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Original Article

Comparison of the treatment of hydrocolloid and saline gauze for pressure ulcer: a meta-analysis of randomized controlled trials

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Abstract: Purpose: To determine the hydrocolloid dressing versus saline gauze for the treatment of pressure ulcer. Methods: Pubmed and Web of Knowledge were searched for randomized controlled trials for the treatment of hydrocolloid and saline gauze for pressure ulcer. The random effect model was used. Sensitivity analysis and publication bias were conducted. Results: Seven randomized controlled trials involving a total of 329 participants were included in this meta-analysis. The combined results suggested that significant association in complete healing were detected among hydrocolloid dressings and saline gauze [Summary RR=2.20, 95% CI=1.21-4.02, I^2=48.5%]. The associations were also significant when we only combine the results for ulcers healed and the treatment duration of 8-12 weeks. No publication bias was found. Conclusions: Our meta-analysis suggested that the use of hydrocolloid dressing increased the likelihood of complete healing by more than two-fold compared with saline gauze dressing.

Keywords: Hydrocolloid, saline gauze, pressure ulcer, meta-analysis

Introduction

A pressure ulcer is a public health problem that affects sick people, the family and society. According to the National Pressure Ulcer Advisory Panel (NPUAP) [1], a pressure ulcer is defined as a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. The sacrum and heel are the most common location of pressure ulcers. They affect thousands of people around the world at the different levels of health care, with the adult and older adult population standing out. In the United States of America, each year, approximately 3,000,000 people develop pressure ulcer. Of these, over 60,000 die each year as a result of the complications caused by the lesion's presence [2].

The hydrocolloids are interactive dressings, made up of an external layer of polyurethane and an internal layer of gelatine, pectin and carboxymethyl cellulose, which produce an ideal humid environment in the wound bed, control the exudate, facilitate the autolytic debridement, contribute to pain management and provide a barrier to external microorganisms [2]. Up to date, a number of epidemiologic studies have been published to explore the relationship between hydrocolloid or saline gauze and the risk of pressure ulcer. However, the results are not consistent. Therefore, we conducted a meta-analysis to (1) assess the association for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk; (2) assess the heterogeneity among studies and publication bias.

Methods

Search strategy

A comprehensive search was conducted for available articles published in English using the databases of PubMed and Web of Knowledge up to March 2015 and by hand-searching the reference lists of the computer retrieved articles. The following search terms were used: 'Pressure Ulcer' in combination with the term

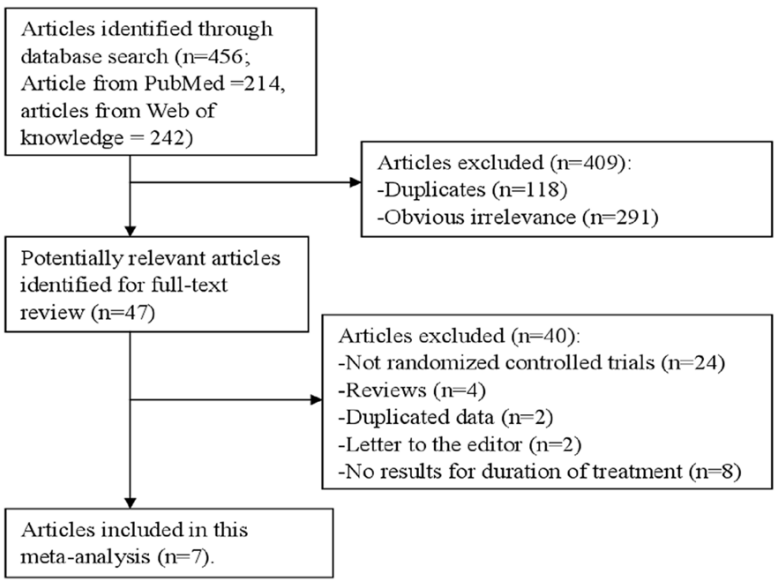

Figure 1. The flow diagram of screened, excluded, and analyzed publications.

'Hydrocolloid' or 'Saline Gauze' or 'Bandages' or 'Occlusive Dressing'. Two investigators searched articles and reviewed of all retrieved studies independently. Disagreements between the two investigators were resolved by consensus with a third reviewer.

