

CLINICAL FOCUS

THERAPEUTIC SURFACES

AVOIDING UNFAIR COMPARISONS OF INTERVENTIONS USED IN THE TREATMENT OF PRESSURE ULCERS: A CRITICAL REVIEW OF RETROSPECTIVE COHORT STUDIES

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There is now a growing body of evidence surrounding the treatment of pressure ulcers. Considering randomized controlled trials (RCT) alone, there are now at least 95 such studies reported worldwide¹, with 15 of these studies comparing different forms of pressure-redistributing (PR) support surface. It is widely accepted that the methodological quality of these 95 studies varies widely and can generally be considered to be quite low. One of the surprising aspects is the common failure to consider the initial size of the pressure ulcer at the time of recruitment to the study. Considering just PR support surface RCT's, the initial size (often given by surface area) of the pressure ulcer(s) experienced by the study subjects was either completely unreported (in 6 studies) or reported with no apparent baseline comparability in the size of the wounds allocated to the different interventions (in 7 trials). This is a key weakness; for it is well known that large pressure ulcers may apparently reduce in area at a faster rate than will smaller pressure ulcers². Such observations prompted a recommendation from the NPUAP in the early 1990's, for studies to stratify subjects based upon the initial size of their pressure ulcer³. Twelve years later it appears that this recommendation has been largely overlooked to the detriment of our interpretation of study findings.

Other study designs exist beyond the RCT and prospective^{4,5} or retrospective⁶ cohort studies can also provide indications of the possible effect of interventions on pressure ulcer healing. Of these, prospective designs may be stronger given the ability to control issues such as wound measurement techniques. Retrospective analyses of administrative data-sets may offer impressions of the effect of specific interventions but such studies can be limited by the methods that had been used to calculate wound size. For example, simple measures of wound length multiplied by width may be the most commonly available indication of wound size in clinical records⁷ but may over-represent the surface area of pressure ulcers by up to 30%⁸.

This research skills summary, will now consider in greater detail the strengths and weaknesses of retrospective cohort studies, given that these superficially offer the potential for analyses based on large numbers of subjects with relatively limited investment in the collection of the data! Their reliance upon previously generated data with the inability to ascertain the reliability or reproducibility of the data used in subsequent analysis has already been mentioned and will not be discussed further.

One recent large scale retrospective cohort study was reported by Ochs et al in 2005⁹. This paper illustrates the strengths and challenges of using retrospective data.

Ochs RF, Horn SD, van Rijswijk L et al (2005). Comparison of Air-Fluidized Therapy with Other Support Surfaces Used to Treat Pressure Ulcers in Nursing Home Residents. *Ostomy Wound Management*; 51(2): 38-68.

This study sets out to compare pressure ulcer healing rates among nursing home patients nursed upon three groups of support surfaces. The three support surface groups (Groups 1, 2 and 3) are based on regulatory groupings of disparate support surfaces and are not natural groupings of support surfaces, based upon their known effectiveness. Data was extracted through a retrospective analysis of clinical notes, with formal reliability checks between the trained data extractors. However, the key outcome measure – wound size – was calculated from reported maximum wound length multiplied by width, with no opportunity to assess the accuracy of these measurements.

From the administrative dataset, eligible records came from nursing home residents who were; present for at least 14 days; with one or more pressure ulcers; and nursed upon a documented group 1, 2 or 3 support surface. This yielded a total sample of 664 residents drawn from a total dataset of 2486 adult nursing home residents. However, it is not clear how many nursing home facilities contributed this total of 664 residents and no comment is offered on any potential centre differences – were some nursing homes ‘better’ at treating pressure ulcers than others?

The data was then treated in two ways:

- i) ‘analysis by person’: rate of healing for the *largest pressure ulcer per resident* over a minimum of five days.
- ii) ‘episode analysis’: rate of healing for *all pressure ulcers per resident* tracked over 7 to 10 day episodes.

This latter approach, which broke each resident’s stay into discrete 7 to 10 day blocks (or episodes), required sophisticated analysis in that it had to try and take account of potential bias inherent where multiple episodes from multiple ulcers were combined. Despite the sophistication of this ‘episode analysis’, the independence of each episode from other episodes gathered from the same nursing home resident is doubtful – if a pressure ulcer is healing in one episode it may be expected that similar progress would be seen in the next and subsequent episodes. In this summary of the study by Ochs et al, the ‘episode analysis’ will be discounted due to two factors – the potential for lack of independence between episodes and the potential for error introduced when measuring relatively small changes in wound size between two close time points (7 to 10 days apart) with inexact measures of wound surface area.

