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The Relationship Between Emergency Department Crowding and Patient Outcomes: A Systematic Review

Eileen J. Carter, RN, BSN[1], **Stephanie M. Pouch, MD**[2], and **Elaine L. Larson, PhD, RN, FAAN, CIC**[3]

[1]Doctoral Student, Columbia University School of Nursing, New York, NY, USA

[2]Infectious Diseases Fellow, New York-Presbyterian Hospital, Columbia University Medical Center, New York, NY, USA

[3]Associate Dean for Research, Columbia University Mailman School of Public Health, Columbia University School of Nursing, New York, NY, USA

Abstract

Purpose—Emergency department (ED) crowding is a significant patient safety concern associated with poor quality of care. The purpose of this systematic review is to assess the relationship between ED crowding and patient outcomes.

Design—We searched the Medline search engine and relevant emergency medicine and nursing journals for studies published in the past decade that pertained to ED crowding and the following patient outcome measures: mortality, morbidity, patient satisfaction, and leaving the ED without being seen. All articles were appraised for study quality.

Findings—A total of 196 abstracts were screened and 11 articles met inclusion criteria. Three of the eleven studies reported a significant positive relationship between ED crowding and mortality either among patients admitted to the hospital or discharged home. Five studies reported that ED crowding is associated with higher rates of patients leaving the ED without being seen. Measures of ED crowding varied across studies.

Conclusions—ED crowding is a major patient safety concern associated with poor patient outcomes. Interventions and policies are needed to address this significant problem.

Clinical Relevance—This review details the negative patient outcomes associated with ED crowding. Study results are relevant to medical professionals and those that seek care in the ED.

Keywords

Emergency department crowding; patient outcomes

Emergency department (ED) crowding poses a significant international patient safety concern (Hoot & Aronsky, 2008; Institute of Medicine of the National Academies, 2007;

Correspondence Eileen J. Carter, Columbia University School of Nursing, 617 West 168th Street, New York, NY, 10032. em2473@columbia.edu.

Moskop, Sklar, Geiderman, Schears, & Bookman, 2009; Pines et al., 2011). During times of ED crowding, the demand for emergency services outweighs accessible resources (Moskop et al., 2009). Studies show that ED crowding is a global problem associated with increased patient mortality and poor quality of care (Bernstein et al., 2009; Pines et al., 2011). Although numerous solutions have been proposed to reduce crowding (Handel et al., 2010; McClelland et al., 2011), ED crowding is common and is becoming more acute (Pitts, Pines, Handrigan, & Kellermann, 2012).

Millions of individuals access healthcare in the ED each year, and recently the demand for ED services has significantly increased in the United States (Schuur & Venkatesh, 2012). From 1999 to 2009, the number of visits to the ED increased by 32% nationwide, from 102.8 to 136.1 million. During the same time period, the number of ED visits that resulted in hospital and intensive care unit admission increased from 13.2 to 17.1 million and from 1.4 to 2.2 million, respectively (Centers for Disease Control and Prevention, 2009; McCaig & Burt, 2001). This suggests that more critically ill patients seek care in the ED. Further, insufficient inpatient hospital capacity has resulted in patients boarding in the ED for extended periods of time (Gilligan et al., 2008). The increase in ED utilization and lack of inpatient resources contribute to the growing problem of ED crowding (Moskop et al., 2009). Still further, while ED crowding data are limited globally, studies show that ED crowding is a major international problem (Cha et al., 2011; Guttmann, Schull, Vermeulen, & Stukel, 2011; Pines et al., 2011; Richardson, 2006).