Inclusion criteria

All relevant studies reporting the association between hydrocolloid or saline gauze and the risk of pressure ulcer were considered for inclusion. The inclusion criteria were as follows: (1) the study design was randomized controlled trials (RCTs); (2) the exposure of interest was the treatment of hydrocolloid or saline gauze; (3) the outcome of interest was pressure ulcer; (4) relative risk (RR) or odds ratio (OR) with a 95% confidence interval (CI) for the treatment of hydrocolloid compared with saline gauze was provided (or data available to calculate them); (5) written in English. Accordingly, the following exclusion criteria were also used: (1) reviews; (2) repeated or overlapped publications.

Data extraction

Two researchers independently extracted the following information: name of the first author, publication year, age for subjects, the ways of treatment pressure ulcer, treatment duration, sample size for the treatments and participants, outcome measures, and RR (95% CI) for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk. If there was disagreement between the two investigators about eligibility of the data, it was resolved by consensus with a third reviewer.

Statistical analysis

The pooled measure was calculated as the inverse variance-weighted mean of the logarithm of RR with 95% CI, to assess the association for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk. Random-effects model was used to combine study-specific RR (95% CI), which considers both within-study and between-study variation [3]. The I^2 was used to assess heterogeneity, and I^2 values of 0, 25, 50 and 75% represent no, low, moderate and high heterogeneity [4], respectively. Meta-regression with restricted maximum likelihood estimation was performed to assess the potentially important covariates that might exert substantial impact on between-study heterogeneity [5]. If no significant covariates were found to be heterogeneous, the "leave-one-out" sensitive analysis [6] was carried out to evaluate the key studies with substantial impact on between-study heterogeneity. Publication bias was evaluated using Egger regression asymmetry test [7]. A study of influence analysis [8] was conducted to describe how robust the pooled estimator was to removal of individual studies. An individual study was suspected of excessive influence if the point estimate of its omitted analysis lay outside the 95% CI of the combined analysis. All statistical analyses were conducted with STATA version 10.0 (StataCorp LP, College Station, Texas, USA). Two-tailed *p*-value ≤ 0.05 was accepted as statistically significant.

Results

Search results and study characteristics

The electronic database searches identified 456 citations. A total of 409 studies were

Table 1. Characteristics of studies on the treatment of hydrocolloid and saline gauze for pressure ulcer

Study year	Treatment for Hydrocolloid			Treatment for Saline Gauze			Ulcer Stage	Outcome Measures	Treatment Duration	RR (95% CI) for Hydrocolloid vs. Saline Gauze
	Mean Age (SD)	Participants	No. of Ulcers healed	Mean Age (SD)	Participants	No. of Ulcers healed				
Alm et al. 1989	83.6 (9.2)	31	17	83.4 (9.4)	25	4	NA	Ulcers healed	10 weeks	3.43 (1.02-8.89)
Chang et al. 1998	57.6	17	10	57.6	17	3	Stage II or III	Mean change in surface area	8 weeks	3.33 (0.78-14.28)
Colwell et al. 1993	68	48	11	68	49	1	Stage II and/or III	Ulcers healed	12 weeks	11.23 (1.40-90.38)
Hollisaz et al. 2004	36.64 (6.04)	31	23	36.64 (6.04)	30	8	Stage I and stage II	Ulcers healed	8 weeks	2.78 (1.08-7.18)
Matzen et al. 1999	82	17	5	84	15	0	Stage III or IV	Ulcers healed Percent change in wound volume	12 weeks	9.74 (0.50-163.33)
Mulder et al. 1993	63.1 (15.3)	21	*	57.2 (13.6)	20	*	Stage II and stage III	Percentage of change/week	8 weeks	1.07 (0.54-1.68)
Xakellis et al. 1992	77.3 (16.9)	18	16	83.5 (10.6)	21	18	Stage II or stage III	Ulcers healed	6 months	1.04 (0.41-2.61)

Abbreviations: SD, Standard deviation; CI, confidence interval; RR, relative risk; NA, not available. *The study did not report the number of ulcers healed, we calculate the RR (95% CI) using the percentage of change (Mean ± SD).

