ORIGINAL ARTICLE

Do split-side rails present an increased risk to patient safety?

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Background: Concerns have been raised about the safety of split-side bed rails for patients in the UK.

Objectives: To investigate whether split-side rails were more likely to be associated with entrapment and injury of patients than other bed rail types. To establish whether there was a difference in the site of injury caused by different bed rail types and whether the outcome of the injury (death versus survival) varied by bedrail type.

Methods: A search of the USA Food and Drug Administration MAUDE database was carried out. The reports were screened using rigorous inclusion/exclusion criteria and then coded for rail type, incident outcome, and area of body involved.

Results: Split-side rail incidents only accounted for 5% of the reports and were more likely to involve the chest or pelvis. Although the biggest overall risk by rail type cannot be determined from these data, the severity of the outcome changed with the equipment type. Incidents involving half rails were more likely to be associated with head, neck, or face entrapments and were also more likely than other bed rail types to result in death.

Discussion: Split-side rail entrapments were not a common occurrence. However, our findings suggest that bed rails are associated with some level of risk of entrapment that potentially could result in death. Healthcare providers should therefore ensure that they follow the guidelines for risk assessment and rail use from the MHRA and other professional bodies so that the cultural norm in the UK continues to be "opt in", where no bed rails are used unless indicated by a documented clinical assessment.

Bed rails (also known as side rails, bed side rails, cot sides, and safety rails) are adjustable metal or rigid plastic bars that attach to the bed and are available in a variety of shapes and sizes from full, three-quarters, half, one-quarter, and one-eighth in length as well as one or two (split rails) for each side of the bed. Full length bed rails are available in two basic designs, trombone (telescoping) and concertina/folding.^{1–2} Examples of the three most common designs (full, split and half) are shown in fig 1.

Bed rails are used in all caring environments from acute facilities to nursing and residential accommodation and in private homes. In the UK full length rails are mostly used whereas, in the USA, the predominant type of rail is the split-side rail. Split-side rails have been widely used in the USA for the last 25 years but they are relatively new in the UK. This difference is related to the use of electric beds which have been widely used in the USA since the 1970s. More recently in the UK hydraulic beds are being replaced with electric profiling beds.³ There are also differences in the culture of rail use. In the UK there has been an "opt in" culture with a recommendation in 1975 that bed rails should not be used routinely and their use should be continually reviewed.⁴ In contrast, the USA has had an "opt out" culture resulting from a recommendation in 1957 that bed rails should be permanently fixed to every hospital bed and used unless written instructions were given by the physician, accompanied by a signed release from the patient.⁵

Concerns were raised about the safety of bed rails in 1997 in the USA.^{6–7} In 1999 the Food and Drug Administration (FDA) set up a working group (Hospital Bed Safety Workgroup, HBSW) to look at risks associated with the use of bed rails.⁸ They identified several functions for rails including a physical barrier to remind the patient of the perimeters of the bed and to provide additional security when the bed and patient are moved. Rails are also used by patients to adjust their position by providing a handhold to assist turning and getting out of the bed. Bed rails can also provide

a feeling of comfort and security for patients and their relatives. However, the HBSW advised that bed rails should be used with caution for people who are frail, elderly, and/or have conditions including agitation, delirium, confusion, pain, uncontrolled body movements, hypoxia, faecal impaction, and acute urinary retention.⁸

Three papers have reported deaths, injuries, and near miss adverse events (AEs) associated with the use of bed rails^{6–9–10} using the AE data from the FDA Manufacturer and User facility Device Experience database (MAUDE).¹¹ This is a voluntary reporting scheme and receives input from

Figure 1 Examples of the different length bed rails: (A) full; (B) split; (C) half.

healthcare providers, manufacturers, patients and carers in acute, residential, nursing and community facilities and private accommodation. There are preset fields for entering information about date, bed model, manufacturer, outcome, and a free text area to describe the incident. The frequency of bed rail related reports has increased in recent years from 111 reports between 1985 and 1995⁵ to 325 reports between 1998 and 2001.¹⁰ This large increase in the reporting rate has been attributed to the FDA Safety Alert¹² issued in 1995.¹³

There is very limited information available in the public domain about incidents involving hospital beds in the UK. At a workshop organised by the Medicines and Health Products Regulatory Agency (MHRA), Marsden¹⁴ presented data from the primary and community care sector (including acute, residential, and private accommodation). He reported that 94 incidents had been reported to the MHRA in 2002 involving bed rails and that there have been 20 deaths in the UK involving bed rails since 1997.