Numerous studies (Kennebeck, Timm, Kurowski, Byczkowski, & Reeves, 2011; Pines, Localio, et al., 2007), including two recent literature reviews (Bernstein et al., 2009; Johnson & Winkelman, 2011), have examined the relationship between ED crowding and poor care processes and quality, such as decreased timeliness of care. To our knowledge, however, no systematic review has been conducted to specifically examine the relationship between ED crowding and patient outcomes. Given the significant increase in ED use and the well-documented relationship between ED crowding and poor care quality, it is important to understand the relationship between ED crowding and patient outcomes. Guided by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (Moher, Liberati, Tetzlaff, Altman, & Group, 2010), we performed a review of the literature to examine the relationship between ED crowding and patient outcomes.

Methods

An iterative process was used to define the search strategy for this review. The data extraction and quality assessment tools were developed a priori.

Search Strategy

With consultation from a research librarian at the Columbia University Medical Center library, we searched the OVID Medline and Ovid Medline In-Process & Other Non-Indexed Citations search engines for studies published in the past decade (between January 2002 and July 2012). Using a Boolean combination of keywords and medical subject headings, outlined in Table 1, we searched for articles pertaining to ED crowding and the following patient outcome measures: mortality, morbidity, patient satisfaction, and leaving the ED

without being seen. Using the same terms and time frame, we also electronically searched the tables of contents of the following journals: *Emergency Medicine Journal*, *Emergency Medicine*, *Journal of Emergency Nursing*, *Annals of Emergency Medicine*, *European Journal of Emergency Medicine*, and *Academic Emergency Medicine*. Finally, we hand searched the reference sections of pertinent articles that were identified in the Medline search and the reference sections of full-text articles that were included in this review.

Study Selection

One researcher screened study titles and abstracts for overall relevance. Three reviewers then independently reviewed remaining study titles and abstracts. Collectively, study authors discussed the rationale for each articles' inclusion or exclusion using an iterative process. Disagreements were resolved through discussion and consensus. Studies that measured ED crowding or explicitly reported to have measured a proxy of ED crowding (e.g., ED length of stay, ED volume, ED capacity, etc.) and measured one of the outcomes of interest were eligible for inclusion. We excluded studies that described (a) interventions to alleviate crowding; (b) care processes associated with crowding, such as timeliness of care, ambulance diversion and patient flow; and (c) tools to forecast or measure crowding. We also excluded commentaries, editorials, articles not published in English, or those without abstracts. No contact was made with study authors.

Data Extraction

We adapted a data extraction tool used previously to address relevant items in the summary and synthesis of articles (Uchida, Pogorzelska-Maziarz, Smith, & Larson, 2013). Fields included in our tool were primary author of the study and year of publication, study design, inclusion criteria and population studied, ED type (e.g. academic, urban, etc.), measure used to quantify crowding, measure used to quantify patient outcome, study results, and study limitations. All researchers piloted this tool using two articles, with high levels of data extraction agreement. One researcher reviewed the remaining studies and completed the data extraction.

Quality Assessment

Recent studies have examined the use of quality assessment instruments in observational studies; yet, a single instrument has not been recommended. The Agency for Healthcare Research and Quality (AHRQ) developed a series of evaluation tools for different study designs (West et al., 2002). We adopted the quality of observational studies' assessment criteria used by AHRQ, which evaluates whether study authors addressed the following domains: (a) study question and population (i.e., whether a clear and appropriate study question was present, whether a description of the study population was provided, and whether a sample size calculation was performed); (b) comparability of subjects (i.e., whether clear inclusion and exclusion criteria were stated, whether comparison groups were comparable); (c) exposure or intervention measurement (i.e., whether the exposure was clearly defined, reliable, and valid); (d) outcome measurement (i.e., whether the outcome variable was clearly defined, reliable, and valid); (e) statistical analysis (i.e., whether the use of appropriate statistical tests were appropriate); (f) results (i.e., whether study results

included confidence intervals and point estimates); and (g) discussion (i.e., whether the study conclusions were supported by study results). For the purposes of our quality appraisal, we excluded the assessment of funding sources.

