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Methodological Issues in Studies of the Effectiveness of Pressure Ulcer Prevention Interventions

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Abstract

PURPOSE—To enhance the wound care practitioner's understanding of the research methods used to obtain information about the effectiveness of pressure ulcer prevention interventions.

TARGET AUDIENCE—This continuing education activity is intended for physicians and nurses with an interest in skin and wound care.

OBJECTIVES—After reading this article and taking this test, the reader should be able to:

1. Differentiate between randomized, historical, and nonrandomized comparison studies.
2. Explain terminology and concepts associated with pressure ulcer prevention research.

INTRODUCTION

In light of the growing recognition of pressure ulcers as an important contributor to patient suffering and the cost of health care,^{1–8} there is an urgent need for the design, implementation, and evaluation of interventions to prevent pressure ulcers in a variety of settings. The target audience for this paper consists of clinicians and health care administrators who are consumers of the published literature on intervention effectiveness and who may undertake studies of preventive interventions in their own health care settings. The goal of this article is to help improve understanding of the research methods used to obtain information about the effectiveness of preventive interventions.

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RANDOMIZED CONTROLLED TRIALS

In a randomized controlled trial (RCT), patients who have agreed to take part in the study are randomized, that is, they are assigned at random, to the intervention group (who receives the new intervention) or to the comparison group (who receives either no intervention or usual care). Both groups are followed for a specified period to determine if they develop a new pressure ulcer (Figure 1).

When considering the relationship between the implementation of an intervention and an observed outcome (such as a reduction in pressure ulcer incidence), results of studies with randomization provide the strongest evidence that the intervention and the outcome are causally related.^{9–12} Two aspects of the RCT (randomization and inclusion of a comparison group) contribute to its ability to provide conclusive results. Randomization is a process by which all study participants have an equal probability of being assigned to either the intervention group or the comparison group.⁹ The randomization process is equivalent to tossing a coin to determine to which group the participant will be assigned. In practice, rather than tossing a coin, published tables of random numbers or computer-generated random numbers are used.¹³ Because group assignment cannot be predicted, randomization reduces the potential for conscious or unconscious bias in the allocation of participants to the intervention and comparison groups. It also helps to make the groups comparable with respect to factors that could affect the outcome. Inclusion of a comparison group strengthens the study design, with the experience of the comparison group representing what the intervention group would have experienced if it had not been exposed to the intervention.

There are many challenges associated with the conduct of RCTs. In many cases, it is simply not feasible to study an intervention with a randomized study. First, an RCT may not be possible because an intervention must be implemented quickly in response to clinical and regulatory demands, allowing too little time for a randomized evaluation study. Second, there are situations where patients are reluctant to agree to being randomized, making it difficult to enroll a sufficient number of patients in a reasonable amount of time. Third, there may be ethical reasons that make it impossible to use randomization.¹⁴ For example, a randomized study to evaluate the effectiveness of regular repositioning of bed-bound patients as a way to prevent pressure ulcers is not feasible because regular repositioning is part of accepted clinical practice. It would not be ethical to withhold this intervention from patients randomized to the comparison group. Finally, RCTs tend to be very time-consuming and costly. Individual clinicians or health care facilities are unlikely to have sufficient resources to conduct a randomized study in a rigorous way.

ALTERNATIVES TO THE RCT

Although RCT is, in theory, the most valid research design for assessing causality in studies of intervention effectiveness,^{9–11} these studies are difficult to do well, and some RCTs (especially those with a small number of participants) turn out to be uninformative. Therefore, researchers sometimes turn to alternative study designs (sometimes called quasi-experimental studies^{10,15}) to evaluate preventive interventions. Two quasi-experimental study designs, studies with a historical comparison group and studies with a nonrandomized comparison group, are discussed in the following sections.

