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Review

Frequency and use of pain assessment tools implemented in randomized controlled trials in the adult burns population: A systematic review

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ABSTRACT

Introduction: Pain continues to be an ongoing issue of concern in adult burn patients. Inadequate pain assessment hinders meaningful research, and prevents the optimal management of burn pain. The objective of this study was to examine the content of existing research in burn pain with the frequency and context of pain assessment tool use in randomized clinical trials in order to further inform their use for future researchers and clinicians.

Methods: Electronic searches of MEDLINE, CINAHL, EMBASE and The Cochrane Library databases from 1966 onwards were used to identify English articles related to clinical trials utilising pain assessment in adult burns patients.

Results: The systematic literature search identified 25 randomized clinical trials utilising pain assessment tools. Unidimensional pain assessment tools were most frequently used pain assessment tools, with multidimensional tools used less often, despite the multifaceted and complex nature of burn pain.

Conclusion: The review highlights the lack of consistency of pain assessment tool use in randomized clinical trials with respect to managing burn pain. We recommend a broader but consistent use of multidimensional pain assessment tools for researchers undertaking clinical trials in this field. The review supports the need for an international expert consensus to identify the necessary critical outcomes and domains for clinicians and researchers undertaking further research into burn pain.

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1. Background

Pain is one of the most common symptoms in adult burn patients and continues to be an ongoing issue of concern [1]. The pathophysiological process that follows burns to tissue and nerves is complex and includes activation of voltage gated sodium, calcium and acid sensing ion channels, leading to intense and repeated activation of nociceptors. There is also a localized and widespread neuro-inflammatory process that includes mast cell degranulation, and the release of a host of pro-nociception mediators and bio amines like substance P and calcitonin gene-related peptide (CGRP), histamine, 5-Hydroxytryptophan (5-HT), bradykinin, prostaglandins and nerve growth factors leading to peripheral sensitization of Aδ and C sensory neurones. This ''peripheral sensitization'' is associated with a localized area of allodynia and hyperalgesia and is generally considered a reversible process which settles down with a reduction in tissue inflammation and healing. However if the peripheral process of nociceptor activation is ongoing or the area of inflammation in widespread and reoccurring, such as in burns, the ongoing barrage of sensory afferents to the Central Nervous System (CNS) (through the dorsal horn of the spinal cord), sets up a potentially irreversible process within the CNS, called ''central sensitization''. Central sensitization involves the superficial layers of the dorsal horn and includes repeated activation of calcium calmodilin kinases and second messengers which leads to the upregulation of receptors like *N*-methyl *D*-aspartate (NMDA) and Neurokinin 1 (NK1). The results of central sensitization including the recruitment of surrounding ''normal'' sensory neurones leads to firing spontaneously or at lower than normal thresholds. This leads to spontaneous pain in surrounding normal tissues and pathological secondary hyperalgesia in surrounding uninjured tissue [2,3].

Uncontrolled acute burn pain has been shown to increase the incidence of mental health disorders such as depression and post-traumatic stress disorder [4], and to correlate with the incidence of suicide following discharge from hospital [5]. Inflammatory process, infection and repeated painful stimuli and tissue trauma may also give rise to neuroplastic adaptations throughout the central nervous system. For example at the level of the dorsal horn of the spinal cord, pain afferent sensory impulses undergo facilitation and amplification to a given stimulus, which contributes to the generation and maintenance of persistent or chronic pain [3].

Chronic pain in burns patients can be difficult to control and often requires a multidisciplinary approach, including the use of multimodal pharmacological and non-pharmacological modalities [6]. The mainstay of pharmacological burn pain management has been opiate treatment, which in turn has been shown to have hyperalgesic properties, adding a further level of complexity to an already challenging clinical problem [7].

Reliable and accurate assessment of pain is necessary and important to ensure patients experience safe, effective and individualized pain management. The assessment of acute pain should include a history and physical examination supplemented with one or more self-report measures of pain that are sensitive, accurate, reliable, reproducible, valid and useful for both clinical and experimental situations [8]. There are many different forms of pain assessment tools currently available to the burns treating team. These range from the recording of patient-subjective experiences [9], unidimensional tools such as verbal descriptive scales, numeric rating scales and visual analogue scales, to more complex and multidimensional tools such as the McGill Pain Questionnaire [10], the Brief Pain Inventory (BPI) [11] and the abbreviated Burn Specific Pain Anxiety Scale (BSPAS) [12].

