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Feature Editor: Mellar P. Davis, MD, FCCP, FAAHPM

PC-FACS (**F**ast **A**rticle **C**ritical **S**ummaries for Clinicians in **P**alliative **C**are) *provides hospice and palliative care clinicians with concise summaries of the most important findings from more than 100 medical and scientific journals. If you have colleagues who would benefit from receiving PCFACS, please encourage them to join the AAHPM at aahpm.org. Comments from readers are welcomed at pc-facs@aahpm.org.*

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Summaries With Commentaries

Results of Intravenous Lidocaine Infusion in the Treatment of Neuropathic Pain Syndrome

Background. Overall, 30%-50% of patients with postherpetic neuralgia (PHN) experience sustained pain for >1 year.[1] What is the analgesic efficacy and emotional response to lidocaine in patients with PHN?

Design and Participants. This randomized, double-blinded study assessed pain relief from onset to 4 weeks after lidocaine infusion in adults with PHN. Patients at the Pain Management Department of West China Hospital received a single 5 mg/kg intravenous lidocaine or placebo infusion. Maintenance pregabalin (150 mg bid) and oxycodone were provided. The primary outcomes were pain measured via Visual Analogue Scale (VAS), Von Frey, and area of allodynia (AOA). The Self-Rating Anxiety Scale (SAS) and Self-Rating Depression Scale (SDS) evaluated anxiety and depression, and the Short Form Health Survey 36 assessed quality of life at 4 weeks. Analyses included t-tests, χ^2, and Wilcoxon rank-sum and Fisher's tests.

Results. Participants (90 lidocaine, 93 placebo) were 52% aged 60-74 years and 49% female. The most common affected dermatomes were thoracic (69%) and craniofacial (17%) with no between-group differences. Mean baseline VAS scores were 5.18 (lidocaine) and 4.99 (placebo); scores decreased to 2.74 and 2.99 (2 weeks), and similar changes occurred in mechanical pain threshold and AOA (insignificant). Lidocaine improved anxiety and depression; mean changes were SAS=3.89 (95% CI=1.43-6.35) and SDS=4.3 (0.63-7.98) (2 weeks; $P<0.05$). Lidocaine also improved quality of life (mean change of 50 (28-72) at 1 week), especially vitality, physical and emotional role functioning, mental health, bodily pain, and general health perceptions (2-4 weeks; all $P<0.05$). Lidocaine was associated with reduced analgesic consumption: relative risk=6.2 (2.24-17; $P<0.05$). Between-group adverse reaction differences were insignificant.

Commentary. PHN is one of many causes of neuropathic pain syndrome encountered in palliative care. Persistent neuropathic pain can be particularly challenging to treat in part because it can cause brain remodeling, resulting in opioid insensitivity and the development of concurrent negative emotions. Lidocaine infusion improved patients' anxiety and depression as well as factors important to function, a sense of self, and life quality within just 2 weeks. Further, the reduction in analgesic requirements may limit adverse effects. Lidocaine generally was well-tolerated; dizziness and dry mouth were treatment-emerging side effects. Analgesia was attributed to down-regulation of N-methyl-D-aspartate receptors,[2] blockade of voltage-gated sodium channels in

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peripheral and sympathetic nerves,[3] and reduced central sensitization.[4]

Bottom Line. Lidocaine infusion is a relatively low-cost and well-tolerated option for treating neuropathic pain syndrome.

Reviewer. Amy L. Davis, DO MS FACP FAAHPM, Drexel University School of Medicine, Philadelphia, PA.

Source. Liu H, Lu F, Zhou D, et al. The analgesic and emotional response to intravenous lidocaine infusion in the treatment of postherpetic neuralgia: a randomized, double-blinded, placebo-controlled study. *Clin J Pain.* 2018;34(11):1025-1031.

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Examining the Roles of Emotion and Ethics in NICU Decision Making

Background. In the neonatal intensive care unit (NICU), disagreements about withholding/withdrawing life-sustaining treatment are common.[1-3] In the future of neonatal bioethics, what changes are imminent?

Design and Participants. This review analyzes strategies for improving how NICU physicians work with parents to make decisions about societally defined gray-zone cases. Until recently, doctors saw their role as providing parents with detailed, objective information about treatment choices and likely outcomes. A newer approach recommends that doctors help parents discern their own values and ethics as they face unanticipated situations and life-altering decisions—a shift of focus from result to process. The author discusses reasons for this shift.

