Title

Evaluating Canadian radiation therapists' and UK therapeutic radiographers' experiences and opinions of a safety strap to secure patients during radiotherapy

Keywords

safety; fall; service evaluation; radiation therapy; evidence-based radiography

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Abstract

Introduction: A serious patient safety incident at a cancer centre in Ontario, Canada saw a patient fall from an elevated treatment couch. A regional investigation recommended the use of a securing safety strap. The authors evaluate the value of the strap through the experiences of the radiation therapists' who use it. A secondary aim is to explore the potential for using a securing safety strap with UK therapeutic radiographers.

Methods: A two stage design was guided by an evidence-based practice (EBP) framework. Stage one used a questionnaire to capture treating radiation therapists' experiences and opinions of the strap at a single cancer centre. Quantitative data was analysed descriptively and free-text data via a content analysis. Stage two used semi-structured interviews with thematic analysis to explore views of three UK therapeutic radiographers.

Results: Twenty-five out of approximately 130 eligible staff responded to the Canadian questionnaire. Of the respondents, 24% (n=6) 'strongly disagreed', 28% (n=7) 'agreed' and 48% (n=12) 'neither agreed nor disagreed' that they would recommend the strap to other departments. Most of the respondents think strap use should be at the staffs' discretion, with patients with dementia/cognitive impairment ranked as the group benefiting most. Ninety two percent (n=23) of respondents confirmed that patients sometimes refuse the strap. Themes arising from stage two interviews are: patient benefit (use for select patients only); patient safety versus control (restraint); practical implementation issues.

Conclusion: The policy of universal use of the strap should be reviewed. Those who use it are equivocal about its value and feel it should be reserved for select patients at the treating professional's discretion. Full evaluation of the effectiveness and acceptability of the device for different patients may promote both staff enthusiasm towards the device and EBP. Adequate resources are required to evaluate implementation of such safety initiatives.

Introduction

Immobilisation devices are designed to achieve a level of reproducibility in a patient's position throughout a course of radiotherapy. Physical comfort contributes to reproducibility, but patient comfort can also be considered as a broader construct encompassing psychological and environmental aspects:[1,2] for example, distress experienced by a significant minority of patients immobilised with a head shell.[3] The need for falls risk assessment has been widely considered in acute healthcare setting.[4] Straps, foam wedges and detachable couch cot-sides may be used selectively in the radiotherapy setting, to promote comfort and safety for patients at greater risk of falling from the treatment couch. Patients perceived to be at an increased risk of falling include the anxious, obese or cognitively impaired[5-7] or those with lateral target volumes. The use of cot-sides is limited by beam attenuation issues and gantry-couch conflicts for radical treatments.[8]

A regional cancer centre in Canada experienced a safety incident in 2012, when a patient sustained a serious injury in a fall from an elevated treatment couch.[9] The incident triggered a comprehensive investigatory root cause analysis. A resultant (2015) collaborative report by regional stakeholders includes a position statement that recommends the routine use of a patient securing strap device[10] – referred to here as the strap (Fig 1). The purpose of the strap is to prevent a patient from unintentionally rolling off the couch. A functional and legal distinction between the strap and a restraint is that the former allows self-release (by a velcro™ fastening).[10,11] The implementation strategy outlined in the 2015 report states that all patients undergoing external beam treatment or simulation (apart from with a fixed head shell) would benefit from use of the strap.

Figure 1 The patient securing safety strap

All 15 regional cancer centres in Ontario have implemented the strap within their treatment protocols, with early indications of a positive reception from staff and patients.[9] Despite the

importance of evidence protocols in radiography, [12] to our best knowledge, no evaluation of the perceived value and acceptability of the device has been published. The aim of this study is to evaluate radiation therapists' (RT) experiences of and opinions on the strap at a Canadian cancer centre. A second aim is to explore the perceived strengths and weaknesses of a securing strap device with United Kingdom (UK) therapeutic radiographers (TR) who do not use it and consider potential use in the UK.

Methods

Study approval was granted by Cardiff University School of Healthcare Sciences Ethics Committee (07/2018): UK NHS REC approval was not required. Site approval to access staff was gained at each site. A two-stage survey design was guided by an evidence-based practice (EBP) framework.[12] EBP provides a framework for quality health practices that integrate professional's clinical experience with patient preferences and the best available external evidence. Consideration of these three components guided the current study service quality improvement study.

