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Multicenter randomized controlled trial comparing the effectiveness and safety of hydrocellular and hydrocolloid dressings for treatment of category II pressure ulcers in patients at primary and long-term care institutions

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ABSTRACT

Background: Pressure ulcers are a major burden to patients because they affect health, well-being, and health-related quality of life. Thus, prevention and early treatment of pressure ulcers is a major challenge for health care professionals.
Objective: To compare the efficacy of hydrocellular and hydrocolloid dressings after 8 weeks of treatment of category II pressure ulcers.
Design: A prospective multicenter clinical trial with blinded outcome assessors.
Participants and settings: Adult patients with category II pressure ulcers from primary and long-term care institutions on Majorca island.
Methods: Category II ulcers were treated with ALLEVYN Adhesive® dressings or VARIHESIVE® GEL CONTROL dressings, with the primary outcome being healing of the ulcers in 8 weeks. Blinded confirmation of ulcer healing was performed by a treatment-group assessment committee. Estimates of cumulative survival probabilities were determined using the Kaplan-Meier method and analyses of effectiveness were performed using the chi-squared test.
Results: A total of 169 patients with pressure ulcers were enrolled, 84 of whom received hydrocellular dressings and 85 of whom received hydrocolloid dressings. A total of 58% were women and 56% were from primary care institutions. The hydrocellular dressing group had a higher percentage of healed pressure ulcers at 8 weeks (90.7% vs. 77.1%, p = 0.039) and a shorter average healing time (3 weeks vs. 4 weeks, p = 0.015). Analysis of safety outcomes at 8 weeks indicated that the hydrocellular dressing group had a smaller proportion of ulcers that were unhealed (3.9% vs. 7.1%) and a smaller proportion of ulcers that progressed to a higher category or infection (5.3% vs. 15.7%), although these differences were not statistically significant.
Conclusions: This study of patients with category II pressure ulcers indicated that hydrocellular dressings were superior to hydrocolloid dressings in terms of healing at 8 weeks and time required for healing, although these two dressings had similar safety profiles.

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What is already known about the topic?

- Pressure ulcers are a major public health issue because of their high prevalence and many associated morbidities.
- Numerous clinical guidelines recommend hydrocellular and hydrocolloid dressings for treatment of non-infected category II pressure ulcers.
- There is no clear evidence on which type of dressing is more effective for treating pressure ulcers.

What this paper adds

- Hydrocellular dressings were more effective than hydrocolloid dressings for healing category II pressure ulcers.
- The two dressings did not differ in cost per healed ulcer.
- Patients and nurses gave higher usability ratings to hydrocellular dressings.

1. Introduction

Pressure ulcers are localized lesions in the skin and underlying tissue that form as a result of intense/prolonged pressure or pressure in combination with shear. If the pressure is not relieved, it can lead to cell death, necrosis, and tissue rupture, and ultimately to osteomyelitis and sepsis, the most severe complications of pressure ulcers (Baena Panadero and Vidal Tomàs, 2009)

Pressure ulcers can also lead to complications such as contracture and atrophy, as well as other conditions such as psychological disorders that may delay improvements in mobility and active rehabilitation, thus preventing a patient's return to an active and independent life. Pressure ulcers affect the physical, emotional, mental, and social life of patients, and can have a considerable negative impact on the quality of life of patients and their caregivers (Alvarez et al., 2001; Gorecki et al., 2009)

Clinicians currently use a four-category system (I-IV) to classify pressure ulcers according to the extent to which tissue is affected (Anon, 2019a): category I, non-blanchable erythema but with intact skin; category II, partial loss of the dermis; category III, full thickness loss of skin with exposed dermis; and category IV, exposure of bone, tendon, or muscle. The National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA) all endorse the usefulness of these categories for more reliably estimating the prevalence and incidence of pressure ulcers.

