ABSTRACT

The Surgical Patients' Pressure Injury Incidence (SPPII) study: a cohort study of surgical patients and processes of care

Background: Surgical patients are at high risk of developing pressure injuries (PIs) due to anaesthesia induced immobility as well as risk factors such as length of surgery and comorbidities. Few Australian studies have investigated the incidence of PIs in surgical patients. This prospective cohort study assessed the incidence of post-surgical PIs and identified gaps in pressure injury prevention (PIP) for elective surgical patients.

Methods: Consecutive elective surgery patients at an urban tertiary referral hospital were recruited who had an expected length of stay of >48 hours. Baseline PI risk (measured by the Waterlow scale) and PIP strategies implemented at five time points were collected from medical records. Two prospective outcome assessments were conducted at 24 and 48 hours post operatively. Data were analysed descriptively.

Results: One patient out of 150 (incidence rate 0.7) developed an intra-operative Stage 1 PI. Four patients developed skin tears. PIP strategies were applied inconsistently throughout the patient journey regardless of risk status.

Conclusions: While the incidence of surgically acquired PIs in this study was low, ongoing staff education is needed about the importance of consistent skin and risk assessments and of implementing strategies appropriate for level of pressure injury risk.
The Surgical Patients' Pressure Injury Incidence (SPPII) study: a cohort study of surgical patients and processes of care

What is already known:

- Pressure injuries (PIs) are widely considered to be an adverse event of hospitalisation and are largely preventable.
- Surgical patients are at risk of developing a pressure injury primarily due to immobilisation following anaesthesia, length of surgery and comorbidities.
- There are few studies on pressure injury incidence and prevention strategies used in the post-operative period.

What this manuscript contributes:

Although the incidence of post-surgical PIs among elective surgical patients was low, there are gaps in pressure injury prevention for this group of patients, including for those deemed at high risk of pressure injury. There is a need for clinicians to improve documentation of risk assessment and strategies implemented to reduce risk of PI, throughout the surgical patient journey.

INTRODUCTION

Each year, over 2 million surgeries are performed in Australia\(^1\) during which, the patient is anaesthetised, immobilised and unable to perceive or voice pain and discomfort from unrelieved pressure to the surgical team\(^2\). These factors may lead to the development of a pressure injury (PI)\(^2-4\). Pressure injuries (PIs), also known as pressure sores, bed sores and decubitus ulcers are defined by the National Pressure Ulcer Advisory Panel as a "localized injury to the skin and/or underlying tissue usually over a bony prominence or related to a medical or other device"\(^5\). The financial impact of PIs for hospitals and health systems is
significant, with the annual costs of medical treatment and extended hospitalisations estimated to be between £1.8 and £2.6 billion in the United Kingdom and US$11 billion in the United States (US). In Australia, the treatment costs of PIs have been estimated to be AUS$983 million per annum, representing approximately 1.9% of all public hospital expenditure.

Surgical patients have been identified as at elevated risk for PI development. PI development can occur between the first hour and 4-6 hours following sustained pressure. Therefore, surgeries that are longer than 4 hours have been shown to increase the chance of PI development. Development of surgery-related PI may result in reduced quality of life, decreased mobility, increased pain, prolonged hospital stay, re-admission and negative psychological consequences. Furthermore, hospital-acquired PIs (HAPIs), including surgery-related PIs, are regarded as a key performance indicator of the quality of care provided by health facilities, particularly of nursing care. In Australia, the National Safety and Quality Health Service Standard 8 requires health service organisations to implement evidence-based systems and guidelines to prevent and manage PIs. The classification of HAPIs as never events (US) or adverse events (Australia) and the introduction of non-payment or financial penalties for HAPIs have placed PIs as a priority for health services. In the US, Medicare introduced non-payment for hospital-acquired conditions including PIs in 2008, whilst financial penalties were introduced more latterly (2013) in the State of Queensland, Australia. The Australian Commission on Safety and Quality in Health Care (ACSQHC) has developed a national list of 16 hospital acquired complications (HAC) which includes pressure injuries, and developed a range of resources to support adoption of the HAC list. Depending on the practice setting, the reported incidence and prevalence of HAPIs ranges from 0.0% to 72.5%. For surgery-related PIs, the incidence varies, ranging...
from 1.3% to 66% depending on the study population, the type of surgery and duration of the surgical procedure\textsuperscript{13, 23, 25-27}. Evidence from a recent systematic review of 17 studies found the pooled incidence of surgery-related PIs was 0.15 (95% CI 0.14-0.16; range 0.003-0.574)\textsuperscript{28}. Of note, none of the included studies were conducted in Australia, highlighting limited research in this area. Indeed, a prospective cohort study at a single-site investigating the incidence of HAPIs remains one of the few studies investigating surgery-related PI incidence in Australia\textsuperscript{23}. Therefore, our knowledge of PI incidence is predominantly based on studies conducted in other countries and may not be indicative of the true incidence in Australian surgical patients.