Results. New research has undermined the old approach: even when informed about the possibility of bleak outcomes, most parents want treatment that doctors think is inappropriate/futile; most neonatologists are unskilled at and uncommitted to a process of shared decision making; framing effects, availability bias, and other predictably irrational thought patterns are inherent to how our minds work; and people's decisions are shaped by how facts/choices are presented (ie, "choice architecture"). NICU cases elicit strong emotions that make it difficult for parents to understand/interpret information about complex probabilities of various outcomes. Doctors must learn to ask parents open-ended questions about hopes, fears, goals, and values as they design the choice architecture within which parents will be empowered to make choices. Emerging technologies are likely to challenge doctors' skills in assisting parent decision making. Prenatal diagnosis and fetal therapy advances, earlier gestational-age treatment options, and artificial placenta research might change how we think about treatment for the tiniest babies.

Commentary. The field of clinical ethics and palliative medicine have long been acknowledged to have a large area of overlap, a concept that is reinforced by this review article which takes into account more recent data about decision making in the NICU. As many palliative care providers will be familiar with, decisions around life-sustaining treatments (LSTs) for children tend to be emotional in nature rather than intellectual. For many years, the bioethical literature has paid increased attention to the need for emotional communication to encourage value-based decision making when navigating the often complex ethical dilemmas that arise in the face of medical uncertainty.[4,5] In addition, in the decision science world, there has been increasing appreciation for the role of emotions in reflecting and expressing core values. In the NICU, where emerging technologies promise to introduce new opportunities and uncertainties, an approach that encourages and elicits such value-based decision making will be a crucial skill for providers.

Bottom Line. Clinicians should encourage and elicit value-based, emotional communication around medical decision making in the NICU.

Reviewer. Adam D. Marks, MD MPH, Division of Geriatrics and Palliative Medicine, University of Michigan, Ann Arbor, MI.

Source. Lantos JD. Ethical problems in decision making in the neonatal ICU. *N Engl J Med.* 2018;379(19):1851-1860.

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Tools for Deprescribing Medications in Elderly or Limited Life Expectancy Patients

Background. Older people often take many medications and are more susceptible to the adverse effects of medications with age.[1-3] What tools can assist clinicians in identifying and reducing/stopping (deprescribing) inappropriate medications?

Design and Participants. This systematic review with narrative synthesis identified and described tools focused on deprescribing medications in frail older people and those with limited life expectancy. Studies had to state explicitly that the tool was designed for (or included specific considerations relevant to) this population. MEDLINE, EMBASE, and CINAHL were searched (inception through 2017) along with grey literature. Articles that described a tool to guide deprescribing were included. Tools that were aimed exclusively at individuals with cancer in the palliative care setting were excluded. Two authors screened the full-text articles and grey literature for eligible publications/resources. All authors discussed the final study selection and agreed on final inclusion.

Results. In this study, 144 full-text articles/resources were reviewed. Four studies addressed individuals with limited life expectancy, 4 addressed frail older people, and 7 addressed both. Fifteen tools were identified and organized into 3 categories: tools (n=2) that described a model or framework for approaching deprescribing, tools (n=9) that outlined a deprescribing approach for the entire medication list, and tools (n=4) that provided medication-specific advice. The complexity of the tools ranged from simple lists to detailed, stepwise protocols. The development methodology varied widely, and the methods used to synthesize the tools generally were not well described. Most tools were expert opinion−based. Only 4 tools have been tested in clinical practice (very low-quality prospective studies).

Commentary. The Beers Criteria (and accompanying clever conference session titles) have been around for decades, yet polypharmacy remains a hazard for frail older adults. Interest in deprescribing has grown given this ongoing problem.[4] Provider-level barriers include lack of self-efficacy and inertia.[5] Specific deprescribing tools are an attractive solution to promote discontinuing medications with no benefit given limited life expectancy and using the fewest drugs and the lowest effective doses to improve adherence and reduce burdens. Deprescribing includes identifying patients, identifying medications to reduce or stop, communicating with patients and families, creating a deprescribing regimen, and monitoring patients. Tools are needed to guide each of these steps. This study found that evidence to inform tools to guide these tasks is incomplete and the tools themselves are not well studied.

Bottom Line. There are several clinical competencies required for effective deprescribing, and no set of tools have yet emerged as the best to guide practice.

Reviewers. Elizabeth Chuang, MD MPH FAAHPM, Albert Einstein College of Medicine, Bronx, NY; Linda Mitchell, MD, Montefiore Medical Center, Bronx, NY.

Source. Thompson W, Lundby C, Graabaek T, et al. Tools for deprescribing in frail older persons and those with limited life expectancy: a systematic review. *J Am Geriatr Soc*. 2019;67(1):172-180.

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Do Older and Younger Patients Derive Similar Survival Benefits from Novel Oncology Drugs?