The estimated prevalence rates of pressure ulcers in Europe are 7.9%–22.9% in hospitals (Vanderwee et al., 2007), 8.4%–13.4% in long-term care institutions (Vanderwee et al., 2007; Capon et al., 2007), 0.44%–5% in community care institutions (Skerritt and Moore, 2014), and 8.5% (95% confidence interval [CI]: 8.0–9.1) in primary care home-care settings (Pancorbo-Hidalgo et al., 2014).

Pressure ulcers are a worldwide public health issue because they prolong hospital stays, and increase direct and indirect medical costs (Soldevilla Agreda et al., 2007). The cost of healing a pressure ulcer increases with ulcer category. However, because category II pressure ulcers have the highest incidence (Bennett et al., 2004), more total health care costs are associated with treatment of these ulcers. Not all pressure damage can be avoided; however the prevalence of pressure ulcers in an institution is directly related to quality of care. (NICE. National Institute for Health and Care Excellence, 2014)

Prevention is the best method for reducing the prevalence of pressure ulcers; hence, efforts in this area should focus on early detection and implementation of preventive measures. The most important preventive measures are skin care, relief of pressure and moisture control (Baena Panadero and Vidal Tomàs, 2009; Anon, 2019a). However, when a pressure ulcer is present, the latest guidelines on prevention and treatment propose moist healing as the treatment of choice, although there are no recommendations regarding the type of dressing (Anon, 2019a; NICE. National Institute for Health and Care Excellence, 2014). Dressings for category II pressure ulcers must absorb fluid from wounds whilst keeping them moist. Noninfected category II pressure ulcers, with or without the presence of exudate, are treated with hydrocellular or hydrocolloid dressings. (Baena Panadero and Vidal Tomàs, 2009; Anon, 2019a; Boyko et al., 2018)

Studies comparing hydrocolloid and hydrocellular dressing versus saline gauze found that hydrocolloid dressing showed a better response than hydrocellular in terms of complete healing of the wound and healing time (Zheng and Li, 2015; Westby et al., 2017). However, we cannot make a strong assumption, because the evidence is still unclear due to the sparsity of the published data and the lack of direct evidence in studies comparing hydrocolloid and hydrocellular dressings (Westby et al., 2017; Reddy et al., 2008). Moreover it is still controversial whether hydrocellular dressings allow better exudate management and are easier to remove than hydrocolloid dressings (Bale et al., 1997; Thomas et al., 1997a; Seeley et al., 1999; Banks et al., 1994).

Hydrocellular dressings consist of polyurethane derivatives that have a hydrophilic structure that is maintained during use. They have a high capacity for autolytic debridement and exudate absorption, and they prevent leaks, skin discoloration, and odors. They also keep the perilesional skin intact without drying the wound bed, decomposing, or leaving residues. Hydrocolloid dressings, by contrast, change their structure upon contact with wound tissue. These dressings are composed of sodium carboxymethylcellulose and adhesive substances, and occasionally hydroactive compounds that affect absorption. Hydrocolloid dressings are covered with a polyurethane sheet, making them occlusive or semi-occlusive. They absorb the exudate and the remains of necrotic tissue to form a gel, with a characteristic color and smell, and have an autolytic capacity to eliminate the necrotic layer in a moist environment (Baena Panadero and Vidal Tomàs, 2009; Anon, 2019a; NICE. National Institute for Health and Care Excellence, 2014).

The aims of the present study were to test the hypothesis that hydrocolloid dressings are more effective than hydrocellular dressings in healing category II pressure ulcers, and to analyze differences in the cost, rate of progression to a higher category, and safety and usability between hydrocellular dressings and hydrocolloid dressings in the treatment for category II pressure ulcers.

2. Methods

2.1. Design and settings

A multicenter, randomized clinical trial with two treatment arms was conducted to compare hydrocolloid and hydrocellular dressings in patients with category II pressure ulcers, all of whom received the usual preventive measures (postural changes, moist healing and/or pressure management). The outcome assessors were blinded to patient allocations. The study was performed in 29 primary care centers and 10 long term care institutions in Mallorca (Balearic Islands, Spain).

