Applying root cause analysis to improve patient safety: decreasing falls in postpartum women

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ABSTRACT

Objective To investigate the effectiveness of interventions to prevent falls designed through hazard analysis using root cause analysis.

Design Prospective longitudinal study. Under preceding root cause analysis, root factors were classified into four major categories: environment and facilities, procedure, individual, and communication. Among them, communication, environment and facilities were recognised as the most vital factors to facilitate intervention accordingly. The fall prevention programme included first intervention with adding live demonstrations and offering a printed education sheet, and second intervention with adjusting rails at the bedside and in the ward, placing anti-sliding pads on the floors of the bathrooms and enhancing local light in the bathrooms.

Setting Two large hospitals in Taiwan, both with an average of 200 or more childbirths per month, with an intervention group and a non-intervention control group.

Participants 2460 (intervention group) and 2451 (control group) participants.

Main outcome measures The number of postpartum falls within 6 months before and after intervention, and the incidence after adjustment by patient-days.

Results In the intervention group, the incidence of postpartum falls before intervention was 14.24 per 1000 patient-days and dropped to 6.02 per 1000 patient-days after intervention. The control group showed no marked decline in incidence with a rate of 13.72 and 14.05 per 1000 patient-days, respectively. Using the Mantel–Haenszel test to compare the incident rate, there were significant differences ($p<0.001$) between the incidence of the intervention group before and after intervention; and between the latter and each incidence of the control group.

Conclusions This study provides direct evidence that root cause analysis can be adopted in analysing causes and in formulating interventions to reduce the incidence of postpartum falls and improve patient safety.

Patient safety is the foremost issue for medical care; however, it is often overlooked because of cost considerations. In response to reimbursement constraints from payers, many hospitals began to reduce costs by shortening length of hospital stay,[1] performing cutbacks of nursing staffs[2 3] or asking staffs for increasing workloads. Nevertheless, decreased level of nursing staffs,[4 5] increased overtime of nurses[4] and resident fatigue[6] all related to poorer patient safety outcomes. A recent study further pointed that payment constraints may harm patient safety.[1] Complex medical procedures are potentially full of risk. This is especially true when care is provided in wards because of the special characteristics of the necessary medical care, with significant numbers of procedures and treatments. The more complicated the care, or the more people involved, the greater the risk for mistakes. In addition, the effect of medical care on the human body is direct and profound. Furthermore, everyone is unique in their physical condition and in response to treatments. The result of treatments, as well as the subject of treatments, offers some uncertainty. Such is often the primary source of medical risk, patient dissatisfaction or medical disputes. In 2000, the report on medical events by the Institute of Medicine pointed out that to err is human. According to estimates of two major studies within the USA, potentially between 44 000 and 98 000 Americans die annually as a result of medical errors, which is higher than the deaths related to traffic accidents.[7] Studies in other countries have demonstrated similar results. In Taiwan, patient safety received more attention recently after some regretful medical incidents, such as wrong injection and wrong medication, led to unexpected patient deaths. Therefore, improving patient safety should be the first priority all over the world.