STUDIES WITH A HISTORICAL COMPARISON GROUP

Studies with a historical comparison group are ubiquitous. In studies such as this, an intervention is carried out in the present, and the outcome is compared with outcomes recorded in the past (Figure 2). Generally, the information on past outcomes is obtained from clinical data sources (eg, medical records) or from the published literature. A hypothetical example is

one where a preventive intervention is implemented in an intensive care unit (ICU) at the beginning of 2003. The incidence of pressure ulcers in the ICU was 17% in 2002; in 2003, after implementation of the intervention, the incidence was 6%. The results are presented graphically in Figure 3. Although it would be tempting to conclude that the intervention was responsible for the decrease in incidence, an alternate explanation is that the incidence would have declined even in the absence of the intervention. One reason why the incidence might have gone down in the absence of an intervention is that the incidence was already declining. This type of phenomenon, which is portrayed graphically in Figure 4, is referred to as a secular trend. If the researchers did not gather data on the years preceding 2002, they would not have seen that pressure ulcer incidence was already decreasing and that the intervention is unlikely to have been causally related to the decrease.

Another reason that the incidence may decline even in the absence of an intervention is regression to the mean. This phenomenon is related to the fact that, even if incidence is inherently stable, there is some natural fluctuation from year to year, and some years will have high incidence just by chance. If the time to intervene was chosen because of unusually high incidence, the following year's incidence is expected to be lower even if the intervention is not effective. This situation is represented in Figure 5 using the same example of an intervention implemented at the beginning of 2003. As with the previous scenario, if the researchers did not gather data on the years preceding 2002, they would not have seen that pressure ulcer incidence was fluctuating and that the intervention is unlikely to have been causally related to the subsequent decrease. Situations such as this are common because the decision to implement an intervention is often triggered by care providers' reaction to an observed increased in incidence.

There are at least 3 other reasons why the incidence might go down in the absence of intervention. First, changes in case mix could have a powerful effect on pressure ulcer incidence. In the example of the ICU intervention, a shift to a less severely ill patient population between 2002 and 2003 may explain the decline in incidence observed in Figure 2. Second, a change in reporting or recording practices could affect the estimated incidence even in the absence of a real change. In the ICU example, a reduction in ICU staffing at the end of 2002 might have resulted in less complete chart documentation, which, in turn, led to the observed decline in incidence. Finally, changes in the clinical environment could be the real cause of the observed decline. For example, changes in staffing, leadership, reimbursement policies, and regulations could all affect pressure ulcer incidence. Given the complexity of the clinical environment and the multiplicity of factors that could affect pressure ulcer incidence, some of which are not measurable without intentional efforts, it may be difficult to separate the effect of background clinical factors from the effect of a specific intervention.

If a change in pressure ulcer incidence is observed after the implementation of an intervention, the results from a study with a historical comparison group can be made more convincing if the researchers can demonstrate that case mix, reporting practices, and the clinical environment have been stable over time. Furthermore, providing information on periods before and after the intervention can help to distinguish intervention effects from those related to secular trends and regression to the mean. In the ICU example, the conclusion that the intervention was causally related to the decline in incidence would have been strengthened if the researchers could show the kind of results displayed in Figure 6.

A real-world example of a quasi-experimental study with a historical comparison group is provided by Thompson et al,¹⁶ who assessed the impact of a pressure ulcer prevention intervention in 2 rural long-term-care facilities. The intervention consisted of modifying the skin care protocols in use at the facilities to include a body wash and application of skin protectant to the perineal and perianal areas after each episode of incontinence. A significant

decline in pressure ulcer incidence was observed—from 32.7% before the intervention to 8.9% after the intervention. In their discussion, the authors addressed some of the issues previously described. First, the research report states that the addition of body wash and skin protectant was the only change in skin care protocol that occurred in the period before and after the intervention. This suggests that changes in the clinical environment other than the intervention of interest are not responsible for the observed decrease in incidence. The authors also state that the results “must be interpreted with caution because products other than the body wash and the skin protectant were occasionally used.” Second, the authors caution readers that “determination of a cause-and-effect relationship could not be made” because it was not possible to control for changes in case mix or process variables. Third, the authors acknowledge that a longer period of observation after the intervention would have helped to determine whether the reduction in incidence of pressure ulcers could be maintained. Secular trends and regression to the mean are noncausal explanations of the study results that cannot be rejected based on the data provided in the report.