2.2. Ethics

This study followed the principles in the Declaration of Helsinki (7th revision), and was approved by the Primary Care Research Committee of the Balearic Islands Ethical Committee of Clinical Research (IB1939/12). Neither of the dressing manufacturing

companies had any role in the design of the trial, analysis of the results, or publication of the protocol or results. The investigators declare receipt of no financial support from Smith & Nephew® or Convatec®.

2.3. Recruitment

Patients were recruited by nurses at the participating centers. Nurses at health centers identified patients with pressure ulcers using home care patient records, and nurses at long-term care institutions identified institutionalized residents who developed pressure ulcers during the study period. The nurses invited the patients to participate, provided them with information on the study, and obtained informed consent.

The nurses performed weekly follow-ups until the ulcer was healed or until the patient had completed 8 weeks of treatment, and then sent photographs of the pressure ulcers taken at baseline and after 8 weeks to the Outcome Assessment Committee.

Risk-based monitoring was used, in that before enrollment all patients were monitored for eligibility criteria, inclusion and exclusion criteria, and signed informed consent documents. After enrollment, all patients were monitored for adverse events and primary outcomes, and a random selection of 5%–10% of patients were monitored for secondary outcomes.

2.4. Patients

All patients at the participating centers with category II pressure ulcers were assessed and referred to a study nurse, who determined if the inclusion criteria were satisfied.

2.4.1. Inclusion criteria

For inclusion, patients were required to be >18 years-old and to have category II pressure ulcers according to the European Pressure Ulcers Advisory Panel. (Anon, 2019a). Grading of the ulcers was carried out by a group of assessors using photographs. In patients with more than one category II pressure ulcer, the ulcer with the greater diameter was included.

2.4.2. Exclusion criteria

Patients were excluded if they had an allergy/hypersensitivity to the materials in the dressings; the pressure ulcer had already been treated with a dressing; the pressure ulcer had previously been subjected to radiation or surgical treatment; signs of basal infection (bacterial sepsis), cellulitis or osteomyelitis were present; the patient had a venous ulcer and/or a diabetic foot; the patient had an extreme, severe, or terminal-phase disease; or the patient had type I diabetes.

2.5. Randomization

Personnel not associated with the trial created the assignment list using computer-generated block randomization (Roberts and Torgerson, 1998), in which the block size was 6. Each recruitment center was provided with an open list of randomization, and eligible patients were sequentially added according to the list.

2.6. Interventions

Investigators trained all nurses to assure adherence to the standardized protocols for treating pressure ulcers. A nurse visited each patient once or twice per week to determine if the dressing should be changed. At these visits, the ulcer was cleaned and washed three times with normal saline, then dried with a sterile gauze and, depending on the size of ulcer, covered with a 10×10 cm or 15×15 cm dressing (hydrocolloid group) or a 7.5×7.5 cm, 12.5×12.5 cm, or 17.5×17.5 cm dressing (hydrocellular group). At each dressing change, the nurse determined if there was any leakage of exudate, lack of adhesion of the dressing, or any situation that endangered the integrity of the dressing. The nurse also evaluated whether anotherdressing was needed.

Nurses treating patients in home care changed the dressing once per week, and explained to the caregiver that the dressing should be changed 2–4 times per week if there was evidence of exudate. In this study the hydrocellular dressing was the ALLEVYN Adhesive® dressing manufactured by Smith & Nephew. It has a trilaminate structure consisting of an adhesive layer which contacts the wound, a soft and highly absorbent central structure, and an external layer that acts as an impermeable bacterial barrier. The hydrocolloid dressing used was the VARIHESIVE® GEL CONTROL dressing manufactured by Convatec, a dressing that has an external layer of polyurethane film over a laminated inner layer of adhesive hydrocolloid which contacts the skin.