Domains were evaluated on whether study authors fully addressed, partially addressed, or failed to address each domain and its subcomponents. For example, in assessing the results domain, a study received a full score if the authors provided confidence intervals and point estimates of their analyses and fully reported on all study aims; in evaluating the exposure domain, a study received a null score if the ED crowding exposure was not clearly stated and if there were no data regarding whether the method of measurement was standardized and tested for validity and reliability. In the event that study authors addressed all but one subcomponent of a domain, the study received a partial score. Each study author independently assessed the quality of two articles using the criteria described earlier. The few disagreements found were resolved through discussion and consensus. One researcher assessed the quality of remaining studies.

Results

A total of 196 article titles and abstracts were screened for study relevance; 176 articles were identified using Medline and 20 articles were found through additional methods (e.g., searching the tables of contents of emergency journals, hand searching reference sections of relevant articles identified in Medline, and hand searching reference sections of full-text articles included in the review). Of these, 180 articles did not meet our inclusion criteria, leaving 16 full-text articles for review. A total of five additional articles were excluded as they were noted to meet exclusion criteria during full-text screening. A total of 11 articles were included in the review. Figure 1 shows the flowchart of study inclusion.

Emergency Department Characteristics

Table 2 provides a detailed description of studies included in this review. A majority of the researchers examined EDs that were located in urban areas or part of tertiary care facilities (Asaro, Lewis, & Boxerman, 2007; Pines, Garson, et al., 2007; Pines et al., 2008; Pines et al., 2009; Polevoi, Quinn, & Kramer, 2005; Richardson, 2006; Vieth & Rhodes, 2006; Weiss et al., 2005). Only one study was conducted in a community teaching hospital (Kulstad, Hart, & Waghchoure, 2010). With the exception of the study by Polevoi et al. (2005), whose ED had an annual visit rate of 35,000, studies generally examined EDs with annual visit rates of 45,000 or more (Asaro et al., 2007; Kulstad et al., 2010; Pines, Garson, et al., 2007; Pines et al., 2008; Pines et al., 2009; Richardson, 2006; Vieth & Rhodes, 2006). Three studies were conducted outside the United States, in Korea, Canada, and Australia. These were the only investigations that included children in analyses (Cha et al., 2011; Guttmann et al., 2011; Richardson, 2006). Of these, two were multisite (Cha et al., 2011; Guttmann et al., 2011). Study periods varied in duration and ranged from 18 days (Weiss et al., 2005) to 7 years (Pines et al., 2009). With the exception of two prospective studies (Pines, Garson, et al., 2007; Weiss et al., 2005), all studies were retrospective or had a retrospective component (Asaro et al., 2007; Cha et al., 2011; Guttmann et al., 2011;

Kulstad et al., 2010; Pines et al., 2008; Pines et al., 2009; Polevoi et al., 2005; Richardson, 2006; Vieth & Rhodes, 2006).

Relationship Between ED Crowding and Patient Outcomes

Measures of ED crowding were collected via ED and/or hospital tracking systems in a majority of studies (Asaro et al., 2007; Kulstad et al., 2010; Pines, Garson, et al., 2007; Pines et al., 2008; Pines et al., 2009; Polevoi et al., 2005; Richardson, 2006; Weiss et al., 2005). The two multisite studies used national administrative databases of ED visit data (Cha et al., 2011; Guttmann et al., 2011). Formal ED crowding scales or indexes were used in two studies (Kulstad et al., 2010; Weiss et al., 2005), and healthcare workers' perception of ED crowding was used in one study (Vieth & Rhodes, 2006). A majority of studies measured waiting room time, waiting room census, ED occupancy, and defined crowding as the highest quartile of the specific measure employed (Cha et al., 2011; Pines, Garson, et al., 2007; Pines et al., 2008; Pines et al., 2009; Richardson, 2006).

