

A Clinical Comparison of a Glycerine Hydrogel Sheet* or a Thin Hydrocolloid to the Standard of Care*** on Heel Blisters**

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ABSTRACT

Purpose: To determine the efficacy using a hydrogel sheet* application verses a thin hydrocolloid** on heel blisters-a comparison to the standard of care***.

Methods: Upon discovery of a heel blister, the surgeon was contacted by the nursing service to establish the institution of the protocol.

The Protocol: Prep the area gently with normal saline and cover with either a **hydrogel sheet*** secured with a porous adhesive tape*****(**Study Group I**) or a **thin hydrocolloid dressing **** (**Study Group II**). Dressing changes were performed by the same treatment nurse every two (2) days.

End point: Rupture or complete resorption of the blister fluid with intact skin and no adverse sequelae. The frequency of rupture to the blisters and initial clinical size with staging of the pressure ulcer was documented. During evaluation to the end point, all additional care was kept identical.

Materials: Normal Saline for skin prep, hydrogel sheet*, thin hydrocolloid dressing**, standard of care*** (thick cotton pad covered with gauze), fiber-filled heel protector boot****, porous adhesive tape*****, were the products used.

Results: Comparison of ten (10) patients and fourteen (14) blisters. Blister size ranged from 1.0 cm to 6.9 cm in both groups.

Study Group I (hydrogel sheet*) included: Of the five (5) patients with a total of 8 blisters, there were three (3) patients with five (5) heel blisters that remained intact for a 62.5% of the total. Two (2) of the three (3) ruptured blisters evaluated by the surgeon were determined as partial thickness and one (1) was a full thickness wound. **Study Group II (thin hydrocolloid dressing**) included:** five (5) patients with six (6) blisters. Two (2) patients with three (3) blisters remained intact and the surgeon determined that one (1) rupture was partial thickness and two (2) other ruptures were full thickness.

Conclusion: This protocol shows that a hydrogel sheet dressing* is a therapeutic alternative for preventing rupture of intact blisters. As shown in the data, the hydrogel* improved the standard of care by 4 times that established for the given LTCF. In addition, when compared to a known material (thin hydrocolloid**), the hydrogel sheet* shows potential to be a better material than those that are currently recommended in the literature as an alternative to gauze for preventing breakdown of heel blisters. Additional studies involving a larger patient population are needed to establish a statistical significant difference between these two dressings. However, they were both noted to be superior to the standard of care*** with the hydrogel sheet* exceeding the performance of the thin hydrocolloid** dressing by an additional 12%.

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Purpose: It has long been known that excessive pressure in combination with shear and friction result in the development of blister formation. With the current trends in healthcare: reforms, managed care, capitated contracts, corporate restructuring, staff downsizing and increasing numbers of elderly patients, the risks for increases of blister and pressure sore occurrences are serious potentials¹. It is well established that surgical patients who are on an operating room table three (3) or more hours frequently experience blister or pressure sore formation within a few days after the surgery. In a recent review of an article by Stotts² the rate of pressure sore formation for surgical patients ranged from 13% to 66%. Patients who remain stagnant in bed in a hospital or long term setting also have a significant incidence of foot blisters. This can and does lead to a significant breakdown in the posterior or lateral aspect of the calcaneus. Some protocols will advocate the use of various types of heel protectors to aid in pressure reduction. Once blister formation occurs, there is a high percentage of these blisters that breakdown into actual pressure ulcers. This study was designed to compare and determine, on a preliminary basis, efficacy of a glycerine-based hydrogel sheet* dressing or a thin hydrocolloid** on heel blisters compared to the retrospective standard of care***- (thick cotton pad covered with gauze) for protecting the blister from further breakdown. The study design was an open labeled prospective alternating assignment basis.

Introduction: Prior to the institution of this study, the "normal" protocol for standard of care for long term care facilities (LTCF) in the Jacksonville, Florida area, based upon "cost factor", was to use a fiber-filled heel protector boot**** on the patients' heels to achieve pressure reduction. In addition, orders were to have the patient turned every 2 hours. Once a blister formed, it was common practice to protect it with a thick cotton pad and cover with gauze and to continue the use of the fiber-filled heel protector boot in attempt to prevent blister rupture and to protect the heel from further damage.



Figure 1

Figure 1 - 89 year old resident in LTCF who developed a heel blister and subsequent Stage IV pressure ulcer which resulted in confirmed osteomyelitis. Cases such as this one has led to evaluating alternative protocols to prevent rupture of the blisters and further tissue breakdown.