2.7. Outcomes

The primary outcome variable was healing of the category II pressure ulcer within 8 weeks. An ulcer was classified as healed when it had a score of 1 or 0 on the Pressure Ulcer Scale for Healing (PUSH). This scale is a reliable tool for monitoring changes in pressure ulcer status over time and has excellent psychometric properties (reliability and validity) (Thomas et al., 1997b). To determine ulcer size, the study nurses used a centimeter ruler to measure the greatest length and the greatest width of the ulcer; the surface area was taken to be the product of these two measurements (length x width). Digital photographs were taken by the study nurses of the ulcers with a ruler placed close to the wound. Photographs were taken at the baseline visit and at the time of healing or, if the ulcers had not healed, at the end of the study. All images were sent to the assessment committee.

The assessment committee comprised four members of the Pressure Ulcer Advisory Group of the Balearic Island. Members of the committee were unaware of the patient treatment-group assignments. Two assessors independently evaluated the ulcer category and resolved all disagreements by discussion. We considered the healing time of 8 weeks as most ulcers are healed within this period of time (Palese et al., 2015). An ulcer was defined as unhealed if it had a score of 2 or more on the PUSH scale, progressed to category III or higher, or developed infection, necrosis, or hypersensitivity to the dressing.

The secondary outcome variables were:

- Direct costs: The study dressings and secondary dressings, time used by nurses, and healing materials were recorded. The costs of the study dressings, secondary dressings, and healing materials were obtained from the Spanish Medicines and Health Care Products Agency; the costs of the nurses' time were obtained from the Health Care Administration Office of the Balearics. (Anon, 2019b)
- Usability assessment: Data on comfort were collected using a Likert scale, from 1 (worst score) to 5 (best score). Patients rated the adhesiveness of the dressing; pain experienced during application and removal; general comfort; and duration of the healing process. Nurses evaluated the adhesiveness of the dressing; ease of application and removal; absorption; condition of the perilesional skin (based on erythema and maceration); and duration of the healing process.
- Progression to a higher category: Progression of an ulcer to category III or IV was recorded.
- Dressing safety: The numbers of ulcers with infection, hypersensitivity, and total adverse events associated with the dressing

(presence of perilesional erythema, maceration, and bleeding of the wound bed when changing the dressing) were recorded.
- Application of preventive measures. All patients were given a diary in which the patient or caregiver recorded the number of postural changes and the use of supports, such as mattresses, cushions, or pillows, to relieve pressure on the ulcer.

2.8. Blinding

The patient and study nurses were aware of the dressing applied, but the outcome assessors were blinded. These outcome assessors confirmed the healing of all ulcers based on photographs.

2.9. Sample size

An initial estimate indicated that a sample size of 410 patients per arm (Schulz and Grimes, 2005) would be required for a statistical power of 80% and alpha risk of 5% and detection of a difference of at least 10% of pressure ulcers healed between the hydrocolloid and hydrocellular treatment arms at 8 weeks was considered as clinically relevant. The proportion of pressure ulcers healed in the hydrocellular treatment group was estimated to be 30%, and a 15% loss of patients to follow-up was anticipated.

2.10. Data analysis

All analyses of effectiveness considered on both a per-protocol (i.e., only those patients who completed the final visit) and intention-to-treat (ITT) basis (i.e., all randomized patients, regardless of participation in any intervention or whether they attended the final visit). All tests were two-sided, and an α-value of 0.05 was considered statistically significant. Crude estimates of per protocol and ITT analyses of the proportion of ulcers healed at 8 weeks were performed using the chi-squared test, and relative risk, absolute risk reduction (risk of healing in the hydrocellular arm–risk of healing in the hydrocolloid arm), relative risk reduction (absolute risk reduction/risk of healing in the hydrocellular arm), and number needed to treat (1/absolute risk reduction) were calculated (Nuovo et al., 2002). Sensitivity analysis was used to estimate the effectiveness of the treatments in the healing of ulcers at 8 weeks by multiple imputation of missing data, using chained regression equations. This approach imputes missing values under conditionally specified models using a Bayesian sampling framework (Chen et al., 2011). All estimates include 95% confidence intervals.