Medical incidents that impair patient safety can be classified into medical error and medical adverse event. The former refers to wrong execution or incorrect planning of medicine. The latter is the harm that results from medical management rather than from the underlying disease itself, which results in prolonged hospitalisation or some disability after discharge. Some adverse events in hospitalised patients can be attributed to negligence.[8] The Harvard study found that adverse events occurred in 3.7% of the hospitalisations and 27.6% of the adverse events were due to negligence.[9] The proportion of UK patients experiencing an adverse event was even higher (10.8%), of which 1% could lead to severe harm or death.[10] Rather, most errors in the events resulted from faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them.[7] Medical incidents contribute to the rising costs of hospital administration, including legal, marketing and organisational costs.[11] Thomas *et al*[12] reviewed approximately 15 000 medical charts and found that the total costs were US$661 889 000 for adverse events and US$308 382 000 for preventable adverse events. Healthcare costs totalled US$348 081 000 for all adverse events and US$159 245 000 for the preventable adverse events. Fall is one of the most frequent events in the ward and can be classified as a "preventable medical adverse event". Falls are generally attributed to multiple factors: personal health, the effect of drugs or anaesthesia on the patient, environment and facilities, and others.[13] It is multifactorial and is the final presentation of accumulation and interaction among such factors. In Taiwan, Lin[14] summarised that the average additional hospital stay due to fracture from a fall in the ward was 8.9 days, and the average additional medical expenditure was US$3036. In Germany, Heinze *et al*[15] found falls in older people were a major problem in both hospitals and nursing homes. Most falls occurred in the older population when attempting to get out of the bed and using bathrooms.[16 17] Current studies, however, focus mainly on exploring the causes and management of falls in the older and psychiatric patients.[18–20] In contrast, studies regarding postpartum falls are extremely lacking. In fact, postpartum women are at the highest risk of falls among all patients. Pregnant women always have blood loss during delivery, which may cause weakness; and the elasticity of vessels does not recover soon after delivery, which may cause postural hypotension. Both situations can induce fainting or falling down on rapidly changing position or standing up. This is the remarkable difference between postpartum falls and other types of falls. Falling down after delivery can result in injuries such as bruises, lacerations, fractures and even intracranial haemorrhage, the effect of which can lead to prolonged hospital stay, increasing medical expenditure and an increased social and financial burden for the patients because the victims have to pay more for prolonged hospitalisation and they require more time for recovery. Hence, lowering the incidence of postpartum falls is very important to medical care.

The topic of falls is a major concern in patient safety and is drawing increasing attention. There are more and more scientific tools available for promoting patient safety. Two of them are root cause analysis and failure mode and effects analysis.[21] Such tools have been widely used in aviation and industrial management to facilitate efficiency and promote safety, and are increasingly used in medical care. Root cause analysis is used to systemically investigate events to find and correct root causes to prevent recurrence. It is a reactive analysis that identifies trends and systems issues across grouping of similar events, thereby supporting process and systems improvements.[22] Failure mode and effects analysis is a prospective and proactive risk analysis, involving close examination of high-risk processes to identify needed improvements that will reduce the chance of unintended adverse events. It emphasises that systems must be redesigned to catch and correct inevitable human errors and process failures.[23] Longo *et al*[24] identified root cause analysis as one of the most important patient safety constructs in evaluating the medical system for promoting patient safety. Root cause analysis has contributed to a decrease in the occurrence of wrong site surgery.[25] It is also used in reducing adverse events during anaesthesia[26] and in analysing near-miss events.[27] Rex *et al*[28] reported through systematic application of root cause analysis followed by intervention that targeted the underlying causes that the incident rate of adverse drug events showed a significant decline of 45%. In addition, through use of root cause analysis and failure mode and effects analysis, Gowdy and Godfrey[29] developed an action plan for fall prevention which resulted in a 43% decrease in falls. Bry *et al*[21] reported a peer review model using root cause analysis, failure mode review and an information collecting system for reducing mistakes by nursing staff to improve patient safety. Compared to traditional focused review, root cause analysis could better disclose basic systemic causes rather than human errors.[30] In summary, the best applications of root cause analysis in medical care include high-volume and high-risk cases such as patient falls, medication errors and parasuicidal behaviour with analysis of a high-risk process, determination of a selected focus for improvement and the design of critical interventions.[22] By applying root cause analysis mentioned above, the study has identified the principle causes and formulated intervention measures. A fall prevention programme is designed as clinical interventions pointing to the principle causes, which aims to reduce the incidence of postpartum falls so as to improve patient safety.

