Injury and Death Associated with Hospital Bed Side-Rails: Reports to the US Food and Drug Administration from 1985 to 1995

ABSTRACT

Objectives. Hospital bed side-rails, while intended for patient protection, can contribute to injury and death. Reports to the Food and Drug Administration (FDA) of hospital bed side-rail entrapment have increased. In this paper entrapment cases are reviewed and the population potentially at risk identified.

Methods. FDA's database was searched for events involving hospital beds from January 1985 to August 1995 and entrapment cases were identified.

Results. Of 111 entrapments, 65% were associated with death and 23% with injury.

Conclusions. Advanced age, female sex, low body weight, and cognitive impairment may be associated with increased risk. Preventive measures are detailed. (*Am J Public Health.* 1997;87:1675–1677)

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Introduction

Hospital beds are used in an estimated 31 million hospitalizations[1] and by approximately 1.5 million long-term care residents[2] each year in the United States. While hospital bed side-rails are intended to protect patients from falls, they may pose a risk of entrapment. In recent years, Canadian and British regulatory authorities have issued notices warning of the potential risk of side-rail entrapment.[3,4,5]

Hospital beds (frames, mattresses, rails) are made by multiple manufacturers and sold both as a unit and as individual components. Hospital beds are regulated as medical devices in the United States. Currently, there are no universal standards, voluntary or mandatory, for hospital beds.

Reports to the adverse event reporting system of the Food and Drug Administration (FDA) continue to document problems associated with use of hospital beds. In 1995, owing to increasing numbers of death and injury reports, the FDA issued a safety alert on hazards associated with side-rails.[6] In this report we review side-rail entrapment cases reported from 1985 to 1995 and identify the population potentially at risk.

Methods

The FDA monitors the safety and effectiveness of medical and radiation-emitting devices by analysis of over 100 000 voluntary and mandatory reports submitted annually through a nationwide surveillance system. Voluntary reports, approximately 3% of the total, are submitted by health care providers and consumers through MedWatch, the FDA's national program for reporting problems with medical products. Mandatory reports of medical device–related deaths, serious injuries, and malfunctions are submitted to the FDA by manufacturers, distributors, and user facilities (such as hospitals and nursing homes).

The FDA's adverse event reports database was computer-searched for all adverse events involving codes for hospital beds reported from January 1, 1985, to August 9, 1995. Episodes of entrapment were identified on the basis of the following criteria: (1) the patient was found caught, trapped, entangled, or strangled by the rail while in a hospital bed and (2) a cloth restraint was not considered to be responsible or was not mentioned. A descriptive analysis of these reports was conducted.

Results

Six hundred forty-nine adverse events associated with hospital beds were reported during the study period. Of these, 112 (17%) were reports of entrapments, 111 associated with side-rails (1 involved the bedframe alone). Seventy-two of these 111 reports (65%) were associated with death, 26 (23%) with nonfatal injury, and 13 (12%) with no adverse effects (owing to staff intervention). Seventy-eight of 97 (80%) events with a date reported occurred after January 1, 1992 (Figure 1).

Characteristics of 111 hospital bed side-rail entrapment events are shown in Table 1. The majority of patients were 65 years or older and over half of these were

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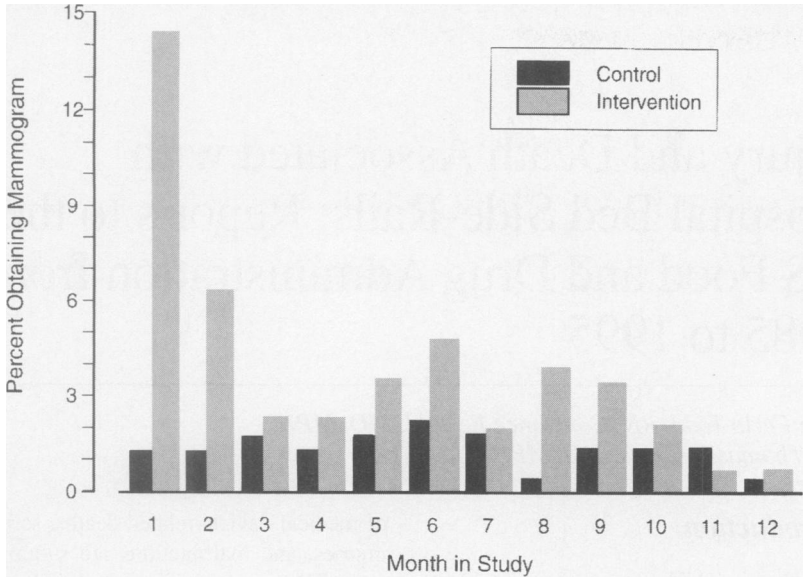

FIGURE 1—Reports of hospital bed side-rail entrapment, by type and year of event: US Food and Drug Administration adverse event reporting database, 1985 through 1995.

85 years or older. Females outnumbered males. Although data on body weight were limited, most of the patients had low weights. Entrapment occurred most often between the side-rail and the mattress, and the head or neck was the most frequently entrapped body part. The majority of entrapments occurred in a nursing home. The largest number took place in the South. The majority occurred in cities with populations of less than 250 000.

Cloth restraints were in use at the time of entrapment, but not considered to be involved in the entrapment, in 17 of the 111 reports; not in use in 4; and not mentioned in the remainder.

In 37 (33%) of the 111 cases the patient had known confusion or restlessness at the time of entrapment or had a diagnosed condition commonly causing cognitive impairment (stroke/seizure, psychiatric illness, dementia, postoperative status, adrenoleukodystrophy). In 8 cases (7%), the person had decreased muscle control.