Healing time was defined as the time from the date of inclusion to the date of healing. To analyze differences in healing time according to type of dressing, estimates of cumulative survival probabilities were determined using the Kaplan-Meier method (Bland and Altman, 1998), with 95% confidence intervals, and compared using a two-sided log-rank (Bland and Altman, 2004) test. The differences in direct costs of the two treatments were compared using Student's *t*-test and Mann-Whitney U test to compare differences in usability parameters. All statistical analyses were performed using R Statistical Software 3.3.2.

3. Results

A total of 169 patients were enrolled between June 2013 and September 2015 (Table 1). Among all patients, 58% were women, the mean age was 81.3 years (standard deviation [SD]: 11.4), and 56% were from primary care institutions (Table 1). According to the Braden scale (Bergstrom et al., 2019), 30% of the patients had a high baseline risk for a pressure ulcer, 21% had a moderate risk, 33% had a low risk, and 16% had no risk. After randomization 13.6% participants were lost to follow-up (Fig. 1), but only one patient withdrew from the trial due to an adverse reaction related to the dressing.

Table 1
Baseline characteristics of the hydrocellular dressing and hydrocolloid dressing groups.

Baseline characteristic	Hydrocellular dressing n/N (%) or mean (SD)	Hydrocolloid dressing n/N (%) or mean (SD)
Age, years	79.2 (13.3)	83.3 (8.7)
Sex, female	45/84 (53.6)	53/85 (62.3)
PUSH score	10.8 (3.8)	10.4 (3.8)
Total Braden score	14.6 (3.8)	15.3 (3.2)
Braden scale assessment score		
High risk	23 (27.4)	28 (32.9)
Moderate risk	16 (19.0)	19 (22.4)
Low risk	31 (36.9)	25 (29.4)
No risk	14 (16.7)	13 (15.3)
Patient origin		
Primary care institution	49/84 (58.3)	47/85 (55.3)
Long term care institution	35/84 (41.7)	38/85 (44.7)
Pressure ulcers location		
Gluteus	21/84 (25.0)	19/85 (22.3)
Sacrum	38/84 (45.2)	37/85 (43.5)
Malleolus	4/84 (4.8)	3/85 (3.5)
Heel	6/84 (7.1)	13/85 (15.3)
Trochanter	6/84 (7.1)	9/85 (10.6)
Other	9/84 (10.7)	4/85 (4.7)

SD: Standard deviation; PUSH: Pressure Ulcer Scale for Healing.

Baseline assessments indicated that the mean PUSH score was 10.6 (SD: 3.8). The two groups were similar in terms of baseline characteristics, use of preventive measures, and location of the pressure ulcer. The hydrocolloid dressing group had a higher proportion of women and a greater mean age.

The two groups showed no differences in the use of measures to prevent pressure ulcer progression, a 60% of patients completed the patient diary. There was a median of 3 postural changes/day (range, 0–7) in the hydrocellular treatment group, and 2 postural changes per day in the hydrocolloid group (range, 0–7). A total of 90% of patients overall used some type of support to relieve pressure on the ulcer, such as a mattress, cushion, or pillow.

Intention to treat analysis of the efficacy of the two dressings after 8 weeks indicated significantly more healing of pressure ulcers in the hydrocellular group than the hydrocolloid group ($p = 0.010$). These differences were also statistically significant in the per protocol analysis (90.8% vs. 77.1%, $p = 0.039$; Table 2).

The data also show that the absolute risk reduction (difference in the risk of healing between the hydrocellular and hydrocolloid groups) was 0.14 (95% CI: 0.02 to 0.26) and the relative risk reduction (the relative decrease of this risk) was 0.18 (95% CI: 0.02 to 0.36). Calculation of the number need to treat indicated that it was necessary to treat 7 ulcers (95% CI: 4–58) for 8 weeks with a hydrocellular dressing to heal one additional ulcer.