Only in the three international studies did authors primarily seek to detect and find a relationship between ED crowding and patient mortality (Cha et al., 2011; Guttmann et al., 2011; Richardson, 2006). In a retrospective cohort, Cha and colleagues (2011) reported that 30-day mortality was significantly greater among pediatric patients exposed to ED crowding, versus pediatric patients not exposed to crowding (hazard ratio [HR] 1.26; 95% confidence interval [CI] 1.02–1.59).

In a retrospective stratified cohort study, Richardson (2006) reported that the risk of 10-day inpatient mortality for patients admitted to the hospital via the ED during crowding periods was 34% higher (relative risk [RR] 1.34; 95% CI 1.04–1.72) compared to those admitted during noncrowding periods. In a population-based retrospective cohort, Guttman et al. (2011) found that the risk for 7-day death among those discharged from the ED was greater among those who visited the ED during shifts with mean patient length of stay ≥ 6 hr than among those who presented to the ED during shifts with mean length of stay <1 hr (odds ratio [OR] 1.79; 95% CI 1.24–2.59). These studies included the largest sample sizes of studies reviewed.

Pines and colleagues (2009) performed a retrospective cohort study to examine the relationship between ED crowding and adverse cardiovascular outcomes (e.g., dysrhythmias, heart failure, cardiac arrest, etc.) among ED patients admitted to the hospital with acute coronary syndrome (ACS)-related chest pain and non-ACS-related chest pain. Authors found a positive relationship between adverse cardiovascular outcomes and several ED crowding measures.

Patient responses to the Press-Ganey patient satisfaction survey were used to investigate the relationship between ED crowding and the likelihood that an individual would recommend the ED to others (Pines et al., 2008). Authors found that patients surveyed during high levels of ED crowding were significantly less likely to recommend the ED to others (e.g., OR of recommending ED among those surveyed during highest quartile of ED occupancy was 0.5; 95% CI 0.4–0.7).

In a prospective cross-sectional study, researchers examined the relationship between ED crowding and perceptions of compromised care among 644 patients (Pines, Garson, et al., 2007). ED crowding measures that predicted patients' perceptions of compromised care included increased waiting room time (OR = 1.05 for each additional 10 min of time spent in the waiting room; 95% CI 1.02–1.09) and receiving care in hallways (OR = 2.02; 95% CI 1.12–3.68).

Five studies examined the relationship between ED crowding and rates of patients leaving the ED without being seen by a care provider (Asaro et al., 2007; Kulstad et al., 2010; Polevoi et al., 2005; Vieth & Rhodes, 2006; Weiss et al., 2005). Study periods ranged from 18 days (Weiss et al., 2005) to 27 months (Asaro et al., 2007). The number of patients who left the ED prior to being seen ranged from 213 (Polevoi et al., 2005) to 14,170 (Asaro et al., 2007). All five studies reported a positive correlation between ED crowding measures and patients leaving the ED prior to receiving care.

Quality Appraisal

Table 3 summarizes results of the quality appraisal. The most common deficit was among the study question and population domain. Only one study included a sample size justification or power calculation (Richardson, 2006). Four studies failed to provide detailed characteristics of their sample, which was reflected in the comparability of subjects domain (Kulstad et al., 2010; Polevoi et al., 2005; Vieth & Rhodes, 2006; Weiss et al., 2005). A majority of studies fully addressed the exposure measure, outcome measure, statistical analysis, and results domains. However, in the study by Vieth et al. (2006), ED crowding was assessed via the perceptions of ED providers, yet authors failed to detail the validity and reliability of this crowding measure. Similarly, in the study by Pines, Garson et al. (2007) researchers evaluated the relationship between ED crowding and care compromise, but "care compromise" was not defined. Further, the psychometric properties of the survey instrument used to measure this concept were not discussed. Survey questions also appeared leading and likely influenced survey responses. Lastly, in the study by Vieth and Rhodes (2006), authors stated that rates of leaving without being seen were significantly correlated with provider perceptions of ED crowding. Yet, the statistical test used and its outcome effect were not provided.