Stage one was a questionnaire that captured RT opinions and experiences of using the strap at a large urban cancer centre in Ontario, Canada. Approximately 130 potential participants were identified as working RT at the centre in 2018. The sampling frame excluded RT not regularly working with patients at the time of recruitment but included pre-treatment staff that rotate through treatment units. The authors developed a questionnaire based on relevant literature and anecdotal reports from radiographers that have used securing devices. Questionnaire clarity, content validity and internal consistency was piloted with two RTs at the study site. Pilot data was not included in the main analysis as question phrasing was modified as a result of feedback. The final questionnaire, which was distributed and returned online [www.smartsurvey.co.uk], comprised 17 five-point Likert-like questions – knowledge of the strap origin; practical experience; patient selection; perceptions of utility and patient acceptability – with opportunities to provide free-text explanation for Likert responses. All eligible RT were emailed the survey. A participant information sheet outlined that responses were anonymous, that consent was assumed on voluntary survey return and participant's right to withdraw.

Stage two consisted of face-to-face interviews with three TR at a major UK cancer centre who have no experience of using a strap device. The rationale was to provide a more theoretical perspective on the value of safety restraint devices. Participants were selected from a convenience sample of willing participants based onthem being experienced linac-based therapeutic radiographers that represented different bands of seniority/professional responsibility. The exploratory nature of the second study aim meant that sample size was not based on data saturation. Interviews were informed by stage one findings, but remained semi-structured within the bounds of an interview guide to avoid arbitrarily missing insightful perspectives.[13] Written consent was provided by participants prior to interviews, which were conducted in a quiet room at the study centre. Transcripts were returned to

participants to check for accuracy and intended meaning. Data was pseudo-anonymised, and identifiable data was deleted on study completion.

Data analysis

The questionnaire data (addressing the primary aim) was analysed descriptively for close-ended responses and via a simple content analysis for free-text.[14] Interview recordings were transcribed verbatim. Data analysis followed Braun and Clarke (2006),[15] who outline a method to identify and analyse data themes that is not tied to a specific theoretical framework. Transcripts were independently reviewed by another member of the research team. Final themes were grouped and agreed by discussion.

Results

Stage one – Canadian experience of the strap

Twenty-six questionnaires were returned, equating to a response rate of 21%. Four respondents (16%) worked in pre-treatment and 20 (77%) on treatment units. Two responses were from managerial staff, one of whom was deemed ineligible and excluded from analysis. Six of the remaining 25 participants had worked at the centre for 1–5 years and the remainder for 6–25 years.

Staff opinions of the strap

Radiation therapist's (RT) opinions about the acceptability of the strap are summarised in Table 1.

Statement	strongly agree	agree	neither agree/ disagree	disagree	strongly disagree
I would recommend other departments use the SS	0	7 (28)	12 (48)	6 (24)	0
I would rather leave the SS out of the set up	6 (24)	6 (24)	9 (36)	4 (16)	0
I would feel comfortable treating a routine patient without the SS	11 (44)	11 (44)	3 (12)	0	0
The SS should be used for all patients	0	4 (16)	11 (44)	9 (36)	1 (4)
The SS adds time to the patient set up	1(4)	3(12)	5(20)	15(60)	1(4)
I would prefer to use other securing devices (eg. metal cot rails)	1 (4)	2 (8)	9 (36)	13 (52)	0

Table 1 Radiation technologist's opinions about the securing strap (SS) [data are n (%)]

Only seven (28%) of the participants would recommend that other departments use the strap: twelve (48%) were neutral on this. No participant was uncomfortable at the prospect of treating a routine patient without the strap. Free text comments reflected and qualified the apparent mixed opinions:

> *'Untested security measure that may or may not prevent a patient falling off the bed.'*

> *'I think it was initially implemented to prevent falls but I don't think the amount of falls has been reduced in our department since introducing the strap.'*

'we were fine without it for many years, but I don't mind putting it on the patients.'

'annoying, unsanitary'

'useful as tool to remind patients not to get up.'

'... uncooperative and unstable patient would benefit from using strap.'

'I don't think the strap actually provides adequate safety in our department. It is usually loosely placed over a pt's clothing and provides the pt with a false sense of security.'

Who gets the strap in their treatment set up?

Eleven (44%) of the participants (correctly) believed that use of the strap was mandated by treatment protocols; nine (36%) disagreed with this statement and five (20%) were unsure. Twelve (48%) and nine (30%) agreed and disagreed respectively with the statement that use of the strap is ultimately at RT discretion, with four respondents being unsure. Multiple free-text comments clarified that:

'A strap is used for ALL patients per protocol unless the patient refuses ...'

