Original Article

Meta-analysis of Randomized Controlled Trials on Hydrocolloid Occlusive Dressing Versus Conventional Gauze Dressing in the Healing of Chronic Wounds

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Chronic wound management is a difficult area in surgical practice. A wide range of dressings have been recommended for the management of chronic wounds. The present meta-analysis was undertaken to determine the effectiveness of hydrocolloid dressing (HCD) in the healing of chronic wounds compared with conventional gauze dressing. All available controlled clinical trials published before December 2001 that compared HCD to conventional gauze dressing in the healing of chronic wounds were systematically reviewed. We identified and analysed 12 randomized trials (11 published; 1 unpublished) comprising 693 patients with 819 ulcers. The overall odds ratio under the fixed effect model was 1.72, that is, 72% more ulcers healed completely with HCD than with conventional gauze dressing. This result was both clinically and statistically significant. [*Asian J Surg* 2004;27(4): 326–32]

Introduction

Management of chronic wounds is a major challenge to society because of its magnitude, complexity and cost. George estimates that the worldwide prevalence of some leg ulcers is 8–10 million, and of pressure sores is 7–8 million.[1]

Many different types of dressings are recommended for the management of chronic wounds. Traditional or conventional dressings include gauze, gauze soaked in saline, tulle gras and knitted viscose dressings. Winter, however, introduced the concept of interactive dressings that can alter the local wound environment, e.g. alginates, collagen films, foams, hyaluronic acid products, hydrocolloids and hydrogels.[2] These dressings are occlusive or semi-occlusive and cause accumulation of water vapour at the surface, which helps to maintain a moist wound environment. These may also insulate the wound surface from excessive heat loss, which is thought to inhibit fibroblast activity. In a more aggressive approach, active dressings that have various properties believed to have a direct role in changing the chemical and cellular make-up of the wound have been developed. Examples of active dressings include skin grafts, growth factors and cellular suspensions. Hydrocolloid dressing (HCD) is an occlusive dressing that contains a hydrocolloid matrix (e.g. gelatin, pectin and carboxymethylcellulose) with elastomeric and adhesive substances attached to a polymer base. On contact with wound exudates, the hydrocolloid matrix absorbs water, swells and liquefies to form a moist gel. This has been claimed to expedite healing by providing a moist and warm environment at the wound surface and also by preventing external bacterial colonization. Applying a dressing that is impermeable to bacteria reduces infection rates by 50%.[3] The bacterial content of wounds under occlusive dressings is less than that of similar wounds treated with conventional absorbent materials, possi-

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bly because active phagocytic cells are retained at the moist wound surface.[4] *In vitro* studies show that relatively low oxygen tension stimulates angiogenesis and fibroblast and epidermal cell turnover and, therefore, is expected to provide good conditions for wound healing.[5] Many studies claim that HCD leads to better healing, but most of these results are based on small trials that show either marginal or no benefit.

To compare the effectiveness of HCD over conventional gauze dressing, we carried out a meta-analysis of the existing randomized controlled trials comparing HCD to conventional gauze dressing in the healing of chronic wounds.

Materials and methods

We conducted electronic searches of MEDLINE for articles published up to 2001. The search was carried out using all possible combinations of the key words: hydrocolloid dressing, paraffin gauze, duoderm, saline gauze, occlusive dressing and conventional dressing. We reviewed all relevant articles found in the searches. Reference lists of all articles were scanned to identify additional articles that were not found in the computerized bibliographic database search.

Studies were included if they were randomized controlled trials published in English, included only chronic wounds, clearly described the time to healing, and used HCD in one treatment arm and conventional dressing such as paraffin gauze or cotton gauze in another. Trials in patients with acute wounds such as burns or skin graft donor sites, studies including primary sutured surgical wounds, reports without data on complete healing and crossover trials were excluded. Partial healing or improvement in healing were considered inadequate because, from the patient's point of view, complete healing is more important than just improvement or percentage area healed.

Study quality was evaluated using six assessment criteria (randomization, blinding, follow-up, whether pain was quantified, whether cost was quantified, and comparability of groups). Two independent reviewers studied the articles, completed data extraction forms separately for each article, and scored each article according to the six criteria. There was complete agreement between the two reviewers.

In addition to the references obtained from the electronic search and cross references, one unpublished trial conducted at our institution (Wound Clinic, Outpatient Department, All India Institute of Medical Sciences) between 1994 and 1997 was also included (Srivastava A, et al. Duoderm occlusive hydrocolloid dressing versus paraffin gauze dressing in management of chronic venous ulcer: a randomized trial. Written communication, January 2001). This randomized controlled single-blinded study of chronic venous ulcers was supported by ConvaTec Inc (Princeton, NJ, USA). A total of 100 participants were enrolled and randomized to receive either HCD or paraffin gauze dressing.