We built a team to address postpartum falls in the obstetric wards. The team included an experienced facilitator, physicians, nursing staffs and ancillary staffs. After collecting information related to the events of falls by incident reporting in the hospital, we performed root cause analysis (figure 1) to find out the key factors of postpartum falls. The factors were classified into four major categories: environment and facilities, procedure, individual, and communication. Among them, communication, environment and facilities were recognised as the most vital factors to facilitate an intervention. Before the intervention, we had educated the women at admission (first stage of labour) by speaking to them about how to prevent falls, but the effect of education seemed poor. Under root cause analysis, we noted that <30% of postpartum women could really understand the prevention of postpartum falls. This was attributed to the fact that pregnant women in labour could not pay attention to the education and that pregnant women had a vague understanding when we provided education by speaking only. The fall prevention programme included first intervention for improvement on communication by adding live demonstrations following the education approach of speaking to the women at admission. In addition, we offered a printed education sheet to remind the women about the details of preventing falls. In environment and facilities, we had noted the highest incidence of postpartum falls when patients were attempting to get out of the bed and when using bathrooms. The critical points of second intervention were to improve assistant facilities by adjusting rails at the bedside and in the ward, to place anti-sliding pads on the floors of the bathrooms and to enhance local light in the bathrooms. These interventions helped postpartum women strengthen body support by using assistant facilities and avoid postural instability due to the environment factor.

METHODS

Study design and sample

Based on previous root cause analysis, we focused on communication, environment and facilities to formulate intervention measures for improvement. The prospective, longitudinal study was then conducted in two large hospitals, both with an average of 200 or more childbirths per month. One was the intervention group, whereas the other was the control group without intervention. Data on the number of postpartum falls within the 6 months before and after the intervention, and the incidence after adjustment by patient-days were collected. The incidence of postpartum falls equals the total number of postpartum falls divided by total patient-days. Because patients with longer hospitalisation will have more chances for falls, calculation of the incidence by total patient-days rather than simple total number of postpartum falls should be a more correct and real reflection of such events.[31]

Postpartum women with remarkable anaemia (haemoglobin <10 g/dl) before delivery, preeclampsia, gestational diabetes and labour-related complications such as postpartum haemorrhage (defined as a total 500 ml of blood loss or more during delivery) were subject to postpartum falls and were excluded to avoid interference. Women completely without a companion relative or caregiver during hospitalisation were also excluded because leaving the patient alone increased the risk of postpartum falls.