In assessing the relative effectiveness of various treatment regimes in clinical practice and research, randomized controlled trials (RCTs) are considered the gold standard [13,14]. As variability in outcome measures across clinical trials hinders evaluation of the efficacy and effectiveness of treatment, dedicated efforts over the past decade have been undertaken to establish core outcome domains and reporting criteria to be considered when designing pain-related clinical trials [15–18].

To date, the frequency and context of pain assessment tools used in RCTs involving burns patients has not been addressed. Evidence-based information regarding the content of pain assessment tools is scarce in this population. The complexity and importance of pain assessment, and the need for future meta-analyses to best inform clinicians with

respect to management of pain in burn patients necessitates the need for a systematic review to examine the content of existing RCTs evaluating pain assessment tool use in this context. In doing so, we hope to explore limitations of previous research examining adult burn pain assessment, and suggest how this may be improved in the future.

2. Materials and methods

2.1. Literature search strategy

A structured literature search was performed in MEDLINE, CINAHL, EMBASE, and The Cochrane Library from 1966 onwards using the keywords related to ''burns'' and ''thermal injury'' with ''pain'', ''rating'', ''assessment'' or ''tool''. In addition to the automated search strategies, reference lists of related journal articles, key journals and existing reviews were hand searched for additional trials. All searches were limited to articles in English.

2.2. Study selection criteria

Included studies were RCTs using patients that were allocated to an intervention aimed at minimizing pain associated with their burn and which referenced at least one pain assessment tool (one that explicitly referred to pain, was related to pain or included pain in the wording or questionnaire's guidelines). We excluded all non-randomized approaches (i.e. quasi-randomized trials, cohort, case-control or observational studies), studies that used psychometric or quality-of-life assessments only, studies referring to qualitative pain inventories and tools and studies that focused on patients less than 18 years of age or with psychiatric disorders or cognitive impairments.

2.3. Data extraction

Three authors (PM, JW and CO'L) extracted the data from the same studies independently. We extracted data on the following information: characteristics of the study (citation, region, and sample size), characteristics of study design, participants, type of pain considered, intervention, reporting of patient recruitment and progress through the study, and use of pain assessment tools.

2.4. Classification of pain

Whilst there are many classifications of pain of which randomized controlled trials can investigate, for the purposes of this review, pain was classified as either acute (pain assessed within two weeks of injury), chronic (pain assessed after two weeks of injury) or procedural (pain predominantly assessed during interventions or periods of physical activity expected to result in an increasing painful stimuli).

2.5. Data analysis management and synthesis

All data were managed and analysed using Microsoft Excel and STRATA 9.2 (Stratasoft Corporation, TX, USA) software respectively. A narrative approach was adopted in order to synthesize the findings of the included studies.

3. Results

The initial search strategy identified a total of 2841 studies for potential inclusion. Independent scrutiny of the titles and abstracts identified 82 potentially relevant articles, of which 22 satisfied the inclusion criteria. A further three studies which were known to the authors and published after the search were included. We excluded 60 studies because they failed to meet the methodological criteria for an RCT or included paediatric or non-burned populations. Therefore, a total of 25 studies formed the basis of this review.

3.1. Study design characteristics

The study characteristics of the included RCTs are shown in Table 1. Randomized controlled trials were conducted in six different countries, although more than half came from the United States of America (13, 52%), followed by Australia (5, 20%), Belgium (2, 8%) and one each from Canada, Iran, India, Turkey, China/Hong Kong and United Kingdom. The most common study design used parallel groups (23, 92%), with two studies using cross-over features (2, 8%). Amongst the parallel studies, 18 (72%) had two intervention arms, whilst the remaining five (20%) had three or more intervention arms. Both cross-over RCTs had two intervention arms.

