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**PRAGMATIC EVALUATION OF AN OBSERVATIONAL PAIN ASSESSMENT SCALE IN
THE EMERGENCY DEPARTMENT: THE PAIN ASSESSMENT IN ADVANCED
DEMENTIA (PAINAD) SCALE**

Running title: EVALUATION OF THE PAINAD IN ED

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AUTHORSHIP

MF conceived, designed and conducted the study and secured funding. RE analysed the data. RE and MF prepared and approved the manuscript.

ABSTRACT

Background

Pain assessment is challenging in older people with cognitive impairment who present to the emergency department and may result in suboptimal management. Therefore the usefulness of the Pain Assessment in Advanced Dementia (PAINAD) tool for older people with cognitive impairment presenting with a painful injury was evaluated.

Methods

In this multi-centre observational sub-study older people (≥ 65 years) suspected of a long bone fracture were screened for cognitive impairment using the Six Item Screening (SIS) tool. Patients with SIS ≤ 4 were assessed using the PAINAD. Descriptive and correlation statistical analyses were performed. Cronbach's alpha was used to estimate the reliability of the PAINAD.

Results

This predominantly female (63%) sample had a mean age of 85.5 ± 7.5 years and a moderately urgent Australian Triage code (mode: 3). Median pain intensity was low (numerical reporting scale: 5.5[3.0-8.0]). Median PAINAD score was 'mild' (1.0[0.0-3.2]) with wide variability (range: 0 to 9). The PAINAD demonstrated good reliability (Cronbach's $\alpha = 0.80$). Most PAINAD items appeared worthy of retention.

Conclusions

The PAINAD has potential as an effective pain assessment tool for older people with cognitive impairment in emergency departments. Strategies such as partnering with carers and family to collaboratively assess pain require further investigation in this setting.

KEYWORDS

Aged, emergency nursing, acute pain, cognitive dysfunction, dementia, PAINAD

PRAGMATIC EVALUATION OF AN OBSERVATIONAL PAIN ASSESSMENT SCALE IN THE EMERGENCY DEPARTMENT: THE PAIN ASSESSMENT IN ADVANCED DEMENTIA (PAINAD) SCALE

INTRODUCTION

Approximately 20% of people presenting to emergency departments (ED) in developed countries are 65 years or older¹⁻⁴. Nearly a third of **these** patients over 65 years have a condition associated with cognitive impairment (CI)⁴⁻⁶. People with CI such as dementia experience particular challenges communicating their pain experience⁷. This may lead to suboptimal pain management and adverse consequences such as confusion, agitation, and family/carers distress increased risk of falls and associated injuries⁸⁻¹¹. Pain management for people with CI is a regular event in ED but international reports indicate that suboptimal pain management is common¹²⁻¹⁶¹⁷.

There is no universally accepted instrument validated for patients who are unable to self-report pain in ED^{18, 19}. As a result emergency clinicians largely rely on patients self-reporting pain intensity²⁰⁻²². Often people with moderate to severe CI are incapable of self-reporting pain^{14, 19}. In order to better manage pain for people with CI, clinicians need an objective pain assessment method.

There are a number of observational pain instruments that have been developed for use in intensive care units and residential aged care settings²³. In North America the Pain Assessment in Advanced Dementia (PAINAD) is recommended for acute pain assessment for people who are unable to self-report²⁴. However, while PAINAD has been tested in acute and dementia in-patient wards in many countries^{22, 25-28} it has not been specifically tested in ED. One pilot study did demonstrate an improvement in time to the administration of analgesia when the PAINAD scale was used for people with dementia who presented with a long bone fracture²⁹. Furthermore emergency nurses in an Australian study selected the PAINAD from five tools as the most objective measure of pain in older people with CI compared to subjective clinical judgement¹⁸. **A** systematic review identified that four adult observational pain assessment instruments, including the PAINAD, developed to assist people who are unable to self-report pain were superior to many others and were potentially appropriate for use in ED³⁰.