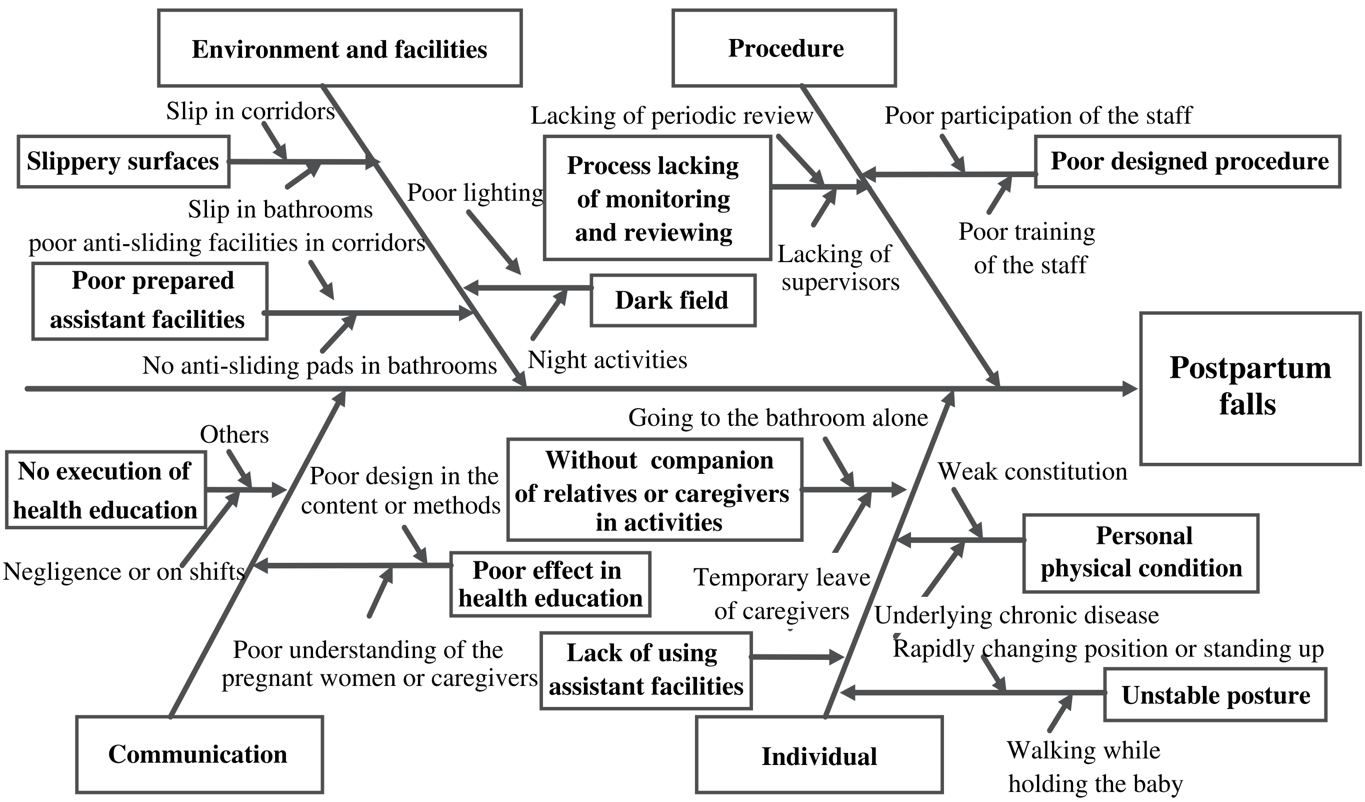

Figure 1 Root cause analysis of postpartum falls.

Data analysis

Data were collected and analysed using SPSS V.10.0.[32] The statistics we used in this study included descriptive statistics, Student t test and χ^2 test to examine the basic differences between characteristics of the groups. To compare the cumulative incidence rate for postpartum falls, we used the Mantel—Haenszel test for the person-time data to examine the differences between the incidence of the intervention group within 6 months after intervention and that before intervention, and each incidence of the control group within each 6 months.

RESULTS

Characteristics of participants

There were 2460 (intervention group) and 2451(control group) participants enrolled in our study. The baseline characteristics of participants between groups were compared. The numbers of divorced and widowed women were both <10 and were included in the married category. There were no significant differences found in items of education status, body mass index, types of delivery, underlying chronic diseases (general medical disorders and disabilities, except remarkable anaemia), age and days of hospital stay between both groups. The same trend existed in the intervention group and control group; dominant were the women whose education was college, university or higher (37.04% vs 37.03%); whose body mass index was from 25 to 29 (61.58% vs 58.79%); whose parity (the total number of viable births including this delivery) of delivery was one (56.02% vs 58.10%); who were married (93.01% vs 88.98%); whose gestational age at delivery was >37 weeks (89.47% vs 92.49%); whose types of delivery was vaginal (68.65% vs 69.88%); and who had no underlying chronic diseases (93.70% vs 92.41%), respectively. For the intervention group and the control group, the mean age was 27.91 and 26.46, respectively; and the mean days of hospital stay were 3.96 and 3.97, respectively. There were notable differences found in the distribution of parity, marriage status and gestational age at delivery between both groups. It is likely that unmarried women do not have the companionship of a husband or other relatives. Postpartum women who delivered before 37 weeks or earlier may have less blood loss during delivery because of the shorter gestation. However, at the beginning of our study, we excluded women without a companion, those having remarkable antenatal anaemia and patients with postpartum haemorrhage so that marriage status and gestational age at delivery should not alter the results of this study. Furthermore, there is no existing research reporting an obvious relationship between parity and the occurrence of falls. Thereby, the results of this study would not change despite the difference in parity between groups (table 1).