The Kaplan and Meier curve (Fig. 2) shows the cumulative probability of an ulcer healing over time. The median survival time (the length of time from the start of treatment to when half of the ulcers have healed) was significantly greater for the hydrocolloid group than the hydrocellular group (4 weeks, 95% CI: 4 to 5 weeks vs. 3 weeks, 95% CI: 3 to 4 weeks; Fig. 2). A log-rank test indicated this difference was statistically significant ($p = 0.015$).

The two groups showed no statistically significant differences in mean PUSH scores for unhealed ulcers at 8 weeks (hydrocellular group: 7.7, SD: 3.1, hydrocolloid group: 8.4, SD: 4.7, $p = 0.710$). A total of 4 ulcers treated with the hydrocellular dressing and 11 ulcers treated with the hydrocolloid dressing progressed to category III.

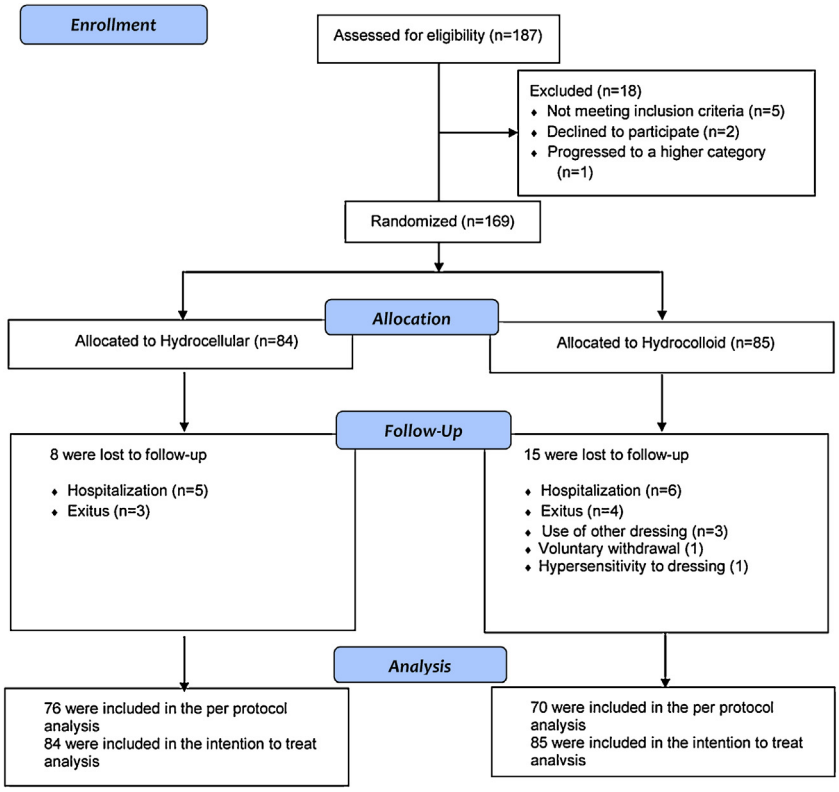

Fig. 1. Flow diagram patient assessment.

Table 2
Intention-to-treat and per protocol analyses of the efficacy of healing of ulcers at 8 weeks in the two treatment groups.

	Hydrocellular n/N (%)	Hydrocolloid n/N (%)	ITT analysis: RR estimated by multiple imputation	p-value	Per Protocol analysis: RR (CI 95%)	p-value*
Ulcers healed at 8 weeks	69/76 (90.8)	54/70 (77.1)	0.30 (0.12–0.75)	0.010	0.34 (0.13–0.89)	0.039

RR: relative risk; CI: confidence Interval, ITT: intention to treat; * Chi-square test.