The majority of the studies assessed pain during or immediately after undertaking procedures (17, 68%), one of which also specifically evaluated acute pain in addition to procedural pain (4%). Five studies assessed pain solely during the acute phase of the burn (20%). Two studies looked solely at chronic pain (8%), with one study assessing both chronic and acute pain (4%) in its design. Studies assessing specific non-pharmacological interventions were more prominent (13, 52%) in comparison to studies assessing pharmacological interventions (11, 44%). One study compared both pharmacological and non-pharmacological interventions (4%). Studies looking at hypnosis (3, 12%) and rapid induction analgesia (2, 8%) as primary interventions were the most common. The median number of final participants of the studies was 32 (interquartile range 20–49).

3.2. Use of pain assessment tools

The pain assessment tools used in the studies are listed in Table 2. The overwhelming majority of studies used either an 11-point numerical rating scale of pain intensity or a visual analogue scale (VAS) (21, 84%). Other frequently used assessment tools included measures to assess anxiety (e.g. State Trait Anxiety Inventory [STAI] or BSPAS), usage of rescue analgesics (13, 52%) and rating scales to assess participants' global improvement and level of satisfaction (10, 40%). Less frequently used tools included the McGill pain questionnaire (5, 20%) and categorical assessments of pain intensity (3, 12%). Pain assessment tools used in only one study each included the Multidimensional Pain Inventory Interface Scale (MPI), Neuropathic Pain Scale (NPS), Beck Depression Inventory

Table 1 – Summary of pain related interventions.

Citation	Type of pain	Sample size	Intervention(s)	Comparator
Choiniere [19]	Acute	24	Morphine PCA	Nurse administered morphine
Jellish [20]	Acute	60	Topical Lignocaine spray 2%; Topical Bupivocaine 0.5%	Placebo
Long [21]	Acute	4	MISS cream 0.01% topical	Placebo cream
Tobiasen [22]	Acute	20	Coping strategies	Standard care
Welling [23]	Acute	49	Jelonet and topical Morphine Sulphate; Jelonet and water	Jelonet
Gray [24]	Acute and Chronic	90	75 mg oral Pregabalin twice daily to a maximum dose of 300 mg oral Pregabalin twice daily	Placebo
Promes [25]	Acute and Procedural	61	Intravenous ibuprofen 800 mg every 6 h for 5 days	Intravenous 0.9% sodium chloride
Field [26]	Chronic	20	Massage therapy	Standard care
LiTsang [27]	Chronic	42	Silicon-gel sheeting	Self massage with lanolin
Askay [28]	Procedural	46	Hypnosis	Relaxation and psychologist attention
Cuignet [29]	Procedural	20	Ropicavaine 0.2% fascia - ilial compartment block infusion	Saline 0.9% fascia-ilial compartment block infusion
Everrett [30]	Procedural	32	Hyponosis; Lorazepam; Hypnoiss and Lorazepam	Placebo
Ferguson [31]	Procedural	11	Music	Standard care
Finn [32]	Procedural	26	Intra-nasal fentanyl 0.34–2.47 mcg/kg with oral morphine	Intra-nasal placebo with oral morphine
Frenay [33]	Procedural	26	Hypnosis	Stress reduction strategies
Harandi [34]	Procedural	44	Rapid induction analgesia	Non-rapid induction analgesia
Haythorthwaite [35]	Procedural	42	Sensory focusing; distraction (music therapy)	Standard care
Konstantatos [36]	Procedural	86	Virtual reality with PCA	PCA alone
Lewis [37]	Procedural	11	Acupuncture-like TENS	Placebo pill
Miller [38]	Procedural	17	Distraction technique	Standard care
Patterson [39]	Procedural	79	Opioids and Lorazepam	Opioids and placebo
Turner [40]	Procedural	99	Therapeutic touch	Sham therapeutic touch
Wasiak [41]	Procedural	45	Intravenous Lidocaine 1.5 mg/kg + 2 × boluses 0.5 mg/kg at 5 min intervals followed by a continuous infusion	Intravenous 0.9% sodium chloride
Wright [42]	Procedural	29	Rapid induction analgesia	Non-rapid induction analgesia
Zor [43]	Procedural	24	1 mg IM tramadol, 1 μg/kg IM dexmedetomidine HCL; 2 mg/kg IM ketamine 1 mg IM tramadol, 0.05 mg kg IM midazolam HCL, 2 mg/kg IM ketamine	2 mg/kg IM ketamine

PCA, patient controlled analgesia; MISS, morphine-induced silver sulfadiazine; TENS, transcutaneous electrical nerve stimulation; mg, milligram; IM, intra-muscular; microg, micrograms; kg, kilogram; H, hourly.