Many participants used different words to indicate they felt that the RT should be the decision maker regarding use, and/or many patient groups could be excluded from its use:

'I feel like it should be up to the radiation therapist discretion.'

'Useful for certain patient population - not necessary to use it for everyone.'

Participants ranked patient groups according to which would benefit most from the strap. The scores presented in Figure 2 represent a weighted sum of all rank counts with items ranked first given a higher 'weight.' The patient group for whom the strap was seen as most useful was 'patients with dementia or cognitive impairment' with a cumulative score of 164 and the lowest score was 36 for 'all adult patients'.

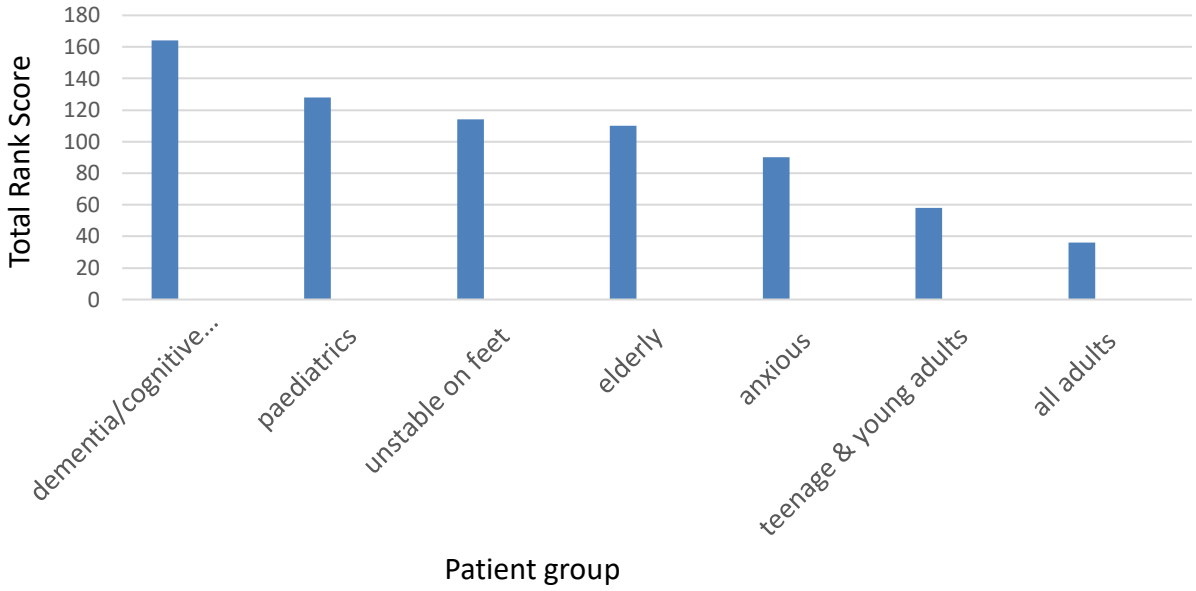

Figure 2 Patient groups ranked by perceived utility of the securing strap [Total Rank Score is a weighted calculation. The score is a sum of all weighted rank counts - items ranked first are valued higher than the following ranks]

Staff experiences of the strap

Experiences of the practical implementation of the strap are summarised in Table 2. A range of conflicting experiences were evident, except for unanimous agreement that a dose correction factor is not applied (or needed) to account for beam attenuation.

Question	yes	unsure	no
Are patients aware the SS will be used at their CT planning scan?	9 (36)	10 (40)	6(24)
Is the SS ever positioned within the treatment field?	10 (40)	1(4)	14(56)
Is an attenuation factor applied at planning to account for the SS?	0	0	25 (100)
Are patients aware the SS will be used for their treatment?	10(40)	8(32)	7(28)
Is the SS cleaned after each patient?	7 (28)	4 (16)	14 (56)

Table 2 Treating radiation technologist's experience of using the securing strap (SS) [data are n (%)]

Multiple free text responses indicated that the device should be disinfected after each fraction, but that this does not always happen:

'Not all therapists clean the strap after every patient, but I do'

'Not placed in contact with skin. Drape sheet barrier used.'