Pressure injury prevention (PIP) is a global quality of care indicator and there are national and international evidence-based clinical guidelines to inform this area of nursing practice\textsuperscript{29}. Conducting risk and skin assessments, coupled with attention to positioning, protecting and padding pressure sensitive and vulnerable areas are primary strategies in PIP for surgical patients\textsuperscript{30-32} are standard PIP processes of care and have the potential to reduce PI incidence\textsuperscript{33}. However, there are only few studies that provide information on PIP processes of care in relation to surgical patients\textsuperscript{31, 34}. Furthermore, these studies are limited as they do not evaluate PIP strategies for at risk patients and there is a need to identify if evidence-based PIP processes of care for surgical patients occurs consistently throughout the entire surgical patient journey, including the pre-operative, peri-operative and post-operative phases. This study therefore aimed to determine the incidence of HAPIs among elective surgical patients and to describe the extent to which PIP processes of care were documented as adhered to throughout the surgical patient journey.

METHODS
Design
A one-sample prospective cohort study design.

Setting
This study was conducted in a large public, (402 beds) metropolitan, tertiary referral hospital in Sydney, Australia between July 2015 and March 2016.

Patients
Eligibility criteria
Patients were eligible for inclusion if they were greater than 18 years of age, scheduled for an elective surgical procedure and had an expected 48-hour minimum hospital stay following surgery. This inclusion criterion reflects findings from other studies which suggest that PIs may take up to 48 hours to appear after relief from periods of pressure, friction or shearing\textsuperscript{13,35}. Patients were excluded from the study if they were admitted for emergency surgery, admitted for elective surgery through the emergency department, or admitted into hospital a day or more prior to their elective surgery. These groups were excluded because of the uncertainty about how long they may have been immobile before their transfer to the operating suite.

Recruitment
Patients were recruited to the study if they met the inclusion criteria and attended the pre-admission clinic prior to surgery. Pre-admission patient lists provided by the admissions unit were used to identify those patients with an expected length of stay (LOS) of $>48$ hours. Using a non-probability sampling method, those patients who met the criteria were approached by a nurse research assistant (RA) in the pre-admission clinic. Patients were
given verbal and printed information about the study, and if agreeable, signed their consent.

If a patient declined to participate in the study, or was expected to have stay of < 48 hours, the next eligible patient was approached.

Data collection and outcome assessment

The following information was collected from patients’ medical records using a standardised data collection form: demographics, patient’s history of PIs in the previous 12 months, comorbidities, length of time in surgery, total time in operating theatre and time in recovery, type of surgery, American Society of Anaesthesiologists (ASA) score, patient transfer method to and from the operating table, patient position and positioning devices and PI prevention strategies implemented pre, intra and post-operatively.

Prior to the study commencement, RAs received training in the use of the data collection tool, the use of the Waterlow scale and the observation and classification, or staging, of PIs according to the European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel Classification System. Inter-tester reliability was 92% which is considered almost perfect agreement.