Analysis

Two effect measures were used in the meta-analysis: the odds ratio (OR) and the risk difference. These measures are defined below.

If x_t is the number of persons with outcomes observed in the treatment group, x_c is the number of persons with outcomes observed in the control group, n_t is the number of persons in the treatment group, and n_c is the number of persons in the control group, then the proportion of the outcomes in the two groups are given by p_t and p_c, respectively, where $p_t = x_t/n_t$ and $p_c = x_c/n_c$.

The OR measures the increased risk (benefit) of a treatment compared with the control group. It is defined as the ratio of the odds of occurrence of events in the treatment group to the odds of occurrence of events in the control group.

If $\{p_t/(1 - p_t)\}$ is the odds of occurrence of the event in the experimental group and $\{p_c/(1 - p_c)\}$ is the odds of occurrence of the event in the control group, then OR = $[p_t/(1 - p_t)]/[p_c/(1 - p_c)]$. For analysis purposes, we use log OR, for which Variance = $[1/ n_t p_t(1 - p_t)] + [1/n_c p_c(1 - p_c)]$.

The risk difference measures the increase in the proportion of events in the treatment group compared with the control group. It is the difference in the proportion of events in the treatment group and the control group. Risk difference = $p_t - p_c$, with Variance = $[p_t/(1 - p_t)/n_t] + [p_c/(1 - p_c)/n_c]$.

The combined effect measure was obtained by applying the fixed effect method and the random effect method. The methods vary in their basic assumptions. The fixed effect method is based on the assumption that the individual study effects are homogeneous and whatever heterogeneity is observed is due to the sampling errors of individual studies. The random effect method incorporates the heterogeneity between studies as a separate component in addition to the variation within studies. The combined fixed effect measure is the weighted average of the individual effect measures, the weights being the precision (inverse of variance) of the individual studies. The combined random effect measure is also the weighted average, but the weights are the inverse of the sum of variance between studies and the variance within studies. To decide which method should be used for the

analysis, a Chi-squared test of heterogeneity is applied under a prior assumption of homogeneity. If this test is statistically significant, it is inferred that the studies have shown that they differ significantly and a random effect model is appropriate. However, if the test of heterogeneity is not statistically significant, we assume that there is not enough evidence to reject the assumption of homogeneity and a fixed effect model would be adequate.

Results

Of the 83 articles found through the literature search, only 11 met the inclusion criteria. In the trial of Viciano et al,[6] the number of patients who achieved complete healing at the end of 12 weeks was not given in the paper, so this information was obtained from Dr. Vicente Viciano through personal, written, communication (July–November 2001). The study by Handfield-Jones et al was excluded because it was a cross-over trial.[7] Lindholm conducted only a cost-effectiveness analysis and did not provide data on complete healing, so this study was also excluded.[8] The analysis was performed both with and without the results from the unpublished Srivastava et al study. The randomization method was not mentioned in any of the articles except the unpublished Srivastava et al article, in which randomization used sealed opaque envelopes containing computer-generated random numbers provided by ConvaTec Inc. Observers were only blinded in the Alm et al study, which was a partially single-blind trial.[9] Some patient characteristics and methods of dressing are highlighted in the Table.

Analysis

The number of completely healed ulcers was recorded from all trials to compare the proportion of ulcers healed in the HCD and conventional dressing groups. Figure 1 shows the Forrest plot for all the trials included in the meta-analysis. A total of 819 ulcers (431 in the HCD group and 388 in the conventional group) were studied. There was complete healing in 51% (221/431) of ulcers in the HCD group compared to 38% (148/388) in the conventional group. Of the 12 studies, that by Gorse and Messner was the largest with 128 ulcers.[10] This study yielded an OR of 2.45, which was statistically significant (p = 0.02; 95% confidence interval, CI = 1.18, 5.12).

Four other studies showed a statistically significant beneficial effect of HCD over conventional dressing: Alm et al,[9] Colwell et al,[14] Ohlsson et al[15] and Srivastava et al (written communication, January 2001). In the study by Colwell et al, there was an unequal distribution of events in the two groups and, hence, the result may not be realistic.[14] The trial by Ohlsson et al included only 28 patients, and the 95% CI (0.97, 37.30) shows unrealistically high limits due to the small sample size.[15] The unpublished study by Srivastava et al yielded an OR of 2.28, which was statistically significant according to the heterogeneity test. Random effects modelling yielded an OR of 1.73, equivalent to the fixed effect method but with a broader 95% CI (1.08, 2.78). Analysis using risk difference yielded similar results (Figure 2). Two large studies, by Gorse and Messner[10] and the unpublished Srivastava et al study, yielded a 20% increase in the proportion of ulcers completely healed by HCD compared to conventional dressing. Colwell et al[14] and Ohlsson et al[15] reported significant benefits but, as described above, these could not be realistic.

