)** |
| Were outcomes measured in an objective way? |  |
| Were known confounders identified and appropriately controlled for? |  |
| Was follow-up of subjects sufficiently long and complete? |  |
| Is the relevance to the question being posed high? |  |
| Is there a high likelihood that the administered drug (or intervention) will have clinically relevant analgesic effect? |  |
| Was conflict of interest stated?  |  |
| Was ethical/institutional review board approval of the study stated? |  |
| Was the statistical methodology (including sample size) of the study appropriate?If “NO” please justify: |  |
| Number of quality items met |  |
| Quality of the study score (1, 2 or 3) *Score = 3 if the study is considered* ***Good*** *(number of quality item met: >6)**Score = 2 if the study is considered* ***Fair*** *(number of quality item met: 3 to 5)**Score = 1 if the study is considered* ***Poor*** *(number of quality item met: <3)* |  |
| **Methodological soundness domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 2 should be transferred to the *CATRAS Table of Results.* Then proceed to Step 3. |

**Table 2 (*continued*)**

STEP 3. Domain 3: Grading of the pain assessment tool (PAT)

1. The original or revised literature describing the development, refinement or validation of the particular PAT being graded should be reviewed and used to answer the items within this domain. In the “Source” column, cite the identified literature which justifies the ascribed item score. The literature must satisfy reviewers that the PAT being graded was designed for assessment of pain in the same context as which it is being utilised in the study being evaluated by the CATRAS (i.e. the same species and the same type of pain).

