CLINICAL INVESTIGATION

Randomized clinical trials in US hospices: challenges and the current state of the art

Conducting prospective studies in hospices can be difficult. We conducted a systematic review to find randomized trials that have been conducted in US hospices and to review them for quality and potential bias. Ten studies met our inclusion criteria; a wide variety of outcomes were studied. Most of the studies had at least moderate risk of bias due either to incomplete reporting of methods or the inability to blind investigators. To provide better evidence-based hospice care, more well-designed trials that are consistently reported are needed.

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Hospice provides care and services for patients with a life-limiting illness and their loved ones. In the USA, eligibility criteria for hospice include a life expectancy of less than 6 months. Care often takes place in the patient's home and focuses on support and comfort rather than cure [1]. In 2013, from 1.5 to 1.6 million patients received some type of service from hospice, up from just over 1.3 million in 2009 [1]. Despite availability of hospice in the last 6 months of a patient's life, median length of stay in US hospices is less than 2 weeks (18.5 days in 2013); mean length of stay is considerably longer (72.6 days in 2013) [1], indicating that the distribution of stay lengths is skewed, with many short stays and a small number of very long stays.

Hospice patients often have advanced illness along with the complicated medical management problems that accompany advanced illnesses [2]. Given that many hospice patients in the USA reside in their own homes, attended by family members with no formal medical training [1,3–4], the information need for patients and family members can be substantial.

While the information needs are considerable, research in a hospice setting can be difficult [2,5–6]. For example, Cassarett *et al.* [2] reported major barriers to conducting research in hospices, including low enrollment that leads to underpowered studies, selection bias that arises when refusal to participate is unevenly applied across the spectrum of patients or the spectrum of hospices, and ethical concerns about including patients who are near the end of life in research. Ethical concerns revolve around whether hospice patients should be viewed as vulnerable and thus off-limits to research or autonomous people who should be able to agree to participate in a study, obtaining and retaining informed consent from people who may have or develop cognitive problems, whether research should be conducted in this population at all, taking patients' limited remaining time away from friends and family, perceived coercion to participate by healthcare providers on whom patients rely, withholding some type of treatment from a control group and whether it is ethical to ask patients to participate in research that is unlikely to benefit them because they are so close to the end of life [6–8].

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In addition, staff and family members often protect patients (gatekeeping), making it difficult for researchers to contact patients or families [7,8]. Conversely, patients may be concerned about causing too much burden for caregivers [9]. The information needs are complicated by the fact that patients with different diagnoses present unique problems that may not apply to other patients [5]. Compared with cancer patients, Zambroski [5] reported that patients with heart failure and their caregivers have been managing symptoms for this chronic disease for a long time and were not as likely to see the potential benefits of a coping skills intervention.

As well, inclusion criteria might create the need to screen large numbers of patients to obtain the targeted number who meet enrollment criteria, leading to questionable generalizability [6]. For example, Zambroski and colleagues [5] screened 648 patients to find 99 who met enrollment criteria, 32 of whom agreed to participate. Given the short length of stay for many hospice patients, there may be little time to recruit participants and deliver an intervention [6], making prospective studies difficult in this population.

But research is how we make things better. Without research, we either maintain the status quo or implement programs that lack evidence. While high-quality randomized controlled trials provide very good evidence with which to guide care, they can be particularly difficult to conduct in the hospice setting. Although hospice researchers report that there is little high-quality evidence specific to providing hospice care [2,6], the number, limitations and quality of existing studies has not been assessed. We therefore searched the literature to find randomized trials that were conducted in a hospice setting and reviewed them for quality and potential bias.

Methods

We restricted our analysis to studies that took place in USA because hospice care in the USA differs importantly from other countries. For example, only patients with a life expectancy of less than 6 months can qualify for hospice services in the USA, most care occurs in patients' homes rather than hospice facilities [1,10], and Medicare pays for over 80% of US hospice care [10]. We included articles that reported a randomized trial that took place in a US hospice, was reported in a peer-reviewed journal (e.g., not a conference abstract), was reported in English, and reported results for the main outcome measure if there were multiple articles for the same study (e.g., substudies were excluded). We excluded staff interventions and studies of hospice admission (versus another treatment location). While we did not limit inclusion based on whether adults, children or both were included in the study population, all of the eligible studies included only adults.