STUDIES WITH A NONRANDOMIZED COMPARISON GROUP

In a study with a nonrandomized comparison group, there is an intervention group (made up of patients who receive the intervention) and a comparison group (made up of patients who do not receive the intervention) (Figure 7). This type of study is similar to the RCT in that the intervention and comparison groups are studied concurrently, whereas in studies with a historical comparison group, information about the comparison group is obtained retrospectively from clinical records or published reports. However, a crucial difference between this design and the RCT is that, in this design, the decision about which patients will receive the intervention is *not* made by randomization. Rather, with the nonrandomized design, the decision about whether a patient will get the intervention is made on the basis of patient characteristics; patient, family, or clinician preference; or facility policy.

Suppose that, in a hypothetical example of this type of study, a preventive intervention is implemented on one unit in a nursing home starting in 2003. Residents of another unit in the same nursing home are used as the comparison group. Thus, the assignment of residents to the intervention or comparison group is based on the nursing home unit in which the participant resided. The incidence of pressure ulcers is monitored for 1 year on both units.

Suppose further that the incidence on the unit that received the intervention is observed to decrease after the intervention while the incidence in the comparison group is constant over the same period. One possible interpretation of these results is that the intervention was effective in reducing the frequency of pressure ulcers. However, as with all studies, especially nonrandomized studies, other possible explanations need to be considered. In this type of study, the major alternative explanation is that the intervention group and comparison group were not comparable. For example, if there were fewer high-risk nursing home residents in the intervention group than in the comparison group, a lower incidence of pressure ulcers in the intervention group would be expected even if the intervention was not effective. There may be other differences between the 2 groups that could explain differences in pressure ulcer incidence. For example, the units may differ in terms of staffing, leadership, policies, and completeness of reporting or recording pressure ulcers.

The results of a study with a nonrandomized comparison group can be made more convincing if the researchers can demonstrate that case mix and reporting practices are similar in the 2 groups and that differences in the clinical environment are not likely to explain the observed results. Furthermore, a variety of statistical methods are available to adjust for case-mix differences.^{17–19} Using these methods, it is possible to estimate what the difference in pressure ulcer incidence between the 2 groups would be if they had a similar distribution of risk factors.

Of course, to use these statistical methods, it is essential that information on the pressure ulcer risk factors be collected on patients in both the intervention and comparison groups. Statistical adjustment for differences between the groups, however, can only be performed for factors that are known to be related to the outcome. The advantage of the RCT in this regard is that randomization ensures comparability, on average, even with respect to risk factors and protective factors that have not yet been identified.²⁰

A real-world example of a quasi-experimental study with a nonrandomized comparison group was reported by Meaume et al,²¹ who evaluated the role of topical agents in preventing the occurrence of pressure ulcers among 1121 high-risk residents of geriatric and long-term-care units. The intervention consisted of the use of corpitolinol 60 (Laboratoires Urgo; Chenove, France), whereas the comparison groups either received no topical agents or received a cream or skin barrier preparation other than corpitolinol 60. The incidence of pelvic pressure ulcers was lower (7.3%) among patients treated preventively with corpitolinol 60 than among patients who received no topical agents or who received a cream or skin barrier preparation other than corpitolinol 60 (15.6% and 16.3%, respectively). The decision about which skin products to use was made by each facility. A strength of this study is that the authors performed a multivariate statistical analysis to adjust for possible differences in pressure ulcer risk between patients who did and did not receive the product of interest; use of corpitolinol 60 was associated with significantly lower pressure ulcer incidence in this analysis.

SAMPLE SIZE

All types of studies, including RCTs, must ensure that the number of participants included in the study is sufficient given the purpose of the research. In the context of evaluating interventions, the main criterion for choice of sample size is power. Power refers to the ability of a statistical test to detect a true effect (difference between the intervention and comparison groups). In most studies, researchers desire power that provides at least 80% or 90% probability of detecting a true effect. Given desired power, the choice of sample size is based on both clinical and statistical factors. All other things being equal, a larger sample size will be needed when the outcome is rare in the target population, when a small difference between the intervention and comparison groups is of interest clinically, and when the type I error (probability of incorrectly finding an effect) is smaller.²² Underpowered studies (ie, studies with too few study participants) can yield inconclusive results. For example, suppose a small study is performed to compare pressure ulcer incidence in a group of patients who received an intervention and in a group of patients who did not. If the difference in pressure ulcer incidence is not statistically significant (P is larger than the type I error), the reason may be that there truly is no effect or that there is an effect but the number of participants was too small to provide strong evidence of an effect (ie, P is less than type I error).