Despite limited evidence of the validity and reliability of the PAINAD^{31, 32} it has been recommended as an appropriate ED pain assessment tool in people with CI³³. The only published evaluation of PAINAD in an Australian setting was conducted in 2003 in an aged care facility²².

In this study we report on findings from a larger interventional (RCT) study in which the impact of an observational pain assessment dementia tool on time from ED arrival to first dose of analgesic medicine was examined. The findings of this RCT have been published elsewhere [citation removed for purposes

of blind review].

The purpose of this sub-study was to evaluate the usefulness of the PAINAD in ED. The specific were to: 1) assess pain intensity level using the PAINAD scale and Numeric Rating Scale (NRS) in the ED for older people with CI and a suspected long bone fracture 2) examine the reliability and validity of the PAINAD to assess pain in older patients with CI in ED and 3) explore the clinical usefulness of the PAINAD i.e. the relationship between pain intensity and analgesia administration.

METHOD

Study sites and participants

This observational sub-study was undertaken in four hospital EDs in metropolitan Sydney, Australia, and included one large teaching hospital and one district (regional) hospital which were interventional sites for the main study. The total number of presentations to the EDs of these health facilities exceeded 168,000 in the year in which the study was conducted. Approximately 20% were aged ≥ 65 years. A convenience sample of patients aged ≥ 65 years with suspected long bone fracture was assessed using the PAINAD scale and NRS.

Procedures

Nurses working in the study sites attended an education program which included pain assessment and recognition, use and case examples in using PAINAD and how to screen for CI using the Six Item Screener (SIS)³⁴. The education program was repeated and site champions consolidated the education to ensure that all emergency nurses received the information.

During the study triage* nurses assessed pain intensity using the NRS according to usual practices. Once the patients' triage categories were assigned the nurse responsible for continuing the patients' treatment screened all patients for CI using the SIS (Range: 0 to 6)³⁵. Patients with a SIS score ≤ 4 (cut-off for moderate/severe CI) were assessed for pain only using the PAINAD. One NRS score was undertaken by the triage nurse and the ED nurse responsible for continuing the patients' treatment obtained a PAINAD score within 5-10 minutes of the first pain assessment. It was usual nursing practice in the study sites for the nurse responsible for the continuing care of the patient in the ED to conduct an independent health assessment (including pain assessment) separate from the triage nurse. In other words although nurses were not formally blinded to the NRS pain score assigned by the triage nurse, it was routine for nurses to document their own health assessment. In this pragmatic study few nurses would have been aware of the NRS score before conducting their own PAINAD assessment.

Measures

The PAINAD scale was developed following a review of existing pain assessment instruments²². The PAINAD is a brief 5-item scale for physiological and psychological pain symptom assessment; breathing, vocalization, facial expression, body language and consolability. The maximum score is 10; each item is assigned a range of 0 indicating absence of pain behaviour to 2 indicating the presence of behaviour suggestive of severe pain^{28, 31, 32}. This is a non-linear scale but a total score >4 is suggestive of severe pain. The instrument has been shown to be a reliable indicator of pain intensity in people with dementia internationally^{22, 25-28, 31, 32}.

¹¹ Triage definition: process for categorising injured people into groups based on their need for or likely benefit from immediate medical treatment; triage nurse is a health professional specifically trained in the technique of categorising patients according to their medical needs

The 11-point NRS (0-10, where 0 = no pain and 10 = worst pain imaginable) is used extensively in emergency practice. Conventional NRS pain categories are: mild = 1-3, moderate = 4-6 and severe ≥ 7 . It may be used to assist patients to rate pain verbally, as was the case in the current study, or in conjunction with a graphical scale (numerical visual analogue scale). The NRS has demonstrated high test-retest reliability and was shown to be highly correlated with the pain visual analogue scale (VAS): $r = 0.94$ (95% CI: 0.93 to 0.95) in a cohort of adult patients presenting to ED with acute pain³⁶.