An experienced medical librarian searched four online databases – Ovid MEDLINE® (Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid MEDLINE and Ovid OLDMEDLINE 1946 to Present), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials, and Scopus – for articles published in print or online from 1985 to 27 April 2015. These databases were searched using the subject terms 'hospice' or 'hospice and palliative care nursing' or 'hospice care' or the word 'hospice*' in the title or the abstract (the * denotes a wildcard character to account for variation in the truncated term, such as random, randomized, or randomised). Results were then combined with publication type 'randomized controlled trial' or the word 'random*' in the title or abstract. Articles were limited to those published in English. We did not perform manual searches for additional studies that were potentially missed by our search strategy, as we wanted to include only studies that had accessible, peer-reviewed reports.

Article abstracts were reviewed by two authors to determine if they met inclusion criteria. If it could not be determined from the abstract whether the article should be included, the article was reviewed. Included articles were divided among the authors for review. Each article was reviewed by two authors. We developed a review document (available from the first author on request) based on the Cochrane Collaboration's tool for assessing risk of bias [11] and the Consolidated Standards of Reporting Trials (CONSORT) checklist of information to include when reporting a randomized trial [12]. Data elements included inclusion criteria, funding source, trial registration number, study purpose and hypotheses, sample size, summary of findings, criteria for assessing bias [11] and items from the CONSORT checklist for reporting clinical trials. For the one instance when an article represented a noninferiority study, the CONSORT extension for reporting noninferiority trials was consulted [13]. When reviewers did not agree, they discussed the article and came to an agreement. It was not necessary to include a third-party reviewer for any of the included studies.

Results

Our search strategy resulted in 165 articles – 77 from Ovid MEDLINE, 63 from the Cochrane Central Register of Controlled Trials, eight from CINAHL and seven from Scopus. A total of 57 articles were retrieved from multiple databases. After removing duplicates, 108 unique articles remained (Figure 1). After reviewing abstracts and articles, ten articles met inclusion

criteria (Table 1). Of the excluded studies, 38 did not include hospice patients, thirty did not take place in the USA, and 23 reported a substudy of a larger trial.

The ten articles were published in eight journals, with publication dates ranging from 2003 to 2015. The earliest included study [18] was published 2 years after the revised CONSORT statement was published (2001) [24]. Despite this, many of the published reports did not include items endorsed by the CONSORT statement. In particular, details regarding how participants were randomized, allocation concealment and blinding were often lacking. Of the ten articles, six were published in journals that have not endorsed CONSORT guidelines according to the website [15,17,19,21–23,12]. Eight research teams conducted the studies, with a team from the University of South Florida conducting three of the ten studies [20–22]. All of the research teams were associated with a variety of departments at US universities; four also included hospice employees [14,19–20,23]. Six of the studies had federal funding for the research, one had funding from a private foundation, and three reported no funding source.

The number of randomized participants varied from 29 to 709. Several of the studies were small, involving 40 or fewer patients, but five randomized over 100 patients and/or caregivers. Median sample size was 103, while the mean was 167.6. One study described patients as living in facilities [16], patient location was not specified in one study [15] and the remaining eight studies involved community dwelling patients or their caregivers.

A variety of interventions were delivered to either patients or their informal caregivers, including hydration [14], medication [19], music therapy [16,18], coping skills training [20,22], massage [23], screening and tailored education to address caregivers' misunderstandings regarding pain management [15], structured assessments used to systematically inform hospice staff [21] and problem-solving training [17]. Concealment of allocation was not possible for several of the trials because hospice staff were involved in delivering the intervention or the intervention was not amenable to concealment [15,17,20–23]. While unavoidable, this put several studies at moderate risk of bias. The two studies with the lowest risk of bias [14,19] were double-blinded studies of hydration and methylphenidate, respectively.