(BDI), Profile of Mood States (POMS), the Brief Pain Inventory Interference Items (BPI) and the Emotional Well Being Scale. Reporting of adverse events and side-effects occurred in only ten studies (40%).

3.3. *Studies comparing pain assessment tools*

There were no RCTs identified in the included studies, which used patients that were allocated to an intervention aimed at minimizing pain associated with their burn and which referenced at least one pain assessment tool, whose primary outcome was to compare the utility of various pain assessment tools in the burns population.

4. Discussion

Despite major advances in burn care over the past few decades, burn pain remains a complex and difficult component of patient management. This systematic review revealed that RCTs in the area of pain assessment in the adult burns population examined a variety of different interventions and over different time frames coupled with relatively small sample sizes. More so, most of the studies included either a NRS or a VAS in their assessment of pain outcomes. Such scales have been shown to be reliable and valid in the assessment of pain intensity, with no one scale consistently demonstrating a greater responsiveness in detecting improvements in pain treatment [44]. Other assessment tools were used less frequently, possibly due to a lack of documented reliability or validity in certain cases, or due to the necessary increase in labour, cost and resources required to undertake these assessments. Tools which have been shown to be both reliable and valid, in some cases more so than visual analogue scales in burns patients, such as the Visual Analogue Thermometer (VAT) [45], were not used in any of the included studies.

The duration of follow-up of unidimensional pain assessment tools such as the VAS or NRS amongst the included

Table 2 – Pain assessment tools reported.

Citation	Pain assessment tools
Choiniere [19]	-Usage of rescue analgesics -Global improvement and satisfaction rating scales -McGill pain questionnaire -Subjective degree of pain relief -Patient and nurse perceptions of efficacy of analgesia
Cuignet [29]	Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales -Usage of rescue analgesics -Range of hip flexion
Everrett [30]	-Numerical pain intensity scale/ VAS -Subjective perception of anxiety
Ferguson [31]	-Numerical pain intensity scale/ VAS -Vital signs -STAI
Field [26]	-Numerical pain intensity scale/ VAS -Categorical rating of pain intensity -MPI -POMS -McGill pain questionnaire -STAI
Finn [32]	-Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales -Usage of rescue analgesics -Level of sedation
Frenay [33]	-Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales -Anxiety levels -Subjective ''control of pain''
Gray [24]	-Neuropathic pain scale -Numerical procedural pain score -Usage of rescue analgesics
Harandi [34]	-Numerical pain intensity scale/ VAS -Anxiety levels
Haythorthwaite [35]	-Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales -BDI -Subjective degree of relief -Procedure related coping strategies -Usage of rescue analgesics
Jellish [20]	-Numerical pain intensity scale/ VAS -Usage of rescue analgesics -Vital signs -Serum levels of local anaesthetic
Konstantatos [36]	-Numerical pain intensity scale/ VAS -Usage of rescue analgesics -BSPAS -Hypnotic susceptibility
Miller [38]	-Numerical pain intensity scale/ VAS -Categorical rating of pain intensity -McGill pain questionnaire -STAI
Lewis [37]	-Numerical pain intensity scale/ VAS
Long [21]	-Use of rescue analgesics -BPI -Anxiolytic use
Patterson [39]	-Numerical pain intensity scale/ VAS -STAI
Promes [25]	-Numerical pain intensity scale/ VAS
Tobiasen [22]	-Emotional well being scale (coping with pain)
Wasiak [41]	-Verbal pain score -Opioid demands and consumption -Usage of rescue analgesics -Global improvement and satisfaction rating scale
Welling [23]	-Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales -Usage of rescue analgesics
Wright [42]	- Numerical pain intensity scale/ VAS -Usage of rescue analgesics -STAI
Zor [43]	-Numerical pain intensity scale/ VAS -Global improvement and satisfaction rating scales