Data analysis

Descriptive statistics were used to summarise the characteristics of the sample and the NRS scores obtained at triage and the PAINAD scale scores (medians and interquartile ranges). Analyses were performed using the pain scores obtained at initial presentation. The reliability (internal consistency) of the PAINAD scale and items was estimated using Cronbach's alpha. This included the Cronbach's alpha for the PAINAD if each item was deleted. Construct validity was explored using known-groups technique for the CI cohort (SIS score ≤ 4 and or/a health history of CI) and the assumption that long bone fractures of the lower limb would yield higher pain intensity scores. The pain intensity level of patients with a fractured femur including neck of femur (NOF) were compared with patients' pain intensity with other injuries using the Wilcoxon Signed Ranks Test ($p = 0.891$). As there was no difference between groups the judgement of the construct validity of the PAINAD was confined to an examination of the correlation of the PAINAD score with the NRS score using Pearson's R, for patients with a SIS score of ≤ 4 . The clinical usefulness of the PAINAD was explored pragmatically using descriptive statistics i.e. the number of patients for whom pain was assessed using the PAINAD in addition to the relationship between PAINAD score and the administration of analgesia. Correlation analyses (Pearson's R) were performed for pain intensity and type and time of analgesia. In addition Chi square tests were used to compare analgesia provided to patients for whom the PAINAD score was ≥ 5 and < 5 (and for ≥ 7 and < 7). In order to confirm or refute this potential relationship Chi square tests were performed to compare patients for whom the NRS score was ≥ 5 and < 5 . Statistical analysis was conducted using Excel and SPSS v24 software (Released 2016. IBM SPSS

Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.). Cohen's criteria were used to determine the magnitude of correlations: small – $r=0.10$; moderate $r=.30$ or strong $r=.50$.

Ethical Approval

A New South Wales (NSW) lead Health District Human Research Ethics Committee (HREC) (approval no. 1212-430M) approved the study. All data were aggregated and de-identified (and were not re-identifiable) before analysis. The potential risk to those involved in the study was considered low to negligible.

RESULTS

Demographic and clinical characteristics of the sample

The mean age of the sample ($n = 181$) was 85 years and two thirds were female. The most frequent (mode) triage category was 3 ($n = 90, 48\%$). The most common reason for presenting was after a fall and the most frequent diagnoses were fractured NOF, fractured shaft of femur and fractured humerus followed by soft tissue injury. Nearly half of the sample were injured while in a nursing home ($n = 84, 47\%$) and a large proportion were injured in their own home ($n = 78, 44\%$). This was reflective of the patients' place of residence. The majority arrived by ambulance ($n = 169, 93\%$). There were 139 patients with a SIS score of ≤ 4 (Table 1).

Pain intensity: PAINAD and NRS scores

Both the NRS and the PAINAD instruments were administered at initial presentation (triage) for 128 patients. At initial presentation the median NRS pain intensity level was moderate (5.5 [3.0-8.0]) and using the PAINAD it was mild (1.0 [0.0-3.2]). The median PAINAD score for patients whose SIS score was ≤ 4 ($n = 139$) was also mild (1.0 [0.0-4.0]) but was moderate when assessed with the NRS. Descriptive data for pain intensity scores at initial presentation are provided in Table 2.

Pain intensity for all patients using the NRS decreased over the time between initial presentation and reassessment by the nurse treating the patient in ED (median 5.0, [2.0-8.0] vs 2.0, [0.0-4.0], $p<0.001$) but the PAINAD score did not show an appreciable change (median 1.0, 0.0-3.2, vs 2.5, 1.0 – 4.0, $p = 0.797$).