Performing studies that are too small to yield a definitive result is wasteful of researcher time and effort, participant time and effort, and financial resources. When designing an effectiveness study, clinical researchers should consult an epidemiologist or biostatistician to ensure that the study design and sample size are adequate to allow reasonable conclusions to be drawn.

QUANTIFYING THE OUTCOME

Both prevalence and incidence are measures of the frequency of an outcome such as pressure ulcers. Incidence is defined as the proportion of individuals at risk for an event (such as a new pressure ulcer) who experience the event over a specified period.²³ For example, say that 454 patients were admitted to a certain hospital in 1 year. Of these, 33 developed 1 or more new pressure ulcers during the 3 days after admission. The estimated 3-day incidence would be 33 of 454 or 7.3%. Incidence can be interpreted as the probability that an individual will develop pressure ulcers over the specified period. In this example, it can be concluded that a patient

admitted to this hospital has a 7.3% probability of developing a new pressure ulcer in the first 3 days of the hospital stay. When estimating incidence in a group of patients, those who have pressure ulcers at the start of the specified period can either be excluded from the at-risk group or included in the at-risk group. These 2 approaches give slightly different kinds of information. If those with pre-existing pressure ulcers are excluded, the incidence can be interpreted as the probability of developing 1 or more pressure ulcers among those with no pressure ulcers; this captures the experience of going from having no pressure ulcers to having one or more. If those with pre-existing pressure ulcers are included, the incidence is interpreted as the probability of developing 1 or more new pressure ulcers at anatomic sites where there were no previous pressure ulcers; this captures the experience of going from not having a pressure ulcer at a given site to having a pressure ulcer at that site. In the example given, estimating incidence was straightforward. In many studies, however, estimation is complicated by participants dying or dropping out before the end of the study. In such studies, alternative statistical methods are needed.^{17,24}

Pressure ulcer prevalence, on the other hand, is defined as the proportion of a population that has a pressure ulcer (new or ongoing) at a particular point in time.²³ For example, suppose that all 95 residents of a long-term-care facility were examined on a single day. Of these, 18 were found to have 1 or more pressure ulcers. The estimated prevalence is 18 of 95 or 19%.

The prevalence measure is used when the outcome of interest includes both new and ongoing cases of pressure ulcers. Thus, prevalence represents a cross-sectional “snapshot” of the population. It is a measure of the burden of pressure ulcers and is an important factor that is considered when planning health services in communities and institutions. However, prevalence does *not* capture the experience of going from having no pressure ulcers to having 1 or more pressure ulcers. Prevalence does not measure the risk of developing pressure ulcers and should not be used for the study of risk factors or protective factors (including preventive interventions).

To understand this concept better, the relationship between prevalence and incidence should be considered. Prevalence is dependent both on the incidence of a disease and on disease duration. For example, a chronic disease with long duration such as diabetes has low incidence but high prevalence. An acute condition with short duration such as the common cold has high incidence but low prevalence. When applied to pressure ulcers, this means that prevalence is based on 2 factors: (1) getting a pressure ulcer (incidence) and (2) continuing to have the pressure ulcer (duration). Duration, in turn, depends on how long it takes for the pressure ulcer to heal and on how long the patient survives.

Suppose that the prevalence of pressure ulcers in a rehabilitation facility was 12% in 2004 and only 5% in 2005. The change could be due to reduced incidence (maybe related to the implementation of a new preventive intervention in 2004), but explanations related to duration should also be considered. Thus, it is possible that the incidence stayed the same, but pressure ulcers healed more quickly in 2005 than in 2004. Another explanation is that the incidence stayed the same, but patients with pressure ulcers died sooner than in 2004. These examples illustrate the flawed interpretations that can result if changes in prevalence are used as an indicator of the effectiveness of preventive interventions.