Outcome

Figure 2 illustrates the numbers of postpartum falls within the 6 months before and after implementing the intervention. Table 2 shows the incidence of postpartum falls within the 6 months before and after implementing the intervention in the intervention group as compared to the control group. In the intervention group, the incidence within 6 months before intervention was 14.24 per 1000 patient-days and dropped to 6.02 per 1000 patient-days after intervention. In contrast, the control group showed no marked decline in incidence with a rate of 13.72 and 14.05 per 1000 patient-days, respectively. Using the Mantel—Haenszel test to compare the incident rate, there were significant differences ($p<0.001$) between the incidence of the intervention group before and after intervention, and between the latter and each incidence of the control group within each 6 months. The results revealed that implementing interventions based on root cause analysis indeed lowered the incidence of

Table 1 Characteristics of participants between two groups

Group	Intervention (n=2460) n	Intervention (n=2460) %	Control (n=2451) n	Control (n=2451) %	Statistics χ^2	Statistics p Value
Education					2.970	0.227
Junior high school or lower	713	28.98	758	30.93		
Senior high school	836	33.98	785	32.04		
College, university or higher	911	37.04	908	37.03		
Body mass index					4.208	0.122
<24	517	21.02	563	22.97		
25–29	1515	61.58	1441	58.79		
>30	428	17.40	447	18.24		
Parity					10.766	0.005**
1	1378	56.02	1424	58.10		
2	738	30.00	760	31.01		
≥3	344	13.98	267	10.89		
Marriage status					24.274	<0.001***
Unmarried	172	6.99	270	11.02		
Married (including divorced and widowed)	2288	93.01	2181	88.98		
Gestational age at delivery					23.30	<0.001***
<30 weeks	40	1.63	51	2.08		
31–36 weeks	219	8.90	133	5.43		
>37 weeks (term delivery)	2201	89.47	2267	92.49		
Types of delivery					0.874	0.35
Vaginal delivery	1689	68.65	1713	69.88		
Cesarean delivery	771	31.35	738	30.12		
Underlying chronic diseases					3.152	0.076
No	2305	93.70	2265	92.41		
Yes	155	6.30	186	7.59		

	Intervention Mean	Intervention SD	Control Mean	Control SD	t	p Value
Age (years)	27.91	3.87	26.46	2.82	1.442	0.149
Days of hospital stay	3.96	1.45	3.97	1.53	0.275	0.783

*p<0.05; **p<0.01; ***p<0.001.

postpartum falls and that the effect of improvement did not originate from the influence of time.

DISCUSSION

Postpartum fall is one of the most frequent incidents that impair patient safety in the obstetric wards. In 2005, the Joint Commission on Accreditation of Health Organization listed "reducing the risk of patient harm resulting from falls" as one of the annual goals on patient safety.[33] To improve patient safety, we can monitor abnormal signs by using the quality index and provide respondent intervention. O'Connor modified existing quality indicators to monitor fall events. Positive patient, practitioner and organisational outcomes suggested that falls safety prevention was feasible by setting quality indicators.[34] An additional example is Tsai's study of using a quality index for monitoring the timing of drug administration. The rate of administering prophylactic antibiotics within 24 h before surgery increased from 20% in 2000 to 35% in 2001.[35] Like quality indices, healthcare organisations should set up safety indices for events that occur frequently, such as falling down or other events with greater influence. The monitoring of safety indices should be assigned to an authorised person, such as a medical manager or

Figure 2 The number of postpartum falls before and after intervention.