Reliability and validity of the PAINAD tool in ED

The inter-item correlations of the PAINAD items were acceptable (> 0.40) (Table 3). The internal reliability, specifically internal consistency, of the PAINAD was acceptable for the entire sample and for patients with a SIS score of ≤ 4 (both Cronbach's $\alpha = 0.80$). For the patient cohort with SIS score of ≤ 4 ($n = 139$) four PAINAD items were worthy of retention resulting in a decrease in the alpha level for the total PAINAD if deleted. The facial item was the exception with the alpha level reaching 0.84 if it was deleted. For patients with a SIS score of > 4 ($n = 45$), four PAINAD items were worthy of retention with the exception of the vocalization item ($\alpha = 0.81$).

A PAINAD score was recorded for all patients with a SIS score ≤ 4 and a fractured femur but an initial NRS score was recorded for 85% ($n=69$) of these patients. The pain intensity score was not significantly different for these patients who presented with a fractured femur ($n=81$), NRS median 5.0 (1.5-7.0) and PAINAD median 1.0 (0.0-4.0), compared to other injuries ($n=56$), NRS median 5.0 (3.0-8.0) and PAINAD median 1.0 (0.0-4.0) ($p = 0.922$ and 0.891 , respectively) so no further analysis for construct validity was performed using this strategy.

Correlation of the total PAINAD score with the NRS score was moderate at $r = 0.39$ for all observations and $r = 0.42$ for patients with CI ($n = 128$). A scatterplot including the R^2 for these data are presented in Figure 1.

Clinical usefulness of the PAINAD

The PAINAD score was documented for all the patients in the cohort ($n = 181$, 100%) but a NRS score was recorded for 70% [$n = 128$] of the sample on presentation to ED. There was little relationship between pain intensity and analgesia administration or type of analgesia; analgesia was administered regardless of pain intensity level: Pearson's R was -0.019 and -0.006 respectively. The majority of patients received some analgesia in ED ($n = 136$, 75%) and where this was reported more than half were opioids ($n=72$ of 135 , 53%). It appeared that the level of pain intensity influenced the likelihood of a patient receiving analgesia for PAINAD score ≥ 5 and < 5 and ≥ 7 and < 7 in the ED. The relationship between these variables was significant, $X^2(1, N = 180) = 3.84$, $p < .05$, however a higher

proportion of patients received analgesia whose pain intensity was < 5 or < 7 (75% and 70% respectively) than ≥ 5 or ≥ 7 . Similarly the relationship between NRS score ≥ 5 and < 5 and likelihood of analgesia administration was significant; $\chi^2 (1, N = 151) = 32.40, p < .01$ but the relationship was in the different direction; 18% of patients whose NRS score was < 5 received analgesia whereas 46% of patients whose NRS was ≥ 5 received analgesia.

DISCUSSION

This cohort of older people with long bone injuries was predominately female and categorised as having a moderately urgent condition. The median pain intensity score was low given the large proportion of patients who presented with femur fractures. Long bone fractures usually result in moderate to severe intensity pain self-reports i.e. NRS > 6 ³¹. The median PAINAD score for all patients was 'mild' with variability in scores. This suggests that pain intensity assessment in people with CI is complex and problematic to assess.

The overall PAINAD scale demonstrated good internal consistency (reliability) for both CI patients and patients who were considered to be cognitively competent. The items of the PAINAD appeared worthy of retention with the exception of the facial item which may require further modification in order to improve the internal consistency of the overall scale for use in the ED. Our evaluation indicates that the PAINAD scale has great potential as an effective pain assessment tool for use in the ED for people with CI. In addition the proportion of patients whose pain intensity was not recorded using the NRS at their initial presentation in contrast to the universal use of the PAINAD particularly suggests that the PAINAD was more appropriate for use in this cohort.

Arguably the descriptors 'sad, frightened, frown' and 'facial grimacing' are too generic to be used specifically to detect pain in people with CI who are assessed and treated in an unfamiliar environment. These facial characteristics in the ED setting may be features of distress and not necessarily a response to pain. This contrasts with the findings of studies conducted in residential nursing homes in which the facial item has been reported to be clinically useful but the reliability of the breathing item questioned³⁷⁻³⁹.