Discussion

Two recent literature reviews (Bernstein et al., 2009; Johnson & Winkelman, 2011) found numerous studies that demonstrate an association between ED crowding and several care processes such as prolonged time to analgesia and antibiotics. While the purpose of this review was to assess data on patient outcomes, we were only able to find four articles that examined patient health outcomes. Several of the additional outcomes examined are inherently more process oriented. Notably, three studies in our review, conducted outside of the United States, primarily investigated the linkage between ED crowding and patient mortality (Cha et al., 2011; Guttmann et al., 2011; Richardson, 2006). The studies included in this review were conducted in EDs that average more visits than the median number of ED visits (Emergency Medicine Network, 2014), perhaps because ED crowding is more

acute in high-volume facilities or because such facilities have the capacity to conduct this type of research.

Methodological rigor varied across studies. A sample size justification was only provided in one study. In terms of crowding measures, only two studies in this review used standardized scales. This is not surprising given that a recent systematic review of ED crowding indexes identified 71 crowding measures (Hwang et al., 2011). Study authors also cautioned that multidimensional crowding scales are complex and that data elements may not be consistently available across institutions.

Findings of this review are clinically important as the ED plays a significant role in the U.S. healthcare system and safety net. Since 1986, The Emergency Medical Treatment and Active Labor Act has mandated that the ED provide care to all individuals regardless of the individual's acuity of illness or ability to pay (Zibulewsky, 2001). While the Patient Protection and Affordable Care Act will extend healthcare coverage to approximately 30 million Americans (James & Savitz, 2011), similar health reform efforts were not associated with an overall reduction in ED utilization in Massachusetts (Smulowitz et al., 2011). In following, the effect of the Affordable Care Act on the national problem of ED crowding is unknown and should be a component of a research agenda.

The continued scientific contributions of nurses and nursing organizations are needed to further understand the impact of ED crowding and to implement solutions to curb ED crowding. Nurse organizations and nurse researchers have advocated for change in the form of policy statements (Emergency Nurses Association, 2006) and scientific research (Johnson & Winkelman, 2011). Such continued efforts will serve to address the problem of ED crowding.

Limitations

This review has several limitations. First, a single researcher initially screened titles and abstracts. Second, a single search engine was used and the grey literature was not examined. Third, articles were limited to those that measured ED crowding or explicitly said to have measured a surrogate of crowding. Thus, relevant articles may have been missed during the selection process. Fourth, study data abstraction and quality assessments were primarily done by one researcher. While a subset of articles was pilot tested for study data abstraction and quality assessments with high inter-rater agreement, there was still a measure of subjectivity in assigning quality scores.

Conclusions

Several studies have detailed the relationship between ED crowding and patient outcomes. Notably, studies found that ED crowding is associated with higher rates of inpatient mortality among those admitted to the hospital from the ED and discharged from the ED to home. Studies also consistently found that ED crowding is associated with higher rates of individuals leaving the ED without being seen. Given the significance and magnitude of ED crowding, policies are needed to address this major patient safety concern.

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Clinical Resources

- American College of Emergency Physicians Crowding Policy Statement: http://www.acep.org/Clinical—Practice-Management/Crowding/
- American College of Emergency Physicians Emergency Medicine Crowding and Boarding Resources: http://www.acep.org/crowding/
- Emergency Nurses Association Position Statement: http://www.ena.org/SiteCollectionDocuments/Position%20Statements/ImprovingFlowThroughputReduceCrowding.pdf
- Urgent Matters: http://urgentmatters.org/overview