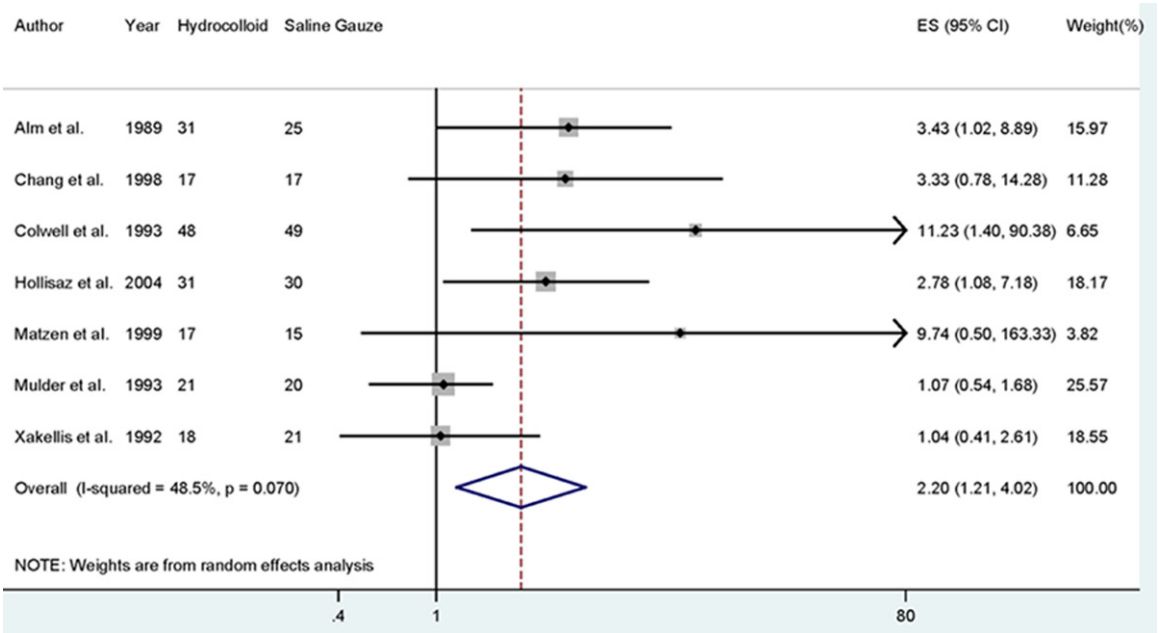

Figure 2. The forest plot for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk.

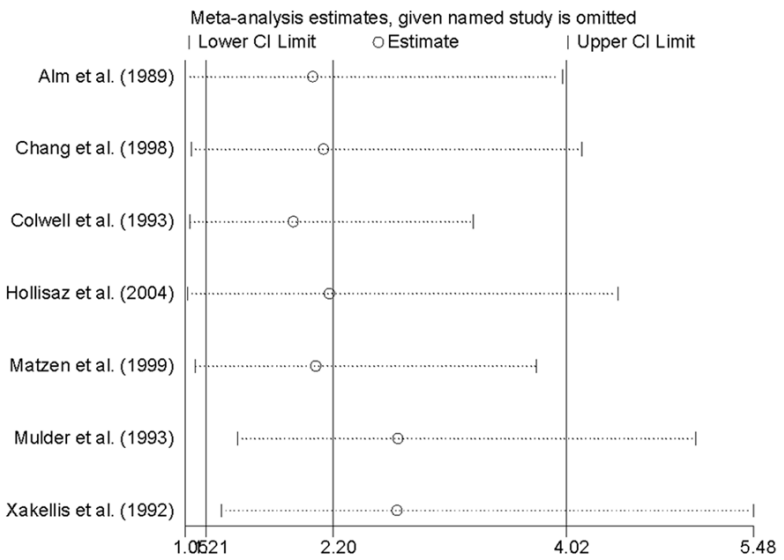

Figure 3. Analysis of influence of individual study on the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk. Open circle, the pooled RR, given named study is omitted. Horizontal lines represent the 95% CIs.

Comparison of the treatment between hydrocolloid and saline gauze

Data from 7 RCTs including 4329 participants were used in this meta-analysis. Three studies reported that hydrocolloid dressing was more complete healing compared with saline gauze, while no significant association was reported in 4 studies. Pooled results suggested that significant association in complete healing were detected among hydrocolloid dressings and saline gauze. [Summary RR=2.20, 95% CI=1.21-4.02, I^2=48.5%] (**Figure 2**).

excluded on abstract review. The remaining 47 studies were reviewed for further details. Additional 40 studies were excluded for various reasons as shown in **Figure 1**. Finally, 7 RCTs [9-15] involving a total of 329 participants were included in this meta-analysis. Characteristics and methodological quality of included studies are presented in **Table 1**.