A notable finding in our study was that the PAINAD pain intensity level of our cohort differed from other cohorts with similar injury characteristics. For example the median PAINAD score for older adults (mean age 78 years) who underwent surgical repair (including internal fixation) of fractured femur was 7.0 (5.0-8.0)³¹ but the median pain intensity score for our cohort of older people with fractured femur was 1.0 (0.0-4.0). This finding also contrasts with results of a UK study in which the utility of the PAINAD to acutely identify pain in people with dementia in nursing homes found that while the PAINAD was highly sensitive (92%) it resulted in high numbers of false positives i.e. people who were assessed to have pain were later thought to be distressed for other reasons²⁵. There are also known floor effects inherent in using the PAINAD to assess pain for people at rest. The scale is known to be most effective when pain is assessed immediately after movement³⁹ however, this would be morally and ethnically wrong in the setting of traumatic injury.

The relatively low pain intensity levels might suggest that clinicians require further training in its use. However a recent literature review and secondary data analysis indicates that the appropriate cut off PAINAD score for a pain treatment trial is 2, a score of 1 indicates the possible presence of pain and scores above 4 indicate moderate to severe pain³⁷.

In an environment in which there is pressure to complete the episode of care (to adhere to strict 4-hour mandatory timelines for ED discharge in Australia) there is little opportunity to explore baseline behaviour for older patients which is not the case in settings where the PAINAD has been previously used. A method of possibly maximizing the potential of the PAINAD in this time pressured environment would be to partner with patients and carers/family members. The presence of care giver has been shown to positively influence pain management in patients who are unable to communicate verbally¹⁶. Therefore a collaboration in which family members could use the PAINAD as a prompt to alert ED clinicians to reassess the patient if the pain had not improved or worsened is one potential solution. Regardless, it is unlikely that the PAINAD or other observational tools⁴⁰ can be used in isolation; a comprehensive assessment approach is required to manage pain effectively in this vulnerable patient group³⁹. A non-linear approach to interpretation is therefore advised.

There are a number of limitations that need to be acknowledged in performing this pragmatic evaluation. Despite our efforts to provide training about the correct use of the PAINAD and pain assessment in the setting of CI for all nurses it is likely that some nurses did not receive this training. Many different nurses performed the pain intensity assessments therefore the inter-rater reliability may have been low. In addition our exploration of the clinical usefulness of the PAINAD scale with regard to the relationship between pain intensity level and likelihood of analgesia administration was influenced by the high proportion of patients who received analgesia and who were allocated low PAINAD scores. However this information adds to our knowledge of the potential cut-off point for a pain treatment trial; clinicians either influenced by the potential for the injury to cause pain or intuitively judged behaviour as indicative of pain.

In addition there were limited contextual data collected which related to potential confounding factors which may affect the experience of pain in this cohort of older people e.g. presence of chronic pain conditions such as arthritis. Temporal changes in patient condition may have also influenced the pain intensity score as the NRS and PAINAD scores were recorded consecutively rather than concurrently. However it is unlikely that this influenced the outcome significantly because the scores were obtained within 5 to 10 minutes of each other and before analgesia was administered in ED on most occasions.

CONCLUSIONS

This study provides evidence that PAINAD may be a useful adjunct to assessing pain in the older person in the ED. Standardised pain assessment tools that are specific to older people with CI should be implemented widely throughout emergency departments albeit as an adjunct to other strategies for assessing pain behaviours such as collaborating with carers/family members. A timely pain assessment and appropriate analgesic response by ED clinicians can lead to positive health outcomes and reduce distress for older people with CI. Reducing the gap between available pain management and emergency care practice is critically important if outcomes of all older people with CI are to be improved. The study and its findings could be replicated in different health care settings, including intensive care and acute orthopaedic/trauma hospital wards. The greater (and correct) use of

specifically designed pain assessment tools for patients with CI experiencing pain could be standardised to ensure best practice, quality and safety.