Cause of death was reported for 38 (53%) of the 72 fatal entrapments. The cause of death for 32 (84%) of these 38 patients was asphyxiation, strangulation, or suffocation; the remainder died of cardiac arrest, cardiac arrhythmias, or pneumonia.

Type of injury, reported for all but one of 26 injury cases, consisted of respiratory or circulatory compromise (unresponsiveness, obstructed breathing, respiratory arrest, cyanosis, or lack of a pulse) in 12 cases (48%); injury to skin, soft tissues, or both in 8 cases (32%); and fractures or sprains in 5 cases (20%).

Discussion

In considering hospital bed side-rail entrapment, limitations of data based on passively reported adverse events must be noted. First, reports of adverse events are generally incomplete and unverified. Although reports are presumed to be device-related, causality cannot be established from individual reports. Second, the number of unreported adverse events is unknown. Third, the incidence of adverse events cannot be determined because of a lack of valid estimates of population exposure to the device. Finally, reports are subject to detection, attribution, and reporting biases.

Despite these limitations, adverse event reports can suggest a profile of patients at risk for side-rail entrapment. Potential risk factors include advanced age, female sex, low body weight, and cognitive impairment. Insufficient information was available to evaluate the potential role in side-rail entrapment of decreased muscle control, cloth restraints, medication use, type of side-rail, and poor mattress fit.

Although the number of reported adverse events associated with side-rail entrapment is small compared with the

TABLE 1—Distribution of Characteristics of Hospital Bed Side-Rail Entrapment Events: US Food and Drug Administration Adverse Event Reports Database, 1985 through 1995

	No.	%[b]
Patient age, y (n = 75)[a]		
0–17	4	5
18–64	7	9
65–74	13	17
75–84	15	20
85–94	32	43
≥95	4	5
Patient sex (n = 80)[a]		
Male	23	29
Female	57	71
Patient weight, lb (adults) (n = 25)[a]		
≤100	9	36
101–150	11	44
151–200	4	16
>200	1	4
Location (n = 111)[a]		
Side-rail/mattress	64	58
Through side-rail bars	25	22
Between split side-rails	18	16
Head- or footboard/side-rail/mattress	4	4
Body part involved (n = 83)[a]		
Head/neck	56	68
Whole body	11	13
Extremity	11	13
Thorax	5	6
Type of facility (n = 108)[a]		
Nursing home	63	58
Hospital	42	39
Private home	3	3
Region (n = 107)[a]		
South	48	45
Midwest	34	32
Northeast	13	12
West	12	11
City population (n = 102)[a]		
<100 000	63	62
100 000–249 999	11	11
250 000–499 999	14	14
500 000–999 999	10	9
≥1 000 000	4	4

[a]This figure reflects the number of reports available with information on this characteristic.
[b]Subgroup percentages may not add to 100% because of rounding.

number of hospital bed users, any deaths or injuries associated with a device intended for patient protection are significant. The number of adverse events due to side-rail entrapment can be decreased if user facilities take the following precautions[6]:

1. Inspect hospital bed frames, side-rails, and mattresses regularly for potential locations for entrapment.
2. Use compatible side-rails and mattresses to prevent gaps in which a patient could become entrapped. Check with manufacturers to verify compatibility of components purchased separately.
3. Verify that side-rails have been installed according to the manufacturer's instructions.
4. Use additional safety measures (e.g., side-rail protective barriers) for high-risk patients.
5. Develop profiles of patients at increased risk of entrapment.

In addition, manufacturers and the user community should develop universal standards for side-rail design.

Adverse events can be reported to the FDA's MedWatch program (Medical Products Reporting Program, MedWatch, HF-2, Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857; telephone [to report an adverse event or to request MedWatch information]: 1-800-FDA-1088). Reporting, although voluntary, is vital to ensure that medical devices continue to be safe. □

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Consequences of Foot Binding among Older Women in Beijing, China

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ABSTRACT

Objectives. This study examined the prevalence and consequences of foot binding in older Chinese women.

Methods. Women older than 70 years in Beijing, China, were assessed for bound feet, falls, functional status, and bone density.

Results. Thirty-eight percent of women aged 80 years and older and 18% of women aged 70 through 79 years had bound-foot deformities. Women with bound feet were more likely to fall, less able to squat, and less able to stand up from a chair without assistance than women with normal feet. They also had 14.3% less functional reach (a test of balance) and 5.1% lower hip bone density.

Conclusions. Foot binding has caused substantial disability that is still evident in many elderly Chinese women. (*Am J Public Health.* 1997; 87:1677–1679)

Introduction

The practice of foot binding began in the Sung dynasty (AD 960–1280) in China, reportedly to imitate an imperial concubine who was required to dance with her feet bound.[1] By the 12th century, the practice was widespread and more severe: feet were bound so tightly and so early in life that women were unable to dance and had difficulty walking.[1,2] When a girl was about 3 years old, all but the first toe on each foot were broken and the feet bound with cloth strips that were tightened over the course of 2 years to keep the feet shorter than 10 cm and to bend the sole into extreme concavity (Figure 1). Foot binding ceased in the 20th century with the end of imperial dynasties and the increasing influence of Western fashion. As the practice waned, some girls' feet were released after initial binding, leaving less severe deformities.

The prevalence and consequences of foot-binding deformity have never been studied. We studied foot-binding deformities as part of a study of osteoporosis in older women in Beijing.

Methods

We randomly selected one health section from each of Beijing's central districts, then randomly selected neighborhoods from each section and randomly ordered streets within the selected neighborhoods. We interviewed all women aged 50 or older on each street until we reached a quota proportional to the population of women aged 50 or older in that district, according to the 1990 China census.

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