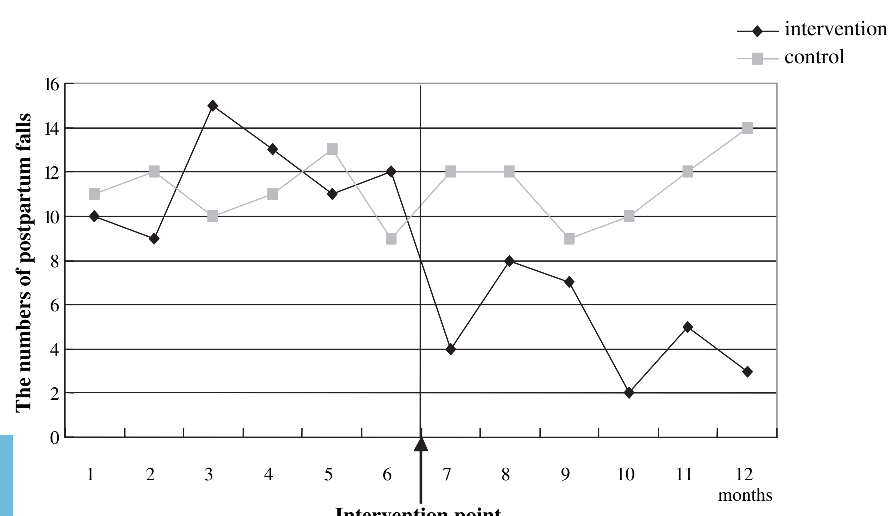

Table 2 The incidence of postpartum falls

Study period	Group	Total number of postpartum falls	Total patient-days	Incidence (numbers per thousand patient-days)
1st–6th months				
	Intervention	70	4917	14.24
	Control	66	4810	13.72
7th–12th months				
	Intervention	29	4814	6.02
	Control	69	4911	14.05

a nursing director. Once an abnormal index appears, the manager or director must survey the underlying causes and develop interventions to avoid further deviation or deterioration. The incidents should also be graded according to how high the effect of the risk is (financial, media exposure, patient harm) and the likelihood of them occurring.[10]

The study provides direct evidence that root cause analysis can be adopted in analysing principal causes and in formulating interventions to decrease the incidence of postpartum falls and improve patient safety. Previous studies revealed that specific interventions most highly associated with reductions in falls and injuries included environmental assessments, toileting interventions and interventions that directly addressed the root cause. The action plans associated with these reductions focused on making specific clinical changes at the bedside rather than formal policy changes or educating staff only.[36] Our study showed similar results. In analysing root causes, individual-associated factors including underlying chronic diseases, weak constitution, the companion of relatives or caregivers and personal education are all beyond our control. Hence, to decrease postpartum falls, we have to implement interventions related to improvable factors. Through root cause analysis, we found that rapidly changing position or standing up, lack of using assistant facilities at the bedside, and holding her baby while walking were the major causes of falls. Based on our findings, we emphasised live demonstrations on how to change position or to get up, the proper use of assistant facilities at the bedside and avoiding holding the baby while moving or walking, and achieved a satisfactory result. By adding live demonstrations and a printed education on paper other than verbal communication only, there was a marked decline in the incidence of postpartum falls. In Taiwan, the percentage of foreign pregnant women is rising, but they are often overlooked when it comes to communication. An easy, concise, printed health education with translation into their native languages is necessary for pregnant women so that they can understand and do well during their care. Another finding in our study was, in most hospitals, the setting of the corridor and toilet in the ward was designed for relatively healthy, younger patients. The special needs of obstetric, paediatric, older and disabled patients were often neglected. Such neglect resulted in an inconvenient, risk-prone circumstance that called for improvement.

Modern medical care is a special service concentrating on the demands of external consumers, often referred to as patient-centred care. In patient-centred care, the topic of patient safety raises more and more concern. Serious medical incidents are often the outcome of paying little attention to patient safety, increasing the operational cost of hospital administration and bringing about the loss of patients indirectly. In response to such crises, executive managers should lay more emphasis on patient safety and take aggressive actions. Also, the organisational culture should be innovated by internalising the concepts of safety control and risk management. Fall prevention for postpartum women in the wards is a good example and important to patient safety. The study provides a model for improving patient safety, which may serve as a practical reference for clinical practitioners and medical managers who plan on researching or solving this problem.

Our study has some limitations. First, the study used participants who received care in two large hospitals. Applying the conclusion to small hospitals or local clinics is limited because of questionable external validity. Second, some characteristics in the postpartum women—for example, socioeconomic status, are not considered in our study. These uncontrolled factors may somewhat affect postpartum falls. Finally, as a longitudinal study, we still cannot completely control some factors varying with time and the change of medical policies. A longer follow-up investigation may overcome this problem and provide a more precise result.

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Competing interests None.

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