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WHAT IS KNOWN ABOUT THE TOPIC?

Pain assessment and management can be improved for older people with cognitive impairment who present to **the emergency department**. Pain assessment and therefore management is particularly challenging for emergency clinicians treating these patients as there is a paucity of objective pain measures for this patient cohort treated in the emergency setting. The PAINAD is **a** potential solution for assessment but has not yet been tested specifically in the emergency department.

WHAT THIS PAPER ADDS OR CONTRIBUTES?

The study adds to the information available about the clinical utility of the PAINAD and its specific use in **the emergency department**. In particular the PAINAD may be a helpful adjunct to pain assessment in this cohort and setting but some behavioural items contained within may not be a reliable feature of pain. A non-linear comprehensive assessment approach may be required in which carers and families collaborate with clinicians to identify pain behaviours in the PAINAD for individual patients.

Tables

Table 1 Selected demographic and clinical characteristics (n = 181)

Characteristic	Statistic
Male, n (%)	50 (37)
Age, years, mean (SD ^a) [Range]	85.5 (7.5) [63 – 100]
Past medical history of CI ^b , n (%)	70 (39)
Australasian Triage Score ^c , mode (range)	3 (2 -4)
Six Item Screener score, median [IQR ^d] (n≤ 4)	1 [1 -4] (139)
Presentation after a fall, n (%)	167 (92)
Diagnosis (injury), n (%)	
Fractured neck of femur	83 (46)
Fractured femur	15 (8)
Fractured humerus	15 (8)
Soft tissue injury	12 (6)
Other	56 (32)
Prehospital analgesia (ambulance), n (%)	94 (52)
Admitted for treatment in hospital, n (%)	153 (85)
Time to analgesia ^e , minutes, median [IQR]	90.0 [54.3 – 166.5]

Notes: ^aStandard deviation, ^b cognitive impairment, ^c a specific process for categorising injured people into groups based on their need for or likely benefit from immediate medical treatment used in Australia, ^d interquartile range, ^e from time of presentation to ED to first dose of analgesia in ED

Table 2: Initial (at presentation) pain intensity scores

Descriptive statistic	NRS ^a score (all, n=128 of 181)	PAINAD score (all, n=181)	NRS score (SIS ≤4, n=89 of 139)	PAINAD score (SIS ≤4, n=139)
Median (IQR ^b)	5.5 (3.0-8.0)	1.0 (0.0-3.2)	5.0 (2.0 -8.0)	1.0 (0.0 -4.0)
Mode (Min, Max)	5 (0, 10)	0 (0, 9)	0 (0, 10)	0 (0, 9)
Severe pain (≥7), n (%)	63 (35)	10 (6)	40 (29)	9 (6)

^a numerical reporting scale, ^b interquartile range

Table 3: inter-item correlations for all items and total score of PAINAD items

ALL patients (n = 181)						
	Breathing	Vocalisation	Facial	Body	Consolability	PAINAD score
Breathing	1	0.55	0.48	0.42	0.47	0.70
Vocalisation		1	0.53	0.49	0.62	0.81
Facial			1	0.55	0.53	0.83
Body				1	0.53	0.76
Consolability					1	0.80
PAINAD score						1
For patients with a SIS ^a score of ≤ 4 (n = 139)						
	Breathing	Vocalisation	Facial	Body	Consolability	PAINAD score
Breathing	1	0.55	0.49	0.44	0.45	0.70
Vocalisation		1	0.56	0.50	0.60	0.81
Facial			1	0.59	0.64	0.83
Body				1	0.54	0.78
Consolability					1	0.82
PAINAD score						1

Notes: inter-item correlations provided for all items and total score, ^a Six Item Screener