The analysis was repeated for both effect measures excluding the unpublished study. This yielded a combined OR of 1.62 using the fixed effect approach, which was statistically significant (p = 0.01; 95% CI = 1.12, 2.37). The random effect method yielded an OR of 1.67 (p = 0.06; 95% CI = 0.97, 2.88).

The trial by Colwell et al yielded an extremely beneficial effect with HCD compared to conventional dressing (p = 0.002; OR = 14.27).[14] Analysis excluding this trial yielded a fixed effect combined OR of 1.63 (p = 0.005; 95% CI = 1.16, 2.29) and a random effect combined OR of 1.58 (p = 0.04; 95% CI = 1.02, 2.46). The combined effect remained significant, with HCD yielding a beneficial effect over conventional dressing. When both the unpublished and Colwell et al[14] studies were excluded, the fixed effect OR was 1.50 (95% CI = 1.04, 2.20), which was statistically significant.

Cost-effectiveness

Though the main aim of this meta-analysis was to measure the proportion of complete healing with HCD compared to conventional dressing, we also considered cost effectiveness in the trials included in our meta-analysis.

Although cost was described in seven of 12 trials, the factors included for calculating cost differed considerably. Therefore, no statistical test was used to analyse cost-effectiveness. In five trials, HCD was significantly cost effective over conventional dressing.[10,12,14,15,17] In the trial by Viciano et al, there was no difference in cost.[6] In the Hansson trial, total weekly cost was the same in both arms, but when average cost per percentage surface area reduction was taken into account, the cost of paraffin gauze dressing (US$12.90) was substantially less than that of HCD (US$32.50).[18]

Table. Characteristics of patients included in the meta-analysis

Study	Year	Place	*N*	*n*	M:F		Age (yr), mean ± SD		CON	Type of ulcer
					HCD	CON	HCD	CON		
Gorse & Messner[10]	1987	USA	128	52	All male	All male	72 ± 12.8	68.4 ± 13.5	Gauze in Dakin solution	Pressure ulcer
Backhouse et al[11]	1987	UK	56	56	11:17	12:16	69.9	67.5	Porous non-adherent dressing with graduated compression bandage	Venous ulcer
Alm et al[9]	1989	Sweden	56	56	1:3 (whole group)*		83.6 ± 9.2	83.4 ± 9.4	Saline gauze	Pressure ulcer
Xakellis & Chrischilles[12]	1992	USA	39	39	1:8	1:20	77.3 ± 16.9	83.5 ± 10.6	Two layers of moistened gauze	Pressure ulcer
Cordts et al[13]	1992	USA	43	43	NS	NS	NS	NS	Unna's boot	Venous leg ulcer
Colwell et al[14]	1993	USA	97	70	6:5	19:18	68	68	Moist gauze	Pressure ulcer
Ohlsson et al[15]	1994	Sweden	28	28	26:4 (whole group)*		Median: 77.6	Median: 73.5	Saline-soaked gauze	Venous/mixed venous arterial leg ulcer
Arnold et al[16]	1994	USA	93	70	13:12 (whole group)*		65	60	Paraffin-impregnated gauze (USA), saline solution/betadine-impregnated gauze (UK) + ZnO paste & compression bandage	Venous leg ulcer
Kim et al[17]	1996	Korea	44	44	23:3	13:5	50.5 ± 18.3	46.9 ± 16.8	Wet saline gauze	Pressure ulcer
Hansson[18]	1998	Sweden, Denmark, NL, UK	97	97	NS	NS	NS	NS	Paraffin gauze	Venous leg ulcer
Viciano et al[6]	2000	Spain	38	38	31:7 (whole group)*		24 (whole group)		Gauze with povidone iodine	Excised pilonidal sinus wound
Srivastava et al (written communication, January 2001)	Unpublished	India	100	100	17:3 (whole group)*		39.7	43	Paraffin gauze	Venous leg ulcer

*Ratio not given separately for the two groups. *N* = total number of ulcers in both groups; *n* = total number of patients in both groups; SD = standard deviation; CON = conventional dressing; HCD = hydrocolloid dressing; NS = not stated; NL = the Netherlands.