VAS, visual analogue scale; STAI, Stat Trait Anxiety Inventory; POMS, Profile of Mood States; PMI, Multidimensional Pain Inventory Interface Scale; BDI, Beck Depression Inventory; BSPAS, Burn Specific Pain Anxiety Scale; BPI, Brief Pain Inventory interference items.

studies varied significantly. Some studies used specific time frames at which they implemented assessment tools (i.e. 72 h post-burn), whereas other studies recorded their assessments following, for example, a number of defined procedures (e.g. after 10 consecutive procedures). Obviously this variability was dependent on the type of pain observed, be it acute, chronic or procedural; however, this heterogeneity made a comparison of pain assessment difficult, even with simple unidimensional tools.

Multidimensional assessment tools were used infrequently along with more complex pain tools that were used in only a handful of studies. This is concerning because burn pain quickly establishes itself in the persistent or chronic pain paradigm and therefore the management of burns patients needs to take this into consideration. Given their lack of uniform use, the value of data captured by tools such as the McGill Pain Questionnaire or the BPI, which are multilingual and validated amongst several patient populations [46], was ultimately dependent on the methodological quality of the

clinical trial itself. On the rare occasion that multiple multidimensional assessment tools were used, such as in the study by Fields et al. [26], this often served to cover multiple pain outcome domains such as emotional functioning and physical functioning. Where careful selection of multidimensional tools is undertaken, such as in this context, these tools may be complementary and produce a broad and useful pain assessment strategy. Alternatively, it has been argued that the over-use of multidimensional tools designed to assess multiple domains and dimensions of pain, does not add to the abundance of currently used instruments but increases the respondent burden and results in sub-obtimal pain assessment [47]. In the majority of the included studies in this review however, multidimensional tools tended to be used in conjunction with multiple unidimensional tools. Frequently, multiple unidimensional assessment tools were used such as the concurrent use of VAS, the usage of rescue analgesics and global improvement and level of satisfaction. Whilst these tools may be complementary and have little overlap in the data collected, they cover a very narrow field of pain outcome domains and should be considered as such when interpreting the data they collect.

In 2002, the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) governed a consensus meeting of 27 specialists from academia, governmental agencies and the pharmaceutical industry to identify core outcome domains that should be considered in clinical trials of treatments for chronic pain [15]. The core outcome domains specific in these IMMPACT consensus recommendations included pain, physical functioning, emotional functioning, participant ratings of global improvement and satisfaction with treatment, symptoms and adverse events and participant disposition [15].

Whilst initially proposed for chronic pain trials, many of these domains could and should be extrapolated to other contexts of burn pain assessment, management as well as research particularly in the context of persistent and established burns pain. Whilst, for the purposes of this review, in order to allow comparison to frequently accepted definitions of acute and chronic pain in other clinical and research contexts, a 2-week time period was used from the time of injury to define pain as either ''acute'' or ''chronic'', chronic pain can and should be considered to occur following tissue healing (which in some cases may take several months). Given that the period of inflammation and healing in burn patients can be significantly prolonged compared to other patient populations, it is during this period that intense acute pain and nociception can set up central sensitization leading to potentially irreversible symptoms of chronic pain. Because this group is at risk of developing these phenomena early on, assessment tools addressing chronic pain should be used at a similarly early time in the inflammatory and healing process so as to identify and allow treatment targeted to prevent these morbid sequelae.