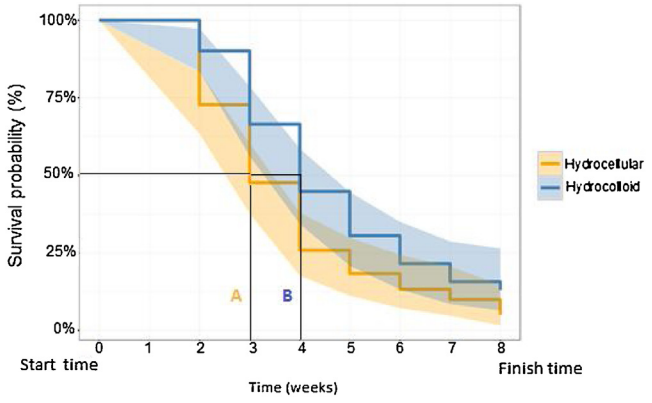

Fig. 2. Kaplan-Meier survival analysis of pressure ulcer healing in the two treatment groups (A: hydrocellular median survival time; B: hydrocolloid median survival time).

There were also 6 adverse reactions to the dressings, all in the hydrocellular group (1 case of ulcer infection, 4 cases of perilesional erythema, and 1 case of dressing hypersensitivity).

There were no differences between the groups in the cost per patient (Table 3). The mean cost per patient treated was €61.80 (SD: €39.80) in the hydrocellular dressing group and €60.10 (SD: €46.40) in the hydrocolloid dressing group.

Nurses, patients, and caregivers all assessed the usability of the dressings (Tables 4 and 5). Patients rated the hydrocellular dressing as significantly better in terms of comfort and pain on removal. Nurses considered the hydrocellular dressing to be significantly better in terms of ease of removal, absorption, effect on perilesional skin, and healing time (Table 5).

4. Discussion

The major findings of this study were that hydrocellular dressings were more effective than hydrocolloid dressings for patients with category II pressure ulcers in terms of the proportion of pressure ulcers that healed, healing time, and usability rating by patients and nurses. Both dressing types were safe for the treatment of pressure ulcers, and their direct costs were similar. Previous studies comparing the effectiveness of hydrocellular and hydrocolloid dressings found no significant differences (Schulz and Grimes, 2005; Nuovo et al., 2002; Chen et al., 2011; Bland and Altman, 1998, 2004; Bergstrom et al., 2019). Nevertheless, all 6 previous trials examined patients with category II or III ulcers, and had small sample sizes, so were only powered to detect large differences. The present results showed that ulcers treated with hydrocellular dressings had a shorter mean healing time than

Table 3
Mean direct costs per patient treated in the two treatment groups.

	Number of units per patient	Cost per unit (€)	Total cost per patient (€)
Hydrocellular			
Dressing	7.09	4.20	29.79
Nurse time (min)	95.01	0.25	23.75
Wound cleansing materials (gloves, saline solution, syringe, plaster and bandages)	46.32	0.18	8.15
Additional dressings	0.17	0.81	0.14
Hydrocolloid			
Dressings	4.76	4.88	23.22
Nurse time (min)	103.16	0.25	25.79
Wound cleansing materials (gloves, saline solution, syringe, plaster and bandages)	55.92	0.18	10.29
Additional dressings	1.37	1.0	1.37

Table 4
Pooled assessment (Likert scale: 1–5) of the usability of the two dressings by caregivers and patients.

	Hydrocellular Mean (SD)	Hydrocolloid Mean (SD)	p-value*
Adherence	4.2 (0.9)	3.7 (1.3)	0.102
Removal pain	4.6 (0.6)	4.3 (1)	0.053
Persistence of pain after removal	4.8 (0.5)	4.6 (0.7)	0.086
Comfort	4.6 (0.5)	4.2 (1)	0.011
Healing time	4.6 (0.6)	4.3 (0.9)	0.090

SD: Standard deviation *Mann Whitney U test.