Background. Older patients may derive less benefit from cancer drugs.[1] Do novel oncology drugs provide differential age-based treatment outcomes for patients in clinical trials?

Design and Participants. This study examined if novel oncology drugs provide differential treatment outcomes for older and young patients enrolled in randomized control trials. A systematic review of trials

cited for efficacy evidence in novel oncology drug approvals by the Food and Drug Administration, European Medicines Agency, and Health Canada (2006-2017) was conducted. Studies reporting age-based subgroup analyses for overall or progression-free survival (OS/PFS) were included. Eligible trials were assessed for the reporting of age-based toxicity and quality-of-life (QOL) analyses. Meta-analyses with random effects were performed. Primary analysis was based on studies' primary endpoints (OS/PFS), comparing patients aged <65 and ≥65 years. Sensitivity analyses were conducted for cancer type, primary endpoint, and systemic treatment.

Results. Of 102 included studies (65,122 patients), 87 administered targeted agents and 15 administered chemotherapy as experimental regimens. The median age of experimental-arm patients spanned 33-76 years, similar to control (32-77). One study reported age-based toxicity and none reported age-based QOL. Pooled hazard ratios (HRs; 95% CIs) for patients <65 and ≥65 years were 0.61 (0.57-0.65) and 0.65 (0.61-0.70), respectively, with no difference between them (P=0.14). Sensitivity analyses results were congruent with primary meta-analysis: for OS, pooled HRs for patients <65 and ≥65 were 0.77 (0.72-0.81) and 0.80 (0.75-0.86), respectively (P=0.37), and 0.51 (0.47-0.56) and 0.54 (0.48-0.61) for PFS (P=0.36). Systemic treatment type−based (targeted agent or chemotherapy) and cancer type−based analyses also showed no subgroup differences.

Commentary. This is an interesting study that found older patients did not have different overall survival or progression-free survival when treated with novel oncology drugs than younger patients. However, the major take-away is that of 102 randomized controlled trials examined, only 1 assessed QOL, and none presented age-based QOL results. Patient-reported outcomes (PROs) are becoming the standard of care, especially in cancer care. Two recent studies in patients with lung cancer compared patient symptom monitoring via web-based PROs versus standard imaging surveillance and found an increased overall survival in patients who completed PROs.[2,3]

Bottom Line. The "efficacy" of medical interventions needs to be more broadly and comprehensively defined and consistently include QOL domains and PROs of symptom burden for each intervention.

Reviewer. Kevin Madden, MD FAAP, University of Texas, MD Anderson Cancer Center, Houston, TX.

Source. Arciero VS, Cheng S, Mason R, McDonald E, Saluja R, Chan KKW. Do older and younger patients derive similar survival benefits from novel oncology drugs? A systematic review and meta-analysis. *Age Ageing.* 2018;47(5):654-660.

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Partners' Overestimation of Patients' Pain Severity

Background. Social support is vital in facilitating adaptation to chronic pain.[1-3] Does concordance between patients' and their partners' reports of patient pain severity relate to the partners' support?

Design and Participants. This study examined how patient-spouse pain-perception congruence relates to partners' social support and behavioral responses in couples coping with chronic pain. Couples were drawn from pain specialty and physical therapy clinics and completed questionnaires[4] about patients' pain severity without sharing questions/answers. Both dyad members rated the partner's social support and negative, solicitous, and distracting responses toward the patient when in pain, and completed the Dyadic Adjustment Scale (relationship satisfaction). Descriptive analyses used t-tests, Pearson correlations, and hierarchical multiple regression.

Results. Fifty-two couples (87% married, mean relationship length 23 years [SD=14]) completed questionnaires. Patients' were mean age 52 years (SD=11) and 42% female (85% low back pain, 10% osteoarthritis). Partners' mean age was 51 years (SD=11), and 59% of patients and 66% of partners completed 1-4 years of college. Couples' relationship satisfaction ratings were correlated (r=0.71, P<0.001); scores (mean=103) were in the satisfied range (≥100). There was moderate patient-partner correspondence in pain severity ratings (r=0.55, P<0.001) and perceptions of negative (r=0.46, P<0.01), solicitous (r=0.47, P<0.001), and distracting responses (r=0.53, P<0.001) but lower correspondence for social support (r=0.28, P=0.046). Fifty-four percent of couples were pain-perception concordant, and 27% of partners overestimated pain (19% underestimated). Pain-perception concordance was unrelated to patients' reports but predicted partners' reports: partners overestimating pain (vs. agreeing/underestimating)

reported giving more social support (β=0.383, *P*=0.016), fewer negative responses (β=-0.332, *P*=0.029), and more solicitous responses (β=0.438, *P*=0.016).