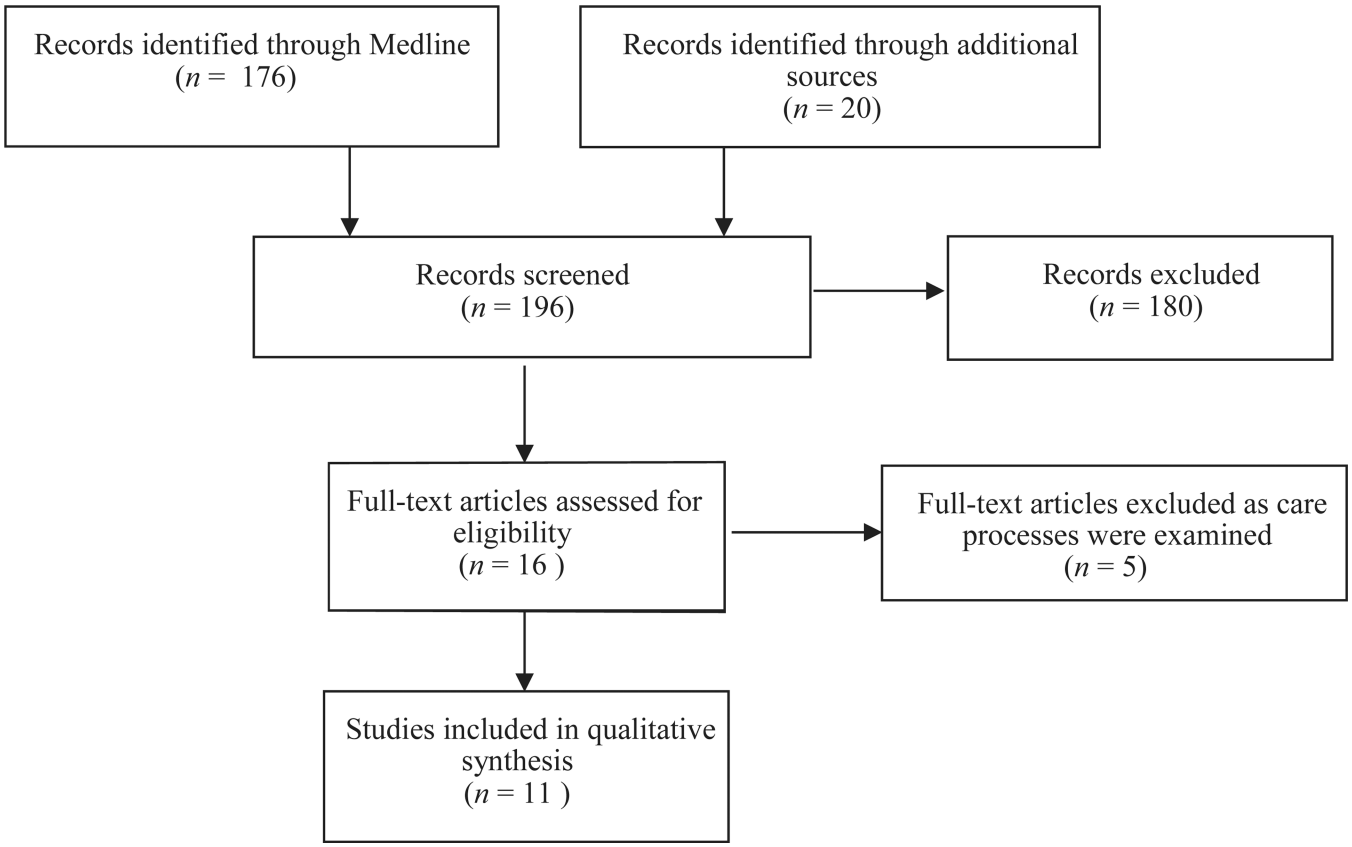

Figure 1.
Flowchart of study selection.