Focusing upon the ‘analysis by person’ it was evident to Ochs et al that the study did not have comparability between treatment groups at baseline – residents allocated to Group 3 surfaces were younger (mean age 67.9 years) than were residents nursed on the other arbitrary support surface groupings (Group 1, mean age 79.3 years; Group

2, 67.6 years). Residents who had been allocated Group 3 support surfaces typically had more pressure ulcers, of larger size and greater severity. Such differences reflect the challenge of using retrospective data, where the allocation to treatment groups was not made randomly but rather reflected the prevailing reimbursement patterns across the care settings. Given the nature of the pressure ulcers among residents nursed upon Group 3 support surfaces, it was not surprising that their pressure ulcers appeared to heal faster, as initial wound size is, as noted by the NPUAP twelve years ago – a predictor of healing rate. In fact, when Ochs et al conducted appropriate regression analyses, initial pressure ulcer size was the key predictor of healing rate, to the extent that the ‘*marked effect of initial pressure ulcer size masked other factors with a potential impact on the healing rate*’. Surprisingly there was no attempt to compare only residents with similar sized wounds within the ‘analysis by person’. When looking at the episodes of time passed on the support surface, Ochs et al did report analyses based on comparably sized pressure ulcers but the range of the wound sizes considered to be comparable (20cm² to 75cm²) appeared extraordinarily wide, so weakening this sub-group analysis.

One of the advantages of cohort studies lies in the ability to obtain large amounts of data rapidly. However, specific interventions may be rarely encountered in administrative datasets and this was the case with the Group 1 and 2 surfaces reported by Ochs et al, where alternating pressure support surfaces were relatively rare (Table 1). This rarity of key interventions such as alternating pressure, effectively precludes analysis of their likely effectiveness and no guidance can be taken from Ochs et al regarding the effectiveness of any single alternating pressure support surface.

Support surface	Group 1	Group 2
Foam	350	0
Water/gel	83	0
Alternating pressure	16	0
Low-Air-Loss	0	62
Powered pressure-reducing	0	35
Powered air overlay	0	12
Non powered advanced pressure surfaces	0	16
Unreported	14	0
Total number	463	125

Table 1. Number of nursing home residents allocated to different Group 1 and 2 support surfaces.

Note: The total number of residents allocated to Group 2 surfaces (n = 125) exceeds the total number of residents noted by Ochs et al to have received Group 2 surfaces (n = 119).

Retrospective data may identify important trends in the management of pressure ulcers but the inability to form comparable groups at baseline weaken such studies. This was the case of Ochs et al, where the initial allocation of support surfaces to the nursing home residents resulted in the largest pressure ulcers being cared for in one treatment arm (Group 3). This inevitably led to the observation that their wounds healed faster, as would be expected given

that 'initial pressure ulcer size is a predictor of pressure treatment outcome'. Ochs et al correctly concluded that this challenge was 'best solved with a prospective study that matches wound sizes between groups at the onset of the study'. So where healing rates are to be calculated and compared, retrospective studies may fail to identify clinically relevant differences between interventions.

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Key Points

- Retrospective study designs may be weakened by inconsistent and unreliable measures.
- Variance in nursing care between different institutions is highly likely to have an impact on outcome.
- Larger wounds appear to heal more quickly, making unmatched comparisons across different support surfaces unreliable.
- Reimbursement groups may not reflect the clinical effectiveness of individual support surfaces.
- Only 16 Alternating Mattress Systems were encountered across the data set reported by Ochs et al, so assertions or assumptions on clinical efficacy for this modality would be inappropriate.
- Group 3 products were almost certain to show a clinical advantage given that the majority of comparative products were Group 1 – Foam!

References

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- 2 Brown GS (2000). Reporting outcomes for Stage IV pressure healing: a proposal. *Advances in Skin and Wound Care*; 15 (6): 277-285.
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- 4 Clark M et al (2002). Collecting pressure ulcer prevention and management outcomes. Part 1. *British Journal of Nursing*; 11(4): 230-238.
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- 6 Ochs BG, Hom SD, van Rijswijk L et al (2005). Comparison of air-fluidized therapy with other support surfaces used to treat pressure ulcers in nursing home residents. *Ostomy/Wound Management*; 51(2): 38-68.
- 7 Eager CA (1997). Monitoring wound healing in the home health arena. *Advances in Wound Care*; 10 (5): 54-57.
- 8 Schubert V (1997). Measuring the area of chronic ulcers for consistent documentation in clinical practice. *Wounds*; 9(5): 153-159.