Parker and Miles⁷ categorised three types of death: (1) entrapment in the mattress rail (or head/foot board) horizontal gap; (2) within the rails, including latch failure where the rail dropped due to patients struggling to free themselves; and (3) entrapment with the body off the bed and the neck or chest compressed by the rail. The risk of entrapment between split-side rails was not identified in their analysis.

Concerns have recently been raised in the UK about the safety of split-side rails and Wells¹⁵ has suggested that they present a greater risk to the patient than full side rails. The MHRA has issued six safety warnings and a device bulletin on bed rails.^{16–22} If split-side beds do increase the risk to patient safety, then this may be an opportunity for the UK to learn from the experience of the USA and proactively manage the risk.

A study was undertaken to investigate whether split-side rails are more likely to be associated with entrapment and injury of patients than other bed rail types. An additional aim was to establish whether there was a difference in the site of injury caused by different bed rail types and to ascertain whether the outcome of the injury (death versus survival) varied with type of bed rail.

METHODS

The FDA database was searched from 1 January 1985 to 31 December 2002 for reports associated with patient injury, entrapment or near miss and bed rails using the product codes (manual, hydraulic and electric beds) and word searches ("bed", "rail", "side", "safety").

Reports were included where the patient was injured or entrapped in a bed rail-related event or fell to the floor when the rail collapsed. Exclusion criteria included (1) duplications of multiple reports for the same event (for example, bed, mattress, headboard and rail); (2) reports relating to (a) electrical faults, (b) bed collapse or malfunction not related to the bed rail, or (c) other bed components (such as subframe, monitor arm, overhead lifting pole, bed alarm, wheels, brake, crank, bed head/foot); (3) no details, just a record number; (4) carer or nurse interaction and/or injury; (5) death by natural causes although a report was filed; (6) other event such as violent patient or rail problem during shipping; (7) cloth restraints (vest, waist, wrist) except where the AE resulted from an interaction of the bed rail and restraint; and (8) paediatric beds, cots and cribs.

Analysis of data

After applying the exclusion criteria, the reports were coded and entered in a database. At this stage additional information was sought with respect to the rail type. When a report included the bed model number and the bed was only

Figure 2 Position of injured patients in relation to the bed and rail reported in the MAUDE database 1985–2002.

manufactured with one rail option, this information was added to the rail type variable in the data. The data were then analysed for rail type (full, half, split or three-quarter), position of injured patients, outcome (death, injury or near miss), and area of the body trapped or injured. Pearson's χ^2 test (SPSS version 11) was used to determine significant differences between rail type and outcome, and area of the body and rail type.

RESULTS

A total of 3466 reports were retrieved. The initial examination eliminated 2670 through duplication from the different search strategies and the application of the inclusion/exclusion criteria. This resulted in a final total of 794 reports which included 396 deaths, 292 injuries, 53 near misses, and 53 unclassified. Near misses are reported for incidents where a patient was found in a bed rail but did not result in an injury or entrapment. 355 reports gave information about the type of bed rail, including 199 split rails, 105 half rails, 37 full rails, and 14 three-quarter rails (the latter were omitted from the analysis due to the small number).

Position of injured patients

Patients were most often found with their head either between the rails or in the gap between the rail and either the head or foot board ($n = 287$, 38%); 164 (22%) were found on the floor following the collapse of the rail, 138 (18%) were found between the rail and the mattress, and 106 (14%) were found with their upper or lower limbs in the rail. Only 34 patients (5%) were found between the split sides (fig 2).

Figure 3 Percentage of adverse event outcomes resulting in death, near miss, or injury by rail type reported in the MAUDE database 1985–2002.

Figure 4 Percentage of adverse events resulting in entrapment of different areas of the body by rail type in the MAUDE database 1985–2002.

Outcome

341 reports were analysed to examine the bed rail type and outcome (fig 3). A significant relationship ($\chi^2 = 28.06$, $p < 0.001$, $df = 4$) found that: (a) half rails ($n = 105$) were more likely to be associated with deaths; (b) full rails ($n = 37$) were more likely to be associated with injuries; and (c) split rails ($n = 199$) had more reports with near misses.