Discussion

Wounds are structural or physiological disruptions of the integument. Chronic wounds do not heal within an expected time frame and may linger for weeks, months or years. Authors differ in the definition of chronic wounds but, in general, wounds requiring more than 6 weeks to heal are labelled chronic.

Management of chronic wounds is a common problem in health care. HCDs have been promoted as an effective method for healing chronic wounds. Immediate benefits include a moist, warm, hypoxic and contamination-free environment that promotes wound healing.[3–5] Moreover, patients require fewer outpatient visits and mobility increases markedly as the dressing is left *in situ* for 7–10 days and is changed only when it leaks. Since HCD is semi-permeable, patients can take regular baths or even swim without the need for a dressing change. The trials reported in the literature give differing opinions regarding the efficacy of HCD. The results vary from no or minimal benefit to significant benefit with HCD compared with conventional dressing.

We therefore embarked on this meta-analysis to confirm the known theoretical advantages of HCD and to arrive at a meaningful conclusion. Bradley et al published a systematic review of wound care management in 1999.[19] The dressings and topical agents compared were topical aloe vera, topical insulin, topical ketanserine, topical allopurinol, topical dimethysulfoxide, topical hyaluronic acid, buffered acidified ointment, cryopreserved cultured allografts, wet-to-dry dressings, different HCDs, collagen sponges, foam dressing, alginate dressing and zinc oxide-impregnated stockinette. The authors compared HCD and traditional dressings separately for pressure sores, venous ulcers and arterial ulcers. Five trials (six reports) (χ^2 = 5.76, df = 4) indicated that HCD increased the odds of healing pressure ulcers by threefold (OR = 2.57; 95% CI = 1.58,4.18).[9,12,14,20,21] Nine trials compared HCD with traditional dressings for venous leg ulcers, yielding a pooled OR of 1.4 (95% CI = 0.83, 2.34).[11,16,22–28] One trial by Gibson and co-workers compared HCD dressing with knitted viscose dressing for arterial leg ulcers.[29] There was no difference in healing rates.

Study	HCD	Conv	Total	OR	95% CI		*p*
Gorse & Messner[10]	54/76	26/52	128	2.45	1.18	5.12	0.02
Backhouse et al[11]	21/28	22/28	56	0.82	0.24	2.84	0.75
Alm et al[9]	17/31	4/25	56	6.37	1.77	22.98	0.00
Xakellis & Chrischilles[12]	16/18	18/21	39	1.33	0.20	9.02	0.77
Cordts et al[13]	8/23	6/20	43	1.24	0.34	4.50	0.74
Colwell et al[14]	11/48	1/49	97	14.27	1.76	115.55	0.00
Ohlsson et al[15]	7/14	2/14	28	6.00	0.97	37.30	0.04
Arnold et al[16]	11/46	14/47	93	0.74	0.29	1.86	0.52
Kim et al[17]	21/26	14/18	44	1.20	0.27	5.26	0.81
Hansson[18]	5/48	7/49	97	0.70	0.21	2.37	0.56
Viciano et al[6]	17/23	11/15	38	1.03	0.24	4.50	0.97
Srivastava et al	33/50	23/50	100	2.28	1.02	5.11	0.04
Fixed combined	221/431	148/388	819	1.72	1.23	2.41	0.00
Random combined	221/431	148/388	819	1.73	1.08	2.78	0.02

Q value of heterogeneity = 18.77, p = 0.06

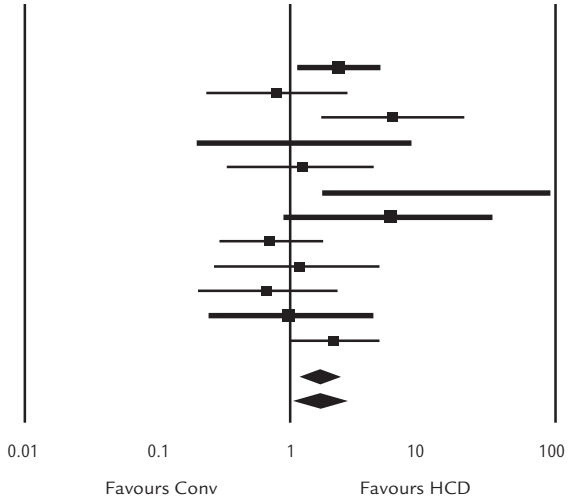

Figure 1. Forrest plot of the odds ratio (OR) of complete healing of wounds, comparing conventional (Conv) to hydrocolloid dressing (HCD).