Skin assessments were recorded at five time-points. The first three skin assessments were conducted before, during and after surgery and documented as part of the hospital’s standard of care in patients’ medical records. At 24 hours and 48 hours post operatively two additional skin assessments were undertaken by the trained RAs as part of the outcome assessment (PI presence) (Figure 1). The number and location of all PIs and any other changes to skin integrity signifying a developing area of PIs were recorded. The staging of any PI that
occurred was verified by the Wound Management Clinical Nurse Consultant (JR). Time to event (defined as from time in operating suite until development of PI) was also recorded.

Sample size calculation

Sample size calculations were based on an assumption of PI incidence of 20% as suggested by previous studies of high risk surgical patients\textsuperscript{13,35}. In consultation with a statistician, a sample size of 250 was estimated from tables for 95% confidence intervals with a 5% margin of error. However, the sample size was changed after recruitment of 150 patients and a low detection of PIs.

Data analysis

Data were entered and analysed using Statistical Package for Social Sciences, version 23 (SPSS, Chicago, Illinois). Baseline demographics and clinical characteristics, risk status and processes of care were reported as frequencies and percentages for categorical variables or means and standard deviations for continuous variables. Incidence was calculated using a binomial confidence interval (95%). Mean length of time in the operating suite was calculated from the time the patient entered the surgical unit, including time in the pre-operative bay and surgery length), to the time the patient was transferred from the operating suite to either the recovery or ICU. Time in recovery was calculated from the time the patient entered the recovery unit until transfer to ward.

ETHICAL APPROVAL

Ethics approval was given by the St Vincent’s Hospital Sydney Human Research Ethics Committee (HREC LNR/15/SVH/137). All patients provided written consent to participate.
Patients who declined study participation or were unable to give informed consent were excluded.

**RESULTS**

Two hundred and twenty-three elective surgery patients were assessed for eligibility (Figure 2). Of 206 patients assessed as eligible to participate, 189 consented to take part in the study. Thirty-nine patients became ineligible following recruitment because their post-operative length of stay was <48 hours, surgery was cancelled or they were referred to palliative care; resulting in a final sample of 150.

Demographic and baseline characteristics of study participants (Table 1) showed the mean age was 60.6 (SD± 16.7, range 18.1-87.1), with an average body mass index (BMI) of 28.6 (SD ±6.3, range 18.3-56.4) and 63% (n=94) were males. All participants could reposition independently in bed (100%). The majority were continent (n=145; 97%), could ambulate (n=131; 87%) and lived independently (n=138; 92%). In terms of physical health status, as measured by the American Society of Anaesthesiologists (ASA), score, most participants (45%) had mild systemic disease (ASA 2), and 34% moderate systematic disease (ASA3). Over 80% of the sample had one or more co-morbidities such as hypertension (n=57; 38%), cardiovascular disease and heart failure (n= 49; 33%) or respiratory disease (n=30; 20%).

Intra-operative participant characteristics showed that the most common operations were neurology (n=38; 25%), orthopaedic (n=28; 19%) and cardiothoracic (n=21; 14%) (Table 1). The average length of time in the operating suite was 4.5 hours (SD±2.35); almost all participants received general anaesthetic (n=143; 94%) and over half were placed in a supine surgical position (n=87; 59%). A third were either transferred directly to ICU from the
operating suite or stayed in recovery for less than 2 hours, or between 2 to 4 hours. The
standard hospital operating theatre overlay was used in the majority of participants (71%).

**Pressure injury incidence**

One participant was documented as having developed a PI (stage 1) in the left knee during
the intra-operative period. The binomial confidence interval analysis showed the incidence of
PIs was 0.7% (CI 0.0002, 0.037). Four patients (2.6%) had skin tears while in recovery. The
PI and the skin tears resolved within 24 hours post-operatively and no other patient developed
a PI during the study period.