In the included RCTs, one study [14] did not report the number of ulcers healed, we calculate the RR (95% CI) using the percentage of change (Mean ± SD). We then pooled the results after excluding this study, and the results was also significant [Summary RR=2.71, 95% CI=1.46-5.03, I^2=26.7%]. For the duration of treatment, six of the included studies ranged

from 8 to 12 weeks, and only one study [15] was duration of 6-month treatment. Significant association between the treatment of hydrocolloid dressing compared with saline gauze was found for pressure ulcer risk when we only combined the studies ranged from 8 to 12 weeks [Summary RR= 2.70, 95% CI=1.33-5.48, I^2=51.4%]. For outcome measures, two studies [10, 14] reported the mean change in surface area and percentage of change/week. When we only combined the studies for the outcome measures of ulcers healed, the results was not change [Summary RR=2.74, 95% CI=1.29-5.80, I^2=39.9%].

Sources of heterogeneity and meta-regression

As seen in the pooled results, moderate heterogeneity (I^2=48.5%, $P_{heterogeneity}$=0.070) was found in the analysis. In order to explore the moderate to high between-study heterogeneity founded in several analyses, univariate meta-regression with the covariates of publication year, location where the study was conducted, outcome measures, treatment duration, and number of participants were performed. No significant findings were found in the above-mentioned analysis. The key contributor of the article to this low between-study heterogeneity assessed by the "leave-one-out" sensitive analysis was the one conducted by Mulder et al. [14]. When we excluding this study, the I^2 was reduced to 26.7%, and the results was not changed [summary RR = 2.71, 95% CI=1.46-5.03].

Influence analysis

Influence analysis showed that no individual study had excessive influence on the association for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk (**Figure 3**).

Publication bias

Egger's test (P=0.150) showed no evidence of significant publication bias was found for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk.

Discussion

Finding from this meta-analysis suggested that hydrocolloid dressing was more complete healing compared with saline gauze.

Mulder et al. reported percentage of change/week of the association for the treatment of hydrocolloid compared with saline gauze and pressure ulcer risk. When we pooled the results after excluding this study, and the result was significant. The study by Xakellis et al. had much longer treatment duration compared with the other 6 studies. This study with hydrocolloid dressing to 6-month treatment with saline gauze showed a similar proportion of complete healing at the end of the treatment period. Besides having longer duration in treatment, it should be noted that the mean surface area of the ulcers at baseline was smaller (< 1 cm^2) than those in the other studies. Furthermore, Mulder and Chang reported the mean change in surface area and percentage of change/week. When we only combined the studies for the outcome measures of ulcers healed, the results was not change.

The use of hydrocolloid for healing pressure ulcers dates from about 30 years ago. The benefits of this method in comparison with conventional methods include reduction of bacterial contamination, facilitation of patient movement, improvement in patient's psychological condition, more convenience and less pain [16, 17]. Hydrocolloid adhesive dressings absorb water and low molecular weight components from ulcer secretions, so they swell to produce a jelly. This jelly protects the ulcer, and new cells proliferate [18]. Moreover, the jelly stimulates the immune system locally by activating granulocytes, monocytes and the complement system [19], decreasing the effects of bacterial colonization and ensuring auto-debridement of the ulcer [20].

Between-study heterogeneity is common in meta-analysis [21], and exploring the potential sources of between-study heterogeneity is the essential component of meta-analysis. For the treatment of hydrocolloid dressing compared with saline gauze for pressure ulcer risk, moderate heterogeneity was found in the pooled results. The between-study heterogeneity might arise from publication year, location where the study was conducted, outcome measures, treatment duration, and number of participants. Thus, we used meta-regression to explore the causes of heterogeneity for covariates. However, no covariate having a significant impact on between-study heterogeneity for the

above mentioned covariates. Thus we used 'leave one out' sensitive analysis, which aims to reduce between-study heterogeneity and explore the potential important causes of between-study heterogeneity. The key contributor of the article to this low between-study heterogeneity assessed by the "leave-one-out" sensitive analysis was the one conducted by Mulder et al. When we excluding this study, the I^2 was reduced to 26.7%, and the results was not changed.

As a meta-analysis of published studies, several limitations need to be cautious. First, other unpublished literatures on relevant pharmaceutical websites were not searched and only studies in English were included, which may lead to a potential publication bias. However, no significant publication bias was found, indicating that our results are stable. Second, lack of information about the distribution of clinical and methodological variables may lead to potential sources of either heterogeneity or inconsistency in every comparison-specific group of trials.

In summary, results from this meta-analysis suggested that the use of hydrocolloid dressing increased the likelihood of complete healing by more than two-fold compared with saline gauze dressing.

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Disclosure of conflict of interest

None.

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