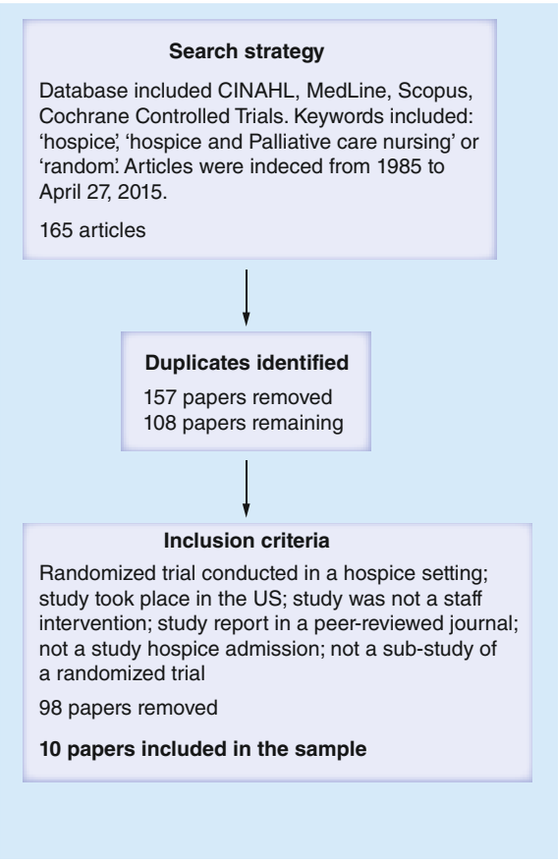

Figure 1. Search strategy and selection of articles.

Discussion

Our search strategy found only ten randomized trials that were conducted in US hospices between 1985 and April 2015 that did not involve a staff intervention or hospice admission. Based on the published reports, most have at least moderate risk of bias. Thus, we concur with others who report that there is a dearth of high-quality evidence regarding hospice care [2,6] and that there are considerable barriers to conducting randomized trials in US hospices [2,5–8]. While we did not look for articles written in languages other than English, we did retrieve abstracts of 15 non-US studies that occurred in hospices and did not study hospice admission or a staff intervention. Hence, the relative paucity of randomized trials conducted in hospices is not limited to the USA. Overcoming the barriers to hospice research is necessary if we are to provide evidence-based, quality care to hospice patients and their families.

While uncontrolled pain is frequently cited as a problem for hospice patients [3,25–27], none of the included studies directly addressed pain. The majority of interventions were psychosocial in nature, designed to hopefully improve misconceptions regarding pain management, improve caregiver knowledge, decrease anxiety and depression or improve quality of life for patients and caregivers. These are all important areas for study, but the total body of evidence represented by these trials is small compared with the information need. Presumably, symptom management for hospice patients has relied on research conducted in other populations (e.g., cancer patients), with the assumption that therapy delivery and results are the same in hospice as elsewhere.

Table 1. Articles reporting randomized clinical trials in a hospice setting, 1985 – April 2015.

Study (year)	Study objective	Sample and setting	Funding	Main findings	Comments	Ref.
Bruera *et al.* (2013)	Determine the effects of hydration on symptoms associated with dehydration, quality of life, and survival in hospice cancer patients	129 cancer patients; patients' homes	R01CA122292 (also R01NR010162, R01CA124481, K01CA151785)	No significant differences for symptoms or survival	Randomization and allocation concealment adequate; low risk of bias	[14]
Cagle *et al.* (2015)	Test preliminary efficacy of EMPOWER, which included staff education, screening for barriers to pain management, and tailored education by hospice staff to address misunderstandings regarding pain management	168 families enrolled, 42 patients died before 2 weeks and were excluded; randomized by agency; location not specified	R03HS019068, 5T32AG000212, 2T32AG000272	At 2 weeks, intervention caregivers reported better knowledge about pain management, fewer concerns about pain and pain medications, and lower patient pain over the past week	Adequate randomization but details not reported; allocation could not be concealed due to the nature of the intervention; measures not compared at baseline, therefore it is unclear whether differences were due to the intervention or baseline differences; moderate risk of bias	[15]
Choi (2010)	Examine the effects of music, progressive muscle relaxation, and a combination on anxiety, fatigue, and quality of life in family hospice caregivers	32 caregivers; caregivers' homes or a quiet room in the patient's facility	None reported	Decreased anxiety and fatigue and increased quality of life in all 4 groups across treatment sessions; no significant differences among groups	Not clear how subjects were selected; details of randomization not provided; allocation concealment unclear; losses and exclusions not discussed; high risk of bias	[16]
Demiris *et al.* (2012)	Compare the effectiveness of a Problem Solving Therapy intervention delivered face-to-face with one delivered via videophone to hospice primary caregivers	126 caregivers of patients receiving home hospice care	R21NR010744	Problem-solving therapy delivered via video was not inferior to face-to-face delivery	Adequate randomization; allocation could not be concealed due to the nature of the intervention; some analyses included all subjects, some included only study completers; moderate risk of bias	[17]
Hilliard (2003)	Evaluate the effects of music therapy on quality of life for hospice patients living at home	80 patients, stratified by age and sex; patients' homes	None reported	Intervention group had better quality of life which increased as the study progressed	No information provided on randomization or allocation concealment; methods poorly described; measures not compared at baseline, therefore it is unclear whether differences were due to the intervention or baseline differences; high risk of bias	[18]

Table 1. Articles reporting randomized clinical trials in a hospice setting, 1985 – April 2015 (cont.).