**Processes of care**

*PI risk assessment*

The numbers of documented PI risk assessments decreased during the patient surgical
journey. Prior to surgery, 80% (n=120) of participants were assessed using the Waterlow
scale; this decreased to 41% (n=62) intra-operatively and 36% (n=54) post-operatively in
recovery (Figure 3). All participants had a Waterlow assessment completed by the RAs at 24
and 48 hours following surgery.

The graph below shows that a higher proportion of participants were classified as being at
high to very high risk of PI as they progressed along the surgical journey. During the pre-
operative period only 8% (n=10) of the sample were identified as being at high or very high
risk of developing a PI; while at 48 hours post operatively, 59% (n=88) fell into the high to
very high-risk category.
Post-operative PI preventive strategies and devices

Documented PI preventive strategies (Table 2) for the post-operative period showed that less than a quarter of participants who were classified as at high or very high-risk of PI, received a specialty support surface such as an alternating pressure mattress. Just over a half in this risk category had documentation of a repositioning regime. Over three quarters of the sample received patient education and almost all had daily skin inspections.

DISCUSSION

The purpose of this study was to prospectively investigate the incidence of post-surgical PIs among elective surgical patients with a minimum hospital stay of 48 hours and to describe the processes of PI care received. Determining PI incidence, which counts the number of PIs developing after admission, rather than a snapshot of prevalence, provides the strongest evidence of quality of care. The findings therefore add to the knowledge about PI quality of care for surgical patients, particularly those who have a hospital stay of 48 hours, because this group is generally regarded as being at high risk for developing PIs.

In our sample the incidence was low, with only one participant developing a PI (Stage 1) intraoperatively. This was identified and documented in the immediate post-operative period and resolved within 24 hours after surgery. Four patients developed intra-operative skin tears, which also resolved within 24 hours. Given that there is mandatory reporting of the occurrence of PIs in the facility in which the study took place, the likelihood of other PIs in this sample not being documented is low. While some studies have found higher post-operative PI incidence rates of up to 27% \(^{34,39-42}\), others such as a prospective study of 337 cardiac surgery reported a PI incidence rate of zero (that is, all patients had intact skin at the time they left the operating theatre)\(^{39}\). Our results were comparable to (albeit lower than) an
Australian prospective cohort study comprising 534 patients that reported an immediate post-operative (defined as being within 1 hour of admission to the post anaesthetic care unit) PI incidence rate of 1.3%.

Variation in reported incidence across studies may be attributable to the differences in the time frame between PI occurrence and data collection time during the post-operative period. Since our aim was to identify PIs attributable to surgery, follow-up to 48 hours post-operatively was selected on the basis that previous research has suggested that the 48 hour post-operative window is the timeframe within which most PIs due to surgery develop.

Incidence of PIs outside this timeframe is considered to be attributable to post-surgical care and not the surgery itself.

Our surgical patient cohort had risk factors for the development of PIs that had been previously identified in the literature. These are, lengthy surgeries between 2-6 hours; multiple comorbidities including diabetes mellitus; and either low or high BMI. In addition, patients in our study underwent a broad range of surgical procedures including cardiac surgery which has been identified in the literature as a risk factor for the development of PIs. Several patients in our study, however, had pre-operative characteristics which may have had a protective effect against the development of PIs and therefore contributed to the low incidence of PIs observed. Several PI protective factors were reported in a study of surgical patients, including having healthy skin, being continent, being able to move independently and being admitted from home. In our study, 87% of patients could ambulate independently pre-operatively, 97% were continent and 99% were admitted from their own home with only 1 patient admitted from an aged care facility. Therefore, the sample was
relatively healthy. In addition, there were a wide range of pressure relieving devices that were used intra-operatively in the majority of patients such as pillows, gel mats and head rings.