Particular outcome domains with respect to burn pain, such as emotional function and physical functioning cannot be underestimated in the evaluation of burn pain [48]. Burns can cause extreme distress both to patients and their families, and it has been shown to directly impact upon their perception of pain [48]. Assessment tools that were frequently used included those assessing for anxiety levels, usage of rescue analgesics and participant ratings of global improvement and satisfaction with treatment. Inclusion of these criteria covered multiple pain-associated outcome domains, and would allow researchers to evaluate pain in the context of factors such as emotional functioning and participant perception of improvement and treatment satisfaction. Although many studies involving procedural pain assessed anxiety levels, specific items targeted towards emotional functioning such as the BDI, POMS and the Emotional Well Being Scale were used only once each in the included studies. Tools such as the BDI and POMS, recommended by the IMMPACT group as core outcome measures for clinical trials of chronic pain treatment efficacy and effectiveness, are well established in terms of their reliability and validity in the assessment of symptoms of depression and emotional distress, and have been used in increasing numbers of chronic pain clinical trials and as such should be carefully considered in the measurement of these particular pain outcome domains [16]. With respect to anxiety levels, the BSPAS which has shown to be a valid and reliable measure of anxiety in burns patients in a wide variety of settings has also been shown to be superior to the STAI [49]. Nonetheless, five of the included studies used the STAI (25%) to assess anxiety levels, and only one included study utilised the BSPAS. In many cases, it was difficult to determine whether patient characteristics such as past pain experiences, substance misuse or lack of coping styles influenced the type of tools used, and these factors should be considered when considering the population that is the subject of the clinical trial. Ongoing consideration should be given with respect to the inclusion of at least one tool assessing emotional function in future RCTs focused on burn pain assessment and management.

Assessments of physical functioning were rare in the included studies, with the MPI and BPI being used only once each. It has been suggested that pain and depression independently contribute to compromised physical functioning with the co-occurrence of these increasing the risk over time amongst burn survivors [50]. The MPI and BPI were pain assessment tools similarly recommended by the IMMPACT group as core outcome measures relevant for clinical trials of chronic pain treatment efficacy and effectiveness [16]. Whilst both have their advantages and disadvantages, they may be complementary and relevant to the burns population. The BPI in particular has the distinct advantage of assessing ratings of mood, social relations and enjoyment of life and may complement pain assessment tools assessing emotional function, notwithstanding care should be taken not to implement tools that directly overlap and contribute to an increasing participant response burden. The incorporation of assessment tools encompassing aspects of physical function in burn pain, particularly chronic burn pain, may provide further information on this vital aspect of burn care.

4.1. *Limitations*

Although the data extraction had multiple investigators, including qualified information search specialists for the

search strategy, a research methodologist, burn care experts and a pain clinician, the review was restricted to electronic databases which may not be representative of all indexed RCTs. Other medical databases, burn and pain specific textbooks, conference proceedings, national registries and non-published RCTs were not systematically searched.

4.2. *Recommendations*

Despite the limited evidence base informed by clinical trials within this field, it is encouraging to observe the increase in RCTs assessing pain management in adult burns patients over time, particularly within the last decade, as treatment advances have occurred both within pain management and burn care. Although many RCTs addressing burn pain have expanded their assessment of pain to cover multiple pain outcome domains, many remain under-investigated. In the field of adult burn pain, the use of multiple assessment tools to cover the many aspects contributing to pain in any one patient requires considerable time and resources. Researchers need to balance these considerations with the goal to incorporate further valid and reliable pain assessment tools encompassing pain outcome domains and dimensions in a way that can be standardized between studies and thus add to our slowly growing knowledge of burn pain.

Pain assessment tools used in burns patients should provide information on the history, intensity, location and quality of the pain, and aim to cover multiple outcome domains without compromising on their validity, reliability or ease of administration. Particularly with respect to multidimensional tools, clinicians and researchers should aim to report the outcomes of pain assessment tools in a manner that is easily transferable within and amongst studies, and aims to identify features of chronic pain early in the patient's clinical presentation. Furthermore, this review identified a notable absence of clinical trials looking at pain management in burns patients where pain assessment tools were compared amongst and against each other to determine their utility. Further research efforts in the field of burn pain might consider the inherent value of designing research methodology in this context to consider bridging this significant gap in the burn pain literature.

It is a matter for the clinician or researcher to determine for themselves the relevant domains which must be covered, based on the present evidence base and their own clinical experience, in order to adequately address the necessary domains when designing RCTs in this context. The purpose of this study was not to recommend mandatory tools that should be used in designing RCTs implementing burn pain interventions; however, like the work described and undertaken by the IMMPACT group almost a decade ago, this should be a matter for consensus amongst key stakeholders at the forefront of clinical practice and research in the fields of pain and burns. An international consensus on the critical domains and dimensions of burn pain and reporting has never been established. There may be great benefit in such a consensus, which would help to standardize pain assessment tools in the burns population and encourage collaborative research in this context.

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