Perceived acceptability of the strap for patients

Staff perceptions of the acceptability of the strap for patients was gauged by asking if, in RT experience, patients ever refuse/decline the device. Twenty-three (92%) responded 'yes', with two reasons provided being '*some [patients] think it's unnecessary'* and *'claustrophobia'*. Six (24%) of respondents felt patients were less anxious about falling when

the strap was used, whilst 14 (56%) were neutral about this. Only four respondents agreed with the statement that patients 'never comment on the strap' with another stating that *'patients do comment on it. Some do not like it.'*

Stage two – UK perceptions of the strap as a securing device

? The three TR interviewed were labelled as P1-P3 to protect anonymity: P3 was band 5 (registered graduate level), P2 band 6 (senior), and P1 band 7 (advanced/team leader). Findings were summarised in three themes.

Variable patient benefit

All participants felt securing devices were not suitable for every patient as '*the majority of our patients can follow instruction'* (P1). Use '*on an individual basis'* (P2) was preferred, with patient groups considered to be at a higher risk of falls, and therefore potentially benefiting from the strap, described as *'bariatric, 'dementia', 'palliative'* and '*on a lot of pain meds'.*

Safety versus control

All participants confirmed they had used or seen methods to secure patients. A distinction was drawn between a device that prevents a fall from the couch (cot sides) and one that limits movement/restrains (micropore tape). Reservations were expressed about the purpose of the strap:

> *'might feel a little claustrophobic, in terms of a lack of control. If you liken it to the head and mask* [sic] *in that you're removing that element of control.'* (P1)

> *'no point in tethering someone to the bed if they're absolutely fine. Maybe for dementia patients or palliative patients that are wriggling. But if they're wriggling that much should you be treating them?'* (P2)

It was suggested that the strap could be used in conjunction with existing immobilisation *'... things like the wingboard, you get like some people who can't really hold it so you could get something to just support their hand'* (P2), provided placement did not limit patient control:

> *'how would a patient tell you if something is wrong if their arms are tied.'* (P3)

Implementation

Perceived practical implementation issues were *'infection control'*, *'cost'* [if disposable], *'dosimetry'* and *'time'* [for training]. The device must be *'wipeable'* and beam attenuation would be easily avoidable if *'used outside the treatment area'* (P1). More substantive, was the wider set of resources required to adequately evaluate a new device:

'...how long have you got to trial for? That was an issue for the other one [a sling device], *we only had it for 20 days. By the time we found somebody to treat after it had been through*

infection control, we then only had 5 days left. …Whether you have got to hand it over to physics, if they've got to do another assessment of the device?

Discussion

Ambivalence after experience

Ambivalence about the strap was evident with only 28% of the professionals that use the device daily saying they would positively recommend adoption by other departments. Almost half held a neutral professional opinion on this, with free-text comments reinforcing a sense of equivocation. Just 16% of respondents would personally prefer to include the strap in treatment set ups. RT acceptance of the strap in the current study does not appear to be as enthusiastic as suggested by a brief report from 2015.[9] Most of the respondents had worked at the centre in the 'pre-strap era', when a device had occasionally been used to help select patients keep still or to provide support. Successive use of the strap does not seem to have led to the intended staff acceptance of the device.[10]

The free-text comment that the device remains 'untested' and therefore 'may or may not' prevent a fall is insightful. The strap implementation strategy developed by Cancer Care Ontario had identified the importance of staff training, patient education and device monitoring.[10] Implementation science suggests that inadequate evaluation of a new device/procedure can create a feedback void to be filled with subjective or historical opinion.[16,17] This situation may underlie or contribute to the equivocal views in our study. Objective evidence about the value of service innovations serves to counter this and is a requisite for evidence-based radiography.[12,18] A second issue is that safety in this context is the absence of harm or a non-event.[19] A number of respondents were skeptical of the value of the strap as there had not been patient falls at the department before or after the strap was mandated.

Perception of purpose(s)

An influential opinion about the value of the strap was that it was not sufficiently strong to prevent a patient fall: the intended function of the device. The concern, as expressed by one RT, was that is provides a 'false sense of security.' A 2016 report of a serious patient fall in neighbouring Manitoba[20] confirmed that the original 2012 Ontario incident is not an isolated event. It also identified an inadequacy in their strap device and implied complacency around its use. These events raise questions as to the intended versus perceived purpose(s) of the strap. Perception of purpose is important here as a modifier of staff and patient behaviour.[21] The 2015 Ontario implementation report alludes to multiple rationale for the strap – as immobilisation, to prevent sitting up prematurely, a reminder to stay still – all of which were raised in our data. Whether the strap can or cannot de facto prevent a patient fall or instead has value as a safety reminder requires clarification. More than one participant perceived the device to primarily be a medico-legal protection against staff litigation. Safety risks can never be eliminated, but clarity surrounding the explicit rationale and capabilities of the strap – whether as physical safety, psychological comfort or as a reminder – is important in a scenario where the '*frequency of occurrence* [of the fall

event] *is low,* [but the] *the severity can be high*'.[10] Most of the participants had worked in the pre-strap era and so were aware that the strap policy had originated from an incident at another institution. The views of newer members of staff are less well represented in our data. An important generic point is that training continues to reinforce the rationale for therapeutic practices, or conversely that service evaluation removes obsolete practices.[18,22]