Study	HCD	Conv	Total	RD	95% CI		*P*
Gorse & Messner[10]	54/76	26/52	128	0.21	0.04	0.38	0.02
Backhouse et al[11]	21/28	22/28	56	–0.04	–0.26	0.19	0.75
Alm et al[9]	17/31	4/25	56	0.39	0.16	0.61	0.00
Xakellis & Chrischilles[12]	16/18	18/21	39	0.03	–0.18	0.24	0.77
Cordts et al[13]	8/23	6/20	43	0.05	–0.23	0.33	0.74
Colwell et al[14]	11/48	1/49	97	0.21	0.08	0.33	0.00
Ohlsson et al[15]	7/14	2/14	28	0.36	0.04	0.68	0.04
Arnold et al[16]	11/46	14/47	93	–0.06	–0.24	0.12	0.52
Kim et al[17]	21/26	14/18	44	0.03	–0.21	0.27	0.81
Hansson[18]	5/48	7/49	97	–0.04	–0.17	0.09	0.56
Viciano et al[6]	17/23	11/15	38	0.01	–0.28	0.29	0.97
Srivastava et al	33/50	23/50	100	0.20	0.01	0.39	0.04
Fixed combined	221/431	148/388	819	0.10	0.05	0.16	0.00
Random combined	221/431	148/388	819	0.11	0.02	0.19	0.02

Q value of heterogeneity = 24.32, p = 0.01

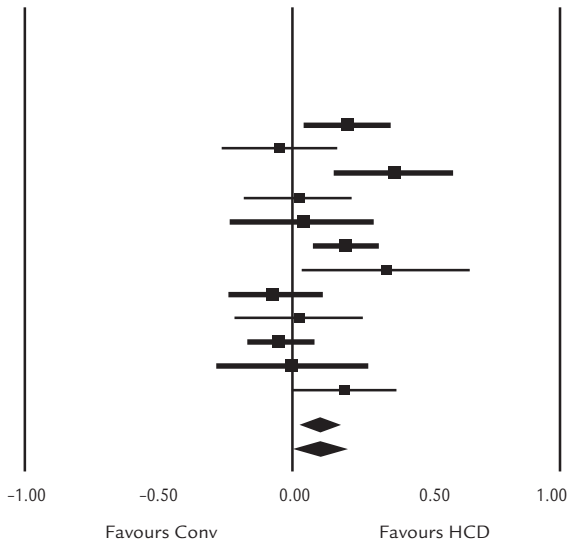

Figure 2. Forrest plot of the risk difference (RD) of complete healing of wounds, comparing conventional (Conv) to hydrocolloid dressing (HCD).

The review of Bradley et al included randomized trials irrespective of date, language and publication status if they were conducted on humans, as well as data from magazines and conference proceedings.[19] The trials in this review that did not meet our inclusion criteria were excluded from our meta-analysis.

Of the 12 studies in our meta-analysis, two large studies (one of which was the unpublished Srivastava et al study) showed that HCD was better than conventional dressing for ulcer healing.[10] Three smaller studies reported a significantly favourable outcome with HCDs.[9,14,15] The other seven studies could not arrive at a conclusion. Meta-analysis of the 12 trials revealed that HCD was significantly better than conventional dressing in terms of complete healing of ulcers.

The studies had several limitations: the randomization method to treatment and control groups was not described. Observers were not blinded. Heterogeneity among the participants might have had a bearing on the overall result of the meta-analysis, e.g. presence of diabetes, arterial or venous disease, infection and concomitant medication such as steroid or immunosuppressive therapy may be detrimental to healing and, hence, affect the outcome. The most important limitation was the small sample size of most of the studies that precluded the authors from arriving at a conclusion. More than one ulcer from one patient was included in some trials.[10,12,14,16] In these trials, patients' intrinsic factors might have created a bias on healing of all the ulcers.

Recommendations

Larger studies that include significant numbers of common types of ulcers, i.e. venous leg ulcer, decubitus ulcer and diabetic foot ulcer, are required to draw a significant conclusion with greater power and confidence. The number of patients should be based on prior sample size calculation. Studies should report the outcome as complete healing, which is more important from the patient's point of view than percentage reduction in ulcer area, and the time to healing (to facilitate future meta-analysis by survival analysis). In addition, only one reference wound should be taken from each patient. Observers should be blinded to ensure that outcome measurements are completely objective. For evaluation of cost, standard criteria should be adopted to maintain uniformity.

Where possible, investigators should join a large group such as the Cochrane Collaboration or Clinical Trials Unit of Oxford University or International Committee on Wound Management for uniformity in study design and conduct.

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