Commentary. Concordance in the assessment of the chronic pain intensity between patients and their partners has previously been associated with positive adaptation to and supportive interactions around chronic pain. This small-scale study demonstrated that nonconcordance between patient and partner on perceived pain severity, specifically the overestimation of pain severity by the partner as compared to the patient, was surprisingly associated with increases in partner-reported social and behavioral supportive responses to that chronic pain. However, under these same circumstances, patients did not report an increase in positive supportive behaviors by their partners. Perhaps unknown factors make the supportive actions reportedly provided by their partners invisible to patients with chronic pain.

Bottom Line. The reported provision of a spouse's social and behavioral support was not perceived as supportive by the patient.

Reviewers. Dan Handel, MD, University of Colorado School of Medicine, Denver Health Medical Center Palliative Medicine Division, Denver, CO.

Source. Junghaenel DU, Schneider S, Broderick JE. Partners' overestimation of patients' pain severity: relationships with partners' interpersonal responses. *Pain Med*. 2018;19(9):1772-1781.

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Analyzing Medication for the Treatment of Delirium in Critical Illness

Background. Delirium affects 50%-75% of patients receiving mechanical ventilation in an intensive care unit (ICU).[1,2] What are the effects of haloperidol or ziprasidone on delirium during critical illness?

Design and Participants. This multicenter, randomized, double-blind trial examined the effects of haloperidol and ziprasidone on delirium during critical illness. Patients with acute respiratory failure or shock and hypoactive/hyperactive delirium received intravenous haloperidol (maximum 20 mg/day), ziprasidone (maximum 40 mg/day), or placebo boluses. The dose was halved/doubled at 12-hour intervals on the basis of side effects and delirium presence/absence (detected via the ICU Confusion Assessment Method). The primary endpoint was number of days alive without delirium or coma during the 14-day intervention. Secondary endpoints included 30-day/90-day survival, time to freedom from mechanical ventilation, and time to discharge. Safety endpoints included extrapyramidal symptoms and excessive sedation. The Kruskal-Wallis test, adjusted proportional-odds logistic regression, and polytomous logistic regression were used (intent-to-treat).

Results. Patients (N=566) were 43% female, 83% white, and median age 61 years (IQR=51-69) with no between-group differences. Of the patients, 89% had hypoactive delirium and 11% had hyperactive delirium: 184 placebo, 192 haloperidol, and 190 ziprasidone. The median drug/placebo exposure duration was 4 days (IQR=3-7), and the mean ($^{+/-}$SD) daily doses were $11^{+/-}$4.8 mg (haloperidol) and $20^{+/-}$9.4 mg (ziprasidone). The median number of days alive without delirium or coma was 8.5 (95% CI=5.6-9.9) in placebo, 7.9 (4.4-9.6) in haloperidol, and 8.7 (5.9-10) in ziprasidone (*P*=0.26 for overall effect across groups). Haloperidol or ziprasidone, vs. placebo, had no effect on the primary endpoint (odds ratios, 0.88 [95% CI=0.64-1.21] and 1.04 [0.73-1.48]). There were no between-group secondary or safety endpoint differences.

Commentary. The MIND-ICU trial builds on previous data showing that antidopaminergic agents, specifically haloperidol and ziprasidone, do not reduce the number of days free from delirium for critically ill patients.[3,4] The medications appeared safe and did not impact mortality, even at relatively high dosages. Since the majority of patients in the study (89%) suffered hypoactive delirium, conclusions cannot be drawn about the utility of these drugs for patients with hyperactive delirium. The study population of primarily patients with sepsis and respiratory failure limits generalizability to other patients in the ICU. Moreover, we cannot draw conclusions about other agents that exert greater antihistaminergic effects. However, for patients with

hypoactive delirium, the use of these antidopaminergic agents did not have any effect on duration of delirium, which calls into question whether these agents should be used in this situation at all.

Bottom Line. The use of haloperidol or ziprasidone did not seem to have an effect on duration of delirium in the ICU despite the use of relatively high dosages.

Reviewer. Jared Lowe, MD, Duke University Health System, Durham, NC; Jason Webb, MD FAPA FAAHPM, Duke Center for Palliative Care, Duke University Health System, Durham, NC.

Source. Girard TD, Exline MC, Carson SS, et al. Haloperidol and ziprasidone for treatment of delirium in critical illness. *N Engl J Med.* 2018;379(26):2506-2516.

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American Academy of Hospice and Palliative Medicine 8735 W. Higgins Road, Suite 300
Chicago, IL 60631, USA
Phone: 847-375-4712
Fax: 877-734-8671
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Website: www.aahpm.org