Study (year)	Study objective	Sample and setting	Funding	Main findings	Comments	Ref.
Kerr *et al.* (2012)	Evaluate the response of fatigue and depression in patients with advanced illness to titrated doses of methylphenidate as compared with placebo	34 patients randomized, 30 analyzed; patients' homes	None reported	Patients taking methylphenidate had significantly lower fatigue scores on day 14 compared with baseline. Patients taking placebo saw no significant improvement in fatigue.	Adequate randomization and allocation concealment; double-blinded; several exclusion criteria; low to moderate risk of bias	[19]
McMillan *et al.* (2006)	Determine whether hospice plus a coping skill training intervention improved family caregivers' quality of life, burden, coping, and mastery compared with hospice plus emotional support or usual hospice care	329 dyads of caregivers and cancer patients; patients were community-dwelling	R01CA77307	The intervention improved quality of life, burden related to patient symptoms, and caregiver tasks compared with standard treatment with or without emotional support	Randomization adequate; data collectors did not know group assignment; personnel delivering intervention had to know group assignment; moderate risk of bias	[20]
McMillan *et al.* (2011)	Determine efficacy of systematic feedback from structured assessment tools for hospice cancer patients and caregivers to improve hospice outcomes	709 dyads of caregivers and cancer patients; patients were community-dwelling	R01NR008252	Patient depression was improved in the intervention group, patient quality of life improved over time in both groups	Randomization and allocation concealment unclear; blinding not possible due to the nature of the intervention; some details lacking in methods; cognitively impaired patients not included; moderate risk of bias	[21]
McMillan *et al.* (2013)	Determine whether hospice plus a coping skill training intervention improved family caregivers' quality of life, burden, depression and anxiety, patient quality of life, emergency room visits, and hospital stays	40 dyads of caregiver and heart failure patients; patients were community-dwelling	R21NR011224	No significant differences for any outcomes	Details of randomization and allocation concealment not provided; blinding not reported but likely not possible; cognitively impaired patients not included; moderate to high risk of bias	[22]
Wilkie *et al.* (2000)	Test the effects of 4 massages on pain, morphine administration, hospital admissions, and quality of life	29 patients living at home	E.L. Wiegand Foundation	No significant differences for any outcomes, intervention is feasible	Randomization and allocation concealment not described; all but 2 hospice staff were blinded; statistical methods not described; moderate to high risk of bias	[23]

CONSORT guidelines were first published in 2001 [24]. It was clear that even some recent trials do not follow CONSORT guidelines for reporting research results. We were unable to determine when the journals that published these studies endorsed CONSORT guidelines, if they did so. In fact, six of the articles were published in journals that do not yet endorse CONSORT guidelines, which surprised us. Without details regarding randomization, allocation concealment, blinding and other potential sources of bias, it is difficult to assess the quality and risk of bias of a randomized trial. It would be helpful if journals either endorsed CONSORT or provided reviewers with equally strong criteria with which to judge the quality of a report of a clinical trial.

Researchers have reported a variety of barriers to conducting research in hospices. Because these patients are nearing the end of life, there is a reticence to bother them with research that will likely not directly benefit them. Some have gone so far as to say that hospice patients should be disqualified from research. Terry *et al.* [28] interviewed 22 hospice patients and suggest that this reluctance has more to do with society and researchers' attitudes; patients were interested in participating in research for a variety of reasons. Likewise, Bruera reported that the majority of patients and families they approached were willing to participate in a trial of artificial hydration [14]. Carefully designed trials of supportive therapies that could improve quality of life for hospice patients seem both feasible and desirable. In particular, determining how to address the uncontrolled pain and distress experienced by many patients [3,25] is a much needed avenue for future research. Kerr [19] reports that clinically significant fatigue is another important domain that negatively affects patients' lives, and several studies have been aimed at reducing distress and improving quality of life for caregivers [15–17,20–22,29].

Zambroski *et al.* [5] reported that several strategies can foster success in hospice research, including screening potential participants for cognitive problems, building strong relationships between hospices and the research team, using experienced research staff who are also hospice employees, and conducting the intervention using staff who have hospice experience to avoid further burdening hospice staff. Wohleber and colleagues echo many of these suggestions, and also recommend that researchers account for attrition when determining sample size, allow adequate time to plan and obtain approvals for the study, use appropriate inclusion and exclusion criteria, conduct pilot testing and provide clear study materials to minimize gatekeeping [7]. Researchers must be sensitive to the needs of patients and their families and be careful to place as little burden as possible on them [8].