Table 5
Assessment (Likert scale: 1–5) of the usability of the two dressings by nurses.

	Hydrocellular Mean (SD)	Hydrocolloid Mean (SD)	P-value*
Adherence	4.1 (0.9)	3.7 (1.4)	0.194
Application	4.6 (0.6)	4.0 (0.8)	0.133
Ease of removal	4.5 (0.7)	3.8 (1.1)	<0.001
Absorption	4.6 (0.5)	4.2 (1.0)	<0.001
Perilesional skin	4.6 (0.7)	4.1 (0.5)	0.007
Healing time	4.7 (0.5)	4.2 (1.1)	0.009

SD: Standard deviation *Mann Whitney U test.

those treated with hydrocolloid dressings (3 weeks vs. 4 weeks). In addition, the patients treated with hydrocellular dressings had a 14% absolute reduction in the percentage of ulcers healed at 8 weeks, and the number need to treat indicated that it was necessary to treat 7 ulcers for 8 weeks with a hydrocellular dressing to heal one additional ulcer.

Our analysis of safety indicated that there were more adverse reactions in patients treated with hydrocellular dressings, although this difference was not statistically significant. This is in agreement with other studies, which found no significant differences in adverse reactions from these two types of dressings. In particular, Seeley et al. (1999) found similar percentages of adverse reactions to these two dressings (10%). Thomas et al. (1997a) found a greater number of adverse reactions to hydrocolloid than hydrocellular dressings (14% vs. 10%), although this difference was not statistically significant.

The costs of the human resources and materials used during the study period were lower in patients treated with hydrocellular dressings, although these differences were not statistically significant. This result is similar to the findings of the only previous study to compare costs associated with these two types of dressings (Bale et al., 1998), although this previous study only analyzed the net costs of the dressings.

Assessments of dressing usability by patients and/or caregivers and nurses indicated that the hydrocellular dressings had a higher usability, in that they provided better comfort, ease of removal, absorption, effect on perilesional skin, and healing time.

Pressure ulcers have a high prevalence and negatively impact patient quality of life. They are also associated with high costs for health care systems. The major strengths of the present study are the use of blinded assessment of the primary outcome and the low rate of patient loss to follow-up. However, some limitations should also be noted. Patient allocation to hydrocellular or hydrocolloid dressings was not concealed. Open randomization lists were used because this facilitates inclusion and treatment during the same visit for home care patients. Such lack of concealment can lead to selection bias, which may affect the estimated effects of the two dressing types.

Another possible limitation is that patients treated with hydrocellular dressings were younger and had a greater number of postural changes (1 additional postural change per day). This may have influenced efficacy results in favor of the hydrocellular dressing. Another limitation is the low number of patients recruited. We estimated the need for a sample size of 820, but only recruited 160 patients, to achieve the recruitment target, based on our calculations of sample size, we extended the inclusion period an additional 6 months. We also included more primary health care centers than originally planned, as well as long-term institutions. Nevertheless, this is the largest clinical trial conducted to date comparing hydrocellular and hydrocolloid dressings in patients with pressure ulcers.

The results of the present study support the use of hydrocellular dressings for patients with category II ulcers who are not terminal and who do not have type I diabetes in primary care and long-term care settings, because these dressings provide a higher rate of healing at 8 weeks, a shorter healing time, and are preferred by patients and nurses.

Authors' contributions

AM, MS, AS, AL, and CV collectively drafted the study protocol, and received funding and ethical approval. AM, MS, and MCV were on the steering committee, and were responsible for management of the trial. AM, MS, AS and MCV were responsible for development and implementation of the training workshop in the practices targeted to nurses. MP and AL are responsible for the data analysis. All authors have read the draft critically, made contributions, and approved the final manuscript. AM is the principal investigator, had full access to all the data, and takes responsibility for the integrity of the data and accuracy of the data analysis.

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Competing interest statement

None declared.

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