In summary, changes in prevalence can reflect changes in incidence and/or duration. Changes in incidence reflect changes in risk factors or protective factors (including preventive interventions). Therefore, incidence is the preferred measure of pressure ulcer frequency in studies of preventive interventions.

DEFINING THE OUTCOME

The way that the occurrence of new pressure ulcers is defined can affect the results of a study evaluating a pressure ulcer prevention intervention. First, interventions may seem more or less successful, depending on whether the definition of the outcome includes Stage I pressure ulcers in contrast to a more restrictive definition.^{25,26} For example, if an intervention is more effective at preventing Stage I pressure ulcers than in preventing more severe wounds, the intervention will seem more successful in a study that includes Stage I pressure ulcers in the definition of the outcome than in a study that limits the outcome to pressure ulcers Stage II or higher. Second, for all types of evaluation studies, results are more convincing if the observers are “blind” to the group to which participants were assigned.²⁷

Blinding is difficult to achieve in studies of pressure ulcer prevention if the intervention consists of a device (eg, mattress or overlay) that cannot be concealed from the observers conducting the study assessments; photography has been suggested as a valid and feasible way to blindly assess the outcome in studies such as this.²⁸ Third, although some researchers and clinicians consider that the outcome in pressure ulcer prevention studies should be defined as the development of 1 or more new pressure ulcers,^{23,25,26} it may be appropriate, depending on the study goals, to consider the number of new pressure ulcers as the outcome.²⁹

SUMMARY

Evidence-based practice requires that decisions about health care be based on, among other things, findings from high-quality research. The adoption of interventions that are not rigorously evaluated can result in ineffective and costly care. The realities of the health care environment, however, demand that clinical decisions must sometimes be made in the absence of evidence from high-quality RCTs. The authors believe that, although such studies provide the strongest evidence regarding the effectiveness of an intervention, results of quasi-experimental studies can also provide useful information. When conducting quasi-experimental studies, researchers should ensure that they incorporate study design features that will strengthen the study conclusions. Interpretation of results of quasi-experimental studies should carefully consider all possible explanations of the observed results. Designing nonrandomized evaluation studies that are methodologically sound makes it easier to meet established standards for reporting of results of this type of study.¹⁴ Reporting results in this standard way, in turn, helps clinicians and policy makers to make informed decisions about pressure ulcer prevention.

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Figure 1.
SCHEMATIC REPRESENTATION OF A RANDOMIZED CONTROLLED TRIAL

Figure 2.
SCHEMATIC REPRESENTATION OF A STUDY WITH A HISTORICAL COMPARISON GROUP

Figure 3.
DECREASE IN PRESSURE ULCER INCIDENCE AFTER IMPLEMENTATION OF A
HYPOTHETICAL PREVENTIVE INTERVENTION AT THE BEGINNING OF 2003

Figure 4.
DECREASE IN PRESSURE ULCER INCIDENCE AFTER IMPLEMENTATION OF A
HYPOTHETICAL PREVENTIVE INTERVENTION AT THE BEGINNING OF 2003,
SHOWING TREND OF DECREASING INCIDENCE BEFORE AND AFTER THE
INTERVENTION

Figure 5.
DECREASE IN PRESSURE ULCER INCIDENCE AFTER IMPLEMENTATION OF A
HYPOTHETICAL PREVENTIVE INTERVENTION AT THE BEGINNING OF 2003,
SHOWING TREND OF FLUCTUATING INCIDENCE BEFORE AND AFTER THE
INTERVENTION

Figure 6. DECREASE IN PRESSURE ULCER INCIDENCE AFTER IMPLEMENTATION OF A HYPOTHETICAL PREVENTIVE INTERVENTION AT THE BEGINNING OF 2003, SHOWING TREND OF HIGHER INCIDENCE FOR 4 YEARS BEFORE THE INTERVENTION AND LOWER INCIDENCE FOR 4 YEARS AFTER THE INTERVENTION

Figure 7.
SCHEMATIC REPRESENTATION OF A STUDY WITH A NONRANDOMIZED
COMPARISON GROUP