While randomized trials are considered the gold standard for comparing treatments, traditional study designs often focus on survival and morbidity, which are not appropriate outcomes for hospice [6]. Casarett *et al.* called for more comparative effectiveness studies that use electronic data [2]. Based on 2007 survey data, however, less than half of hospices used electronic health records, and of those who had them, the most commonly collected data elements were patient demographics and clinical notes [30]. While many US healthcare providers are required to adopt electronic health records, hospices are not; further, there have been few electronic systems specifically designed for use in hospices. As electronic health records become more hospice-friendly and more hospices adopt them for their patient data, secondary analysis of patient data will become feasible. It must be kept in mind, however, that such studies involving nonrandomized treatment assignment are potentially biased, and care must be taken to account for this using such methods as propensity score adjustment.

Comparative effectiveness studies that use two active comparators rather than a placebo or usual care arm also avoid the problem of asking patients or caregivers to participate in a study that is unlikely to benefit them. We often know that a treatment is better than placebo, but might not know which treatment is better, or for which patients. For example, rather than comparing one pain medication to placebo, which would have severe ethical problems, two different pain medications or two different delivery systems can be directly compared. Hospice patients who were interviewed about research were more positive about active comparator trials than placebo-controlled trials [28], lending further support to this approach. Further, research on how to best inform and support caregivers is needed, and a great deal of useful evidence can be gathered from other study designs.

In a recent study that compared responses from surveys administered in 2000 and 2011–2013, participants (mostly relatives of decedents) reported that unmet needs for pain management had increased, as had anxiety and depression [26]. There was also a decline in the proportion of participants who reported that overall care for their loved one was excellent. It is clear that many opportunities exist for improving end of life care for hospice patients. Although funding for palliative medicine increased between 2001 to 2005 and 2006 to 2010, only 0.2% of NIH grants awarded from 2006 to 2010 were related to palliative care [31]. The proportion specific to hospice is undoubtedly lower. These studies, coupled with the small number of trials providing solid evidence for hospice care included in our study, highlight the critical need to develop an evidence base for hospice care.

Limitations

Our study is subject to some limitations. First, it is possible that some relevant studies were not identified by our search. To minimize this risk, we searched four databases and were assisted by an experienced medical librarian. Further, some trials were conducted in mixed populations of palliative care and hospice patients; if results were not reported separately for hospice patients, we excluded the study. Thus, our results underestimate the number of clinical trials that were conducted in hospices. Our conclusions regarding risk of potential bias were entirely based on information contained in the published article. It is possible that some details were omitted from articles, leading to inaccurate conclusions regarding study quality.

Conclusion

The number of clinical trials conducted in US hospices is low, and most published studies appear to have at least a moderate risk of bias. Researchers have found several barriers to conducting research in hospices, including low enrollment, selection bias, gatekeeping, limited time in which to conduct a study and ethical concerns. Despite these barriers, several research teams have found ways to overcome at least some of the barriers, indicating that it is possible to conduct clinical trials in hospices.

Future perspective

Conducting well-designed trials that do not place undue burden on patients, families or staff will lead to better evidence to providing care for hospice patients and informal caregivers. As electronic health records become more prevalent in hospices, comparative effectiveness studies using existing data will also be feasible. Improving care for hospice patients and their families depends, at least in part, on conducting high quality research within the context of hospice care. Building the evidence base for hospice care is both possible and desirable.

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Executive summary

- A systematic search of the literature retrieved only ten randomized trials that were conducted in US hospices between 1985 and April 2015 that met our inclusion criteria.
- Median study enrollment was 103, and several enrolled 40 or fewer participants.
- Only two of the studies had low risk of bias, two had high risk of bias and the remainder were at moderate risk. Most risk of bias was due to either inadequate reporting or the inability to blind group assignment due to the nature of the intervention.
- Despite the availability of CONSORT guidelines for reporting clinical trials, methodological details were notably lacking for six of the ten studies.
- Most of the interventions were psychosocial in nature.
- Focusing future studies on comparing two active treatments rather than comparing an active treatment to placebo will minimize ethical concerns about asking patients to participate in research that is unlikely to provide them with any benefit.
- Increasing use of electronic health records in hospices should expand opportunities for comparative effectiveness research involving hospice patients.
- There is a critical need to develop the evidence base for quality hospice care.

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