Table 1

Search Strategy for OVID Medline and Ovid Medline In-Process and Other Nonindexed Citations

No.	Search term	Results yielded
1	Crowding.mp. or Crowding/	6,319
2	Overcrowding.mp.	1,496
3	1 or 2	7,454
4	Emergency Service, Hospital/	37,757
5	emergency department.mp.	32,257
6	4 or 5	54,749
7	3 and 6	776
8	"Outcome Assessment (Health Care)"/ or Treatment Outcome/ or patient outcomes.mp.	580,860
9	Mortality/	32,368
10	Morbidity/	21,691
11	Patient Satisfaction/	52,050
12	Infection/	29,285
13	leaving without being seen.mp. or "Length of Stay"/	51,340
14	Hospital Mortality/	18,780
15	8 or 9 or 10 or 11 or 12 or 13 or 14	739,169
16	7 and 15	225
17	limit 16 to (abstracts and English language and humans and yr = "2002 – Current")	176

Table 2

Description of Studies

Author (year)	Study design	Sample and ED characteristics	Crowding measure	Outcome measure	Results
Polevoi et al. (2005)	Case-crossover	*N* = 213 patients LWBS Annual ED visits = 35,000	ED capacity (number of patients in the ED divided by the number of licensed bed)	LWBS rates	≥140% ED capacity positively associated with increased LWBS rates (OR = 1.96, 95% CI 1.22–3.17)
Weiss et al. (2005)	Prospective observational	*N* = 312 patients LWBS Annual ED visits = 60,000	NEDOCS	LWBS rates at presentation and 2, 4, and 6 hr after presentation	LWBS and NEDOCS scores correlated at presentation, 2, and 4 hr after presentation to the ED (Spearman r's 0.66, 0.67, 0.67, $p < .05$)
Richardson (2006)	Retrospective stratified cohort	*N* = 34,377 crowded group patients; *n* = 32,231 noncrowded group patients Annual ED visits = 50,000	Mean total patient care hours rendered to ED patients per shift[a]	10-day mortality	Inpatient mortality higher during crowding (RR = 1.34, 95% CI 1.04–1.72)
Vieth & Rhodes (2006)	Correlational study	*N* = 1,081 patients LWBS Annual ED visits = 48,000	Survey responses from attending physician and charge nurse at 6-hr intervals	LWBS rates	Survey responses correlated with LWBS rates ($p < .01$). No additional mention of analyses or results.
Asaro et al. (2007)	Retrospective observational	*N* = 14,170 patients LWBS Annual ED visits = 78,000	Number of boarders (patients waiting an inpatient bed in the ED); daily number of ED visits; percentage of ED patients admitted to hospital during 24-hr period, etc.	LWBS rates	LWBS rates were higher in visits that occurred during the 80th percentile of ED crowding than visits that occurred during the 20th percentile of ED crowding measures (OR = 2.00, 95% CI 1.93–2.07 for daily ED arrivals), etc.
Pines, Garson et al. (2007)	Prospective cross-sectional	*N* = 644 patient surveys; 716 nursing surveys; and 703 resident physician surveys Annual ED visits = 57,000	WR time (time patient stayed in waiting room)[a]; WR census; nurse-to-patient ratio; ED occupancy rate, etc.	Care compromise rated by nurses, physicians, and patients	Predictors of comprised care among nurses were WR time (OR = 1.05 for additional 10-min wait, 1.01–1.08), etc. Predictors among physicians were nurse-to-patient ratio (OR = 1.39, 95% CI 1.09–1.20), etc.
Pines et al. (2008)	Retrospective cohort	*N* = 1,469 patients Annual ED visits = 55,000–57,000	WR time[a]; WR census, ED occupancy, number of boarders, etc.	Patient satisfaction	OR of recommending ED among those surveyed during high levels of ED occupancy was 0.5 (95% CI 0.4–0.7), etc.
Pines et al. (2009)	Retrospective cohort	*N* = 803 patients with ACS-related chest pain; *n* = 3,771 with non-ACS related chest pain Annual ED visits = 50,000–55,000	WR census[a]; patient care hours (sum of hours that patients present in ED have stayed in ED), ED occupancy, etc.	Adverse cardiac outcomes, e.g., dysrhythmias, cardiac arrest, etc.	OR of adverse cardiac outcomes in ACS-related chest pain cohort was 3.7 when WR census ≥12 (95% CI 1.3–11.0) and 3.5 (95% CI 1.4–8.4) in non-ACS-related chest pain cohort, etc.
Kulstad et al. (2010)	Retrospective observational	*N* = 1,193 patients LWBS Annual ED visits = 85,000	EDWIN and ED occupancy rates	LWBS rates	Area under receiver operator curve predictive of >2 patients LWBS in one day was 0.97 (95% CI 0.93–1.0) for occupancy rate and 0.94 (95% CI 0.89–1.0) for EDWIN