Area of the body injured

134 reports with data on the area of the body injured were analysed to establish which areas were more likely to be injured in the different types of rail (fig 4). A significant relationship ($\chi^2 = 20.25$, $p < 0.001$, $df = 4$) found that: (a) head/neck/face entrapment/injuries ($n = 69$) were more likely to be associated with half rails; (b) pelvis/chest entrapment/injuries ($n = 27$) were more likely to be associated with split rails; and (c) upper and lower limb entrapment/injuries ($n = 38$) were more likely to be associated with full rails.

DISCUSSION

It is evident that bed rails can result in patient deaths from entrapment and injury. The analysis in this paper has investigated entrapments associated with three different designs of bed rails. Although we cannot conclude which bed rail type has the largest overall risk from these data, we

Figure 5 Entrapment between split-side rails.

can conclude that, if there is an incident associated with bed rails, then the outcome of the incident will change with the bed rail type, with more serious outcomes associated with half rails. It is important to note that the design of bed rails has changed considerably since 1985 and we do not believe that the half-length rail model associated with the greatest risk (as illustrated in Parker and Miles⁷ and fig 1C) has been used in the UK.²

We found that, although split-side rails have been available in the USA for over 25 years, the between split-side rail entrapments only accounted for 34 reports (5%). This is likely to be related to the design of the rail, the gaps within it, and the interface between the rail and other components of the bed such as the head board or mattress. The between split-side rail gap is usually wider and so less likely to trap the head or neck. The analysis found that between split-side rail reports more often involved the chest or pelvis (fig 5). This further supports our contention that the between split-side rail gap is less hazardous than other smaller width gaps. The MHRA safety bulletins and other publications²³ have addressed the within rail gap (less than 120 mm); bed and rail compatibility; fitting and adjustment of rails; maintenance; patient assessment and the selection of bed/rail, rail design; and mattress compatibility. The between rail gap dimension is specified in the British Standard²⁴ at either less than 60 mm (to minimise the risk of neck entrapment) or 250–400 mm. The appropriate anthropometric dimensions should be used to ensure that products fit (not trap or injure) the designated user population.

Split-side rails are more likely to be associated with a near miss report than a death or injury. This may be due to their availability on electric beds and subsequent location of use. Electric beds have tended to be used more in acute than community care where there may be more frequent observation by healthcare staff.

Limitations of the study

The reports in the MAUDE database are voluntary so are likely to represent only a proportion of the bed rail incidents that actually occur and will be subject to detection, attribution, and reporting biases. This is a particular problem if certain types of bed rails were more likely to be reported than others, although there is no evidence to suggest why this kind of selective reporting should occur. The data are drawn from all care giving environments—acute, community facilities, and residential, nursing and private homes—which means that the probability of death associated with the different types of rails cannot be calculated based on hospital stay data.

Key messages

- Bed rails can result in patient deaths from entrapment.
- There have been 20 reported deaths from bed rail entrapment in the UK since 1997.
- Entrapments mostly involved incidents within the rail or between the rail and the head or the footboard.
- Between split-side rails incidents only accounted for 5% of incident reports in the USA.
- Half-length rails were more likely to be associated with deaths and with head, neck or face entrapments in the USA.
- Healthcare providers should do a risk assessment whenever bed rails are used.

Data are not available to identify the market share of each of the bed rail types within the USA or the UK. Information is available from manufacturers regarding the bed models but unfortunately some beds could be manufactured with multiple rail options and these details are unavailable. This means that it is also not possible to estimate the overall risk associated with each rail type because we do not have information regarding the denominator of interest (the number of each of the different types of bed rail in use).

Recommendations for future work

Our findings from the MAUDE database suggest that bed rails are associated with some level of risk of entrapment that potentially can result in death. Although we cannot say which rail type has the biggest overall risk, if there is an incident related to bed rails the severity of the outcome will change with the equipment type, with half rails presenting a higher relative risk than split-side rails. Healthcare providers should therefore ensure that they follow the guidelines for risk assessment and rail use from the MHRA²⁵ and other professional bodies to ensure that the cultural norm continues to be “opt in” where no bed rails are used unless indicated by a documented clinical assessment. Additionally, O’Keeffe²⁶ has suggested—and our findings provide further evidence of the need for—a randomised controlled trial to look at the use of bed rails in more detail.

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