Our investigation of documentation of evidence-based PI care throughout the surgical patient journey indicated variability in processes of care. Gaps in documentation of PI were evident with Waterlow completion rates for risk assessments in the intra-operative and immediate post-operative periods as low as 41% and 36% respectively. Such low completion rates could be due to the fast turn-around of patients and the clinical imperative to quickly transfer patients to either the recovery or the intensive care unit; thereby making completion of risk assessment unfeasible. Moreover, this information was collected from the patients’ medical record, which may reflect a documentation issue rather than a lack of assessments performed. Lack of time by nursing staff has been previously reported to be a barrier to completing patient documentation, even though accurate, consistent and appropriate documentation is recognised as a fundamental part of patient care\textsuperscript{50} and essential for monitoring changes in PI risk status throughout the patient admission. Failure to achieve complete documentation at all time periods means that there is high potential for early identification of skin changes and a missed opportunity for instituting preventive strategies.

Only up to 14% of patients classified as being at high and very high-risk of PI were allocated a pressure-relieving support surface and just over half were documented as having a repositioning regime. This suggests that improvement is urgently needed in the prescription of these interventions for high-risk patients\textsuperscript{51} especially given that HAPIs are regarded as a major patient safety issue and that in our sample the numbers classified as being at high risk increased exponentially from admission to 48 hours post-operatively. However, other processes of care documented were well performed, irrespective of risk category, such as
patient education and daily skin inspections. At the study hospital, a multi-strategy approach and patient PIP education has been in place since 2011. Patient education has been proven to be an important component of PI prevention strategies because it provides patients and family with a degree of ownership for their care\textsuperscript{52, 53}. The reasons for strategies that are the cornerstones of evidence based PIP guidelines, such as allocation of pressure-relieving devices and recording of a repositioning regime not being done requires investigation. Another study similarly found that even where formal risk assessment is well-established, this is not necessarily followed up with appropriate PIP\textsuperscript{38}.

**Strengths and limitations**

This study had a number of strengths. Our study design was a prospective cohort study which is the optimal design to study incidence. We used a combination of data collection methods including medical record documentation for the pre, peri and post-operative periods as well as direct skin observation and assessment for outcome assessment 24 and 48 hrs after surgery. To ensure consistency of reporting, RAs were trained in skin assessment, PI staging and medical record data collection. In addition to capturing PI incidence, this study also reported evidence-based processes of care along the surgical patient journey.

Study limitations include firstly, that it was conducted at one large inner-city hospital and the results may not be generalisable to other health facilities, particularly in rural areas. Secondly, only elective surgical patients were recruited and these patients may have been healthier than surgical patients admitted via the emergency department. However, the study sample had comparable general characteristics to those documented in other studies and was representative of patients who undergo surgery requiring a 48 hour stay at the study site facility\textsuperscript{13, 23, 34}. Thirdly, we only followed patients for 48 hours post-operatively and it may be
that PIs developed after this period, particularly for patients that were identified as being at
very high-risk of developing a PI and it may have been useful to continue to follow up these
patients to observe any PI development. However, it is debatable whether PIs developed
more than two days post-operatively could be directly attributable to the surgical procedure.

CONCLUSIONS

Nurses along the health care continuum play an important role in preventing the development
of PIs in surgical patients by conducting risk assessments, monitoring skin integrity and
implementing preventive strategies peri-operatively and in the post-operative period until
patients are independent and able to reposition themselves and mobilise. Even where the
incidence of PIs is very low, improvements are needed in terms of documenting and
instituting appropriate PIP for high to very high-risk patients before, during and following
surgery. In particular, an understanding of how nurses interpret and use the information from
PI risk assessments to make decisions about, and for informing a PIP plan for those at high
risk, would be of value for improving practice.

Authors’ contributions

CM coordinated the study and contributed to the design, data collection, data analysis and
manuscript. EM and JR conceived, designed and assisted in coordinating the study. RP
conducted part of the data collection and assisted with coordinating the study and data
analysis. AG and PD conducted the main data analysis. All authors contributed towards,
drafting and revising the paper and approved the final manuscript.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.
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Figure legends

Figure 1: Study Processes
Methods section, Portrait orientation

Figure 2: Recruitment of study patients
Results section, Portrait orientation

Figure 3: Waterlow assessment rates pre-operative to 48 hours post-operative (n=150)
Results section, Landscape orientation