Not for all

A common thread running through all quantitative and qualitative data was that the strap should not be used for all patients. This was despite uncertainty regarding the actual protocol prescription of use for all (except where a head shell fulfils this function or patients refuse.) The clear position from the participants was that use of the strap should be at professional discretion. Standardisation is a strong feature of radiotherapy,[23] however universal application of the strap has created tension with the application of EBP through decision-making informed by professional experience. The two patient groups perceived to derive most benefit from the strap were those with dementia/cognitive impairment followed by paediatric patients. A pragmatic approach suggested by the data might be to default to strap use for these groups, but use according to treating TR discretion for other patients. However, the use of restraint can be notably distressing for people with dementia.[24]

Patients as the third component of evidence-based radiography

This study's data is clear that patients can and do occasionally refuse the strap, as anticipated by the original implementation guidance.[10] This choice is recorded in patient records and acted upon each day unless the patient changes their mind. Some respondents attributed enhanced patient relaxation and reassurance to the strap. Against this was the concern that ambulatory, able people were being secured with little benefit for the patient, thus threatening the autonomy that is vital for cognitive and physical health.[5] A balanced evaluation of the strap would appreciate how alien the treatment environment can be to the uninitiated patient.[2,25] One person may welcome the strap when elevated in a darkened room with few familiar landmarks: for another it may heighten the darkness of their predicament. Actively listening to both these patients and incorporating their perspectives into our care is key to EBP. This study's data clarified that patients were informed verbally about the strap and this often happened just before the first fraction. Including this information in written materials delivered at an early point in the treatment pathway would enable adequate consent for the strap and promote patient autonomy.[26]

UK opinions on potential use of the strap

Views of therapeutic radiographers about practical implementation of the strap in the UK were very similar to those based on Canadian experience. Infection control was the practical implementation issue raised by all participants. The interviews added a distinct, broader theoretical perspective on securing devices. Participants were unanimous that the decision for their use should be at the individual patient level. The point at which increasing levels of

restraint become an indicator of a patient who is inherently unsafe/unready to treat was an intriguing point of discussion. It was proposed that the move to universal strap use could be viewed as a failure of radiographers to conduct an adequate risk assessment. Overall, the potential for using this particular device in the UK was viewed as limited. The importance of the broader patient safety debate was however noted given that falls are excluded from radiotherapy error coding in the UK,[27] despite anecdotal reports that this has happened. Evaluating patient safety incidents and service responses is vital for service quality improvement.

Limitations

As a single centre evaluation, we cannot assess how generalisable our data is to other centres: a survey of all regional centres is indicated. The 21% response rate and small sample size suggest the representativeness of our data should be treated with caution. Our sample does encompass a range of staff experience and seniority including managerial level but is skewed towards more experienced staff.,so We have relied on staff perception of patient acceptability as our ethical approval did not extend to patient participation. The interview sample was very small and participants were partly chosen based on a subjective judgement of their reflexivity, but this was considered acceptable to address the exploratory aims.

Conclusion

Despite straps being used for years in some radiotherapy departments, this study is the first reported evaluation of the value of the safety strap based upon the views of those who use it. Benefits of the strap were identified for select patients, but our data suggest its use is not supported for most and its purpose is not sufficiently clear. We recommend that the policy of universal use is reviewed. A comprehensive service evaluation with a service quality improvement purpose would take account of the best available research evidence, staff experience and patient views. The direct patient voice is needed, which can often surprise. Routinely recording patient incident data is crucial to evaluate safety developments; especially in a context where safety is a dynamic non-event and the incidence of fall events is extremely low. Implementation of devices such as the strap are most likely to be accepted and accrue patient benefit when based on principles of EBP. This requires adequate resources to integrate data of effectiveness with the tacit knowledge of professionals and particularly patients.

Contributors: All authors contributed to the conception or design of the work, the acquisition, analysis, or interpretation of the data. All authors were involved in drafting and commenting on the paper and have approved the final version.

Funding: This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing interests: All authors have completed the ICMJE uniform disclosure form and

declare: no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Informed consent was obtained from all participants. The REB (institution) approved the study.

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