Author (year)	Study design	Sample and ED characteristics	Crowding measure	Outcome measure	Results
Cha et al. (2011)	Retrospective cohort	*N* = 125,031 pediatric patients; 35,924 patients in crowded group; 89,107 patients in noncrowded group; 34 adult-pediatric EDs	ED patient volume by shift[a]	30-day mortality	HR of 30-day mortality among crowded group compared to noncrowded group was 1.26 (95% CI 1.02–1.59)
Guttmann et al. (2011)	Population based retrospective cohort	*N* = 13,934,542 visits that resulted in ED discharge 125 EDs in Ontario, Canada	Mean ED patient LOS by shift	7-day mortality	OR of 7-day mortality among group that presented to the ED during shifts with mean LOS ≥ 6hrvs. <1hrwas 1.79 (95% CI 1.24–2.59)

Note. LWBS = left without being seen; ED = emergency department; HR = hazard ratio; OR = odds ratio; RR = relative risk; WR = waiting room; ACS = acute coronary syndrome; LOS = length of stay NEDOCS = National Emergency Department Overcrowding Scale; EDWIN = ED Work Index,

[a]Authors used the highest quartile of ED crowding measure(s) to define ED crowding

Table 3

Quality of Studies

Study author (year)	Domains						
	Study question & study population[a]	Comparability of subjects[b]	Exposure or intervention[c]	Outcome measure[d]	Statistical analysis[e]	Results[f]	Discussion[g]
Polevoi et al. 2005)	◐	◐	●	●	●	●	●
Weiss et al. (2005)	◐	◐	●	●	●	●	●
Richardson (2006)	●	●	●	●	●	●	●
Vieth & Rhodes (2006)	◐	◐	◐	●	◐	○	◐
Asaro et al. (2007)	◐	●	●	●	●	●	●
Pines, Garson et al. (2007)	◐	●	●	○	●	●	●
Pines et al. (2008)	◐	●	●	●	●	●	●
Pines et al. (2009)	◐	●	●	●	●	●	●
Kulstad et al. (2010)	◐	◐	●	●	●	●	●
Cha et al. (2011)	◐	●	●	●	●	●	●
Guttmann et al. (2011)	◐	●	●	●	●	●	●

Note. ● = domain completely addressed; ◐ = domain partially addressed; ○ = domain not addressed.

[a] Study question & population domain: Was the study purpose clear and appropriate? Was the study population adequately described? Was a sample size justification provided?

[b] Comparability of subjects domain: Were specific inclusion/exclusion criteria provided for all groups? Was group comparability adequately described? Were comparison groups similar? Additional criteria for case-control studies: Was an explicit case definition used? Were controls similar to cases except without exposure?

[c] Exposure or intervention domain: Was there a clear definition of exposure? Was the method of assessment standard valid and reliable? Was exposure measured equally in all groups?

[d] Outcome measure domain: Were primary and secondary outcomes clearly defined? Was the method of assessment standard valid and reliable?

[e] Statistical analysis domain: Were statistical tests appropriate?

[f] Results domain: Was an outcome effect and measure of precision provided?

[g] Discussion domain: Were conclusions supported by results?