|  |  |  |  |
| --- | --- | --- | --- |
| **Question** | **Scoring Legend** | **Score** | **Source\*** |
|  |  |
| **PAT development: Item selection and content validation** |
| **1.1** | Does the PAT assess multiple important indicators or dimension of pain? Nb. Each tool receives 2 points if it contains both ***psychomotor/visual assessment*** of pain (e.g. posture, comfort, activity, demeanour) and ***interactive assessment*** of pain (e.g. response to palpation of potential pain loci), 1 point, if it contained only ***psychomotor/visual assessment*** or only ***interactive assessment*** of pain, and 0 points if it did not cover either of these dimensions/indicators of content validity. | **2:** PAT covers all important items or dimensions**1:** PAT covers important items or dimensions to a moderate extent**0:** PAT does not seem to cover important items or dimensions |  |  |
| **1.2** | Was the process of item selection described? | **2:** PAT was developed for a specific population, using a theoretical or conceptual framework, or a qualitative approach was used (e.g. consultation with clinicians)**1:** PAT was developed based on literature review only**0:** No information is provided about item selection |  |  |
| **1.3** | Was content evaluated by experts (content validation)? | **2:** Content was evaluated by experts in the field, and Content Validity Index (CVI) were calculated for each item included in the PAT**1:** Content was evaluated by experts, but no CVI is reported**0:** No information is provided about content validation  |  |  |
| **1.4** | Are limitations of some items presented or discussed? | **1:** No limitations or if any limitations, they are presented and item modifications have been made or precautions have been stated**0:** No information is provided |  |  |
| Subtotal – PAT development (0-7) |  |  |
| Subtotal weighted score – PAT development (0-2) |  |
| **PAT testing: Reliability** |
| **2.1** | Was internal consistency (Cronbach’s α coefficient) of the PAT calculated? | **2:** 0.70 < α < 0.90**1:** 0.60 < α ≤ 0.70 or α ≥ 0.90**0:** α ≤ 0.60 or no information provided |  |  |
| **2.2** | Was inter-rater reliability (Cohen’s kappa coefficient if quantitative) calculated? | **2:** kappa > 0.60 or intra-class correlation coefficient (ICC) > 0.80**1:** 0.60 ≥ kappa > 0.40 or 0.60 < ICC ≤ 0.80**0:** kappa ≤ 0.40, ICC ≤ 0.60 or no information provided |  |  |
| **2.3** | Was inter-rater reliability tested with other raters besides the research team? | **1:** Other raters than the research staff members were involved**0:** Only research staffmembers were involved |  |  |
| **2.4** | Was intra-rater reliability tested?Optional – to be examined if ICC < 0.80 for inter-rater reliability. | **2:** kappa > 0.60 or ICC > 0.80**1:** 0.60 ≥ kappa > 0.40 or 0.60 < ICC ≤ 0.80**0:** kappa ≤ 0.40, ICC ≤ 0.60 or no information provided |  |  |
| Subtotal – PAT development (0-5 or 0-7 if intra-rater reliability testing required) |  |  |
| Subtotal weighted score – PAT development (0-6) |  |
| **PAT testing: Construct validity** |
| **3.1** | What is the total of participants for the purpose of testing the PAT? | **2:** *N* > 50**1:** 20 < *N* ≤ 50**0:** *N* ≤ 20 |  |  |
| **3.2** | Criterion validation: Was the PAT correlated with the current “gold standard” or with a measure renowned in the field of interest if no “gold standard” has been established? | **2:** *r* > 0.60 with the comparison measure**1:** 0.40 < *r* ≤ 0.60**0:** *r* ≤ 0.40 or no information provided |  |  |
| **3.3** | Criterion validation: Was the sensitivity of the PAT calculated? | **2:** Sensitivity > 80%**1:** 60% < Sensitivity < 80%**0:** Sensitivity < 60% or no information provided |  |  |
| **3.4** | Criterion validation: Was the specificity of the PAT calculated? | **2:** Specificity > 80%**1:** 60% < Specificity < 80%**0:** Specificity < 60% or no information provided |  |  |
| **3.5** | Sensitivity to change: Was the PAT able to differentiate between different situations (e.g. between pain and no pain; before and after the administration of an analgesic; changes in health status of the patient)? | **2:** A significant difference was found**1:** A difference was found but was not significant**0:** No difference was found or no information is provided.  |  |  |
| Subtotal – PAT development (0-10) |  |  |
| Subtotal weighted score – PAT development (0-8) |  |
| **PAT Feasibility** |
| **4.1** | Is the PAT easily applied to the clinical setting? | **1:** PAT is short and manageable **0:** PAT is more complex or no information is provided |  |  |
| **4.2** | Are directives of use of the PAT clearly described? | **1:** Yes, directives of use including the scoring method are described**0:** No information about directives of use is provided |  |  |
| Subtotal – PAT development (0-2) |  |  |
| Subtotal weighted score – PAT development (0-2) |  |
| **PAT Relevance** |
| **5.1** | Was the relevance of the PAT or impact of its implementation in patient outcomes examined? | **1:** PAT is considered to be useful and relevant to practice by more than 80% of clinicians; use of the PAT yielded a significant change into practice (e.g. better use of medication, increase in patients’ assessments)**0:** PAT is not considered to be useful/relevant to practice by more than 20% of clinicians; use of the PAT did not yield a significant change in practice or no information provided |  |  |
| Subtotal – PAT development (0-1) |  |  |
| Subtotal weighted score – PAT development (0-2) |  |
|  |
| Total weighted score (0-20) |  |
| **Standardisation of results** |
| **Total weighted score** **(range)** | **Calculation of the PAT score** (*calculation based on total weighted score*) | **PAT score**  |
| 0 to 11.9 | PAT score = total weighted score / 12 |  |
| 12 to 14.9 | PAT score = 1 + (total weighted score - 12) / 3  |
| 15 to 20 | PAT score = 2 + (total weighted score - 15) / 5  |
| **Grading of the PAT domain score (%)** *Quality score divide by 0.03* |  |
| The **domain score (%)** achieved for Domain 3 should be transferred to the *CATRAS Table of Results.* |

**Table 2 (*continued*)**

## \*Source (references) – Grading of the PAT

**Table 2 (*continued*)**

Summary of Results

|  |
| --- |
| CATRAS Table of Results  |
| Reviewed article:  |
| Does the article provide a positive answer to the PICO question? (YES/NO) |  |
| Domain scores (%)*The domain scores reflect the strength of the answer to the PICO question* |
| Domain 1. Level of Evidence |  |
| Domain 2. Methodological Soundness |  |
| Domain 3. Grading of the Pain Assessment Tool |  |
| Radar Chart (optional) |  |