Figure 2

Figure 2 - Normal protocol for "standard of care" for LTCF's

1. Apply standard fiber-filled heel protector boot **** to the patients' heels to aid in pressure reduction and protect the area from blister formation.
2. Turn the patient every 2 hours.
3. If a blister formed: the blister was covered with a thick cotton pad covered with gauze and then protected with the fiber-filled heel protector boot****.

The Balanced Budget Act of 1997 requires long term care facilities (LTCF) to report the frequency of staged pressure sores on the MDS 2 form. The use of hydrogel sheet or a thin hydrocolloid have been recommended to prevent the rupture of the blister and allow for systemic resorption of the body fluid.

A retrospective review of eighteen (18) patients' charts dated from June 1997 to September 1998 revealed an incidence of twenty-two (22) heel blisters in a LTCF. These patients were all treated with the **standard of care***- thick cotton pads covered with gauze**. All patients used the fiber-filled protector boots**** for additional protection to the heel area. Turning schedules for patients was every 2 hours and charted as such. Only three (3) blisters did **not** result in open ulcerations. The remaining nineteen (19) blisters, 86% developed into ulcers ranging from Stage II to Stage IV pressure sores when utilizing the standard of care protocol.

At the LTCF's wound care team quarterly meeting, the decision was made to evaluate alternative protocols. A comparative study was initiated using a **hydrogel sheet dressing* (Study Group I)** versus a **thin hydrocolloid dressing** (Study Group II)**. These two dressings were chosen because of the considerable differences in physical properties of the materials and chemical structure of the components of the two products. **The study was instituted in a 180 bed LTCF and was performed from October 1998 to July 1999.** All patients with a foot blister were considered and the decision to track only heel blisters was made to eliminate bias associated with areas which may not have potential for constant pressure.

Methods: Upon the reporting of a heel blister, nursing service immediately instituted the "new" established protocol and notified both the family and podiatric physician.

New Protocol:

1. Prep the area by gently cleansing with normal saline with care being taken to not break the thin layered blister skin.
2. Measure the size of the blister itself.
3. Cover the blister with either a glycerine hydrogel sheet* and secure with porous adhesive tape***** (Study Group I) or a thin hydrocolloid dressing** (Study Group II) covered with gauze.
4. Apply the fiber-filled heel protector boot**** for additional padding and protection.

Dressing Changes were performed by the same treatment nurse every two (2) days. **End point:** Rupture of the blister or complete resorption of the blister fluid with the blister skin intact and no adverse sequelae. The frequency of rupture of the blisters and initial clinical size with staging of the pressure ulcer were documented. During the course of the study, periodic evaluations were conducted and included in the final end point while all additional wound care was kept essentially identical.



Figure 3

Figure 3: Ruptured blister which has resulted in partial thickness ulceration with the need to de-roof the blister and allow the wound to heal, while using "moist wound" healing techniques (Study Group I & Study Group II).

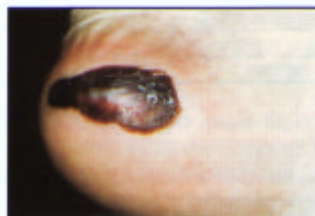


Figure 4

Figure 4: Complete resorption of the blister with intact skin and minimal hematoma formation beneath the skin.



Figure 4A

Figure 4A: During the course of the study, Study Group I used the hydrogel sheet* covered with a porous tape***** to protect and prevent the blister from rupturing.



Figure 4B

Figure 4B: During the course of the study, Study Group II used the hydrocolloid to protect and prevent the blister from rupturing.

Materials: Normal Saline for skin prep, hydrogel sheet*, thin hydrocolloid dressing**, porous adhesive tape*****, fiber-filled heel protector boots*****.

Results: A comparison of ten (10) patients with a total of fourteen (14) blisters was made. Patients were randomized by randomly assigning a number to each patient. **Odd numbered** assignments were **Study Group I**, patients with **even numbered** assignments were **Study Group II**. This resulted in a total of five (5) patients with eight (8) blisters as the Study Group I (hydrogel sheet*). Five (5) patients with six (6) blisters as Study Group II (thin hydrocolloid**). Blister size ranged from 1.0 cm to 6.9 cm. **Patient data is shown in Table 1.** The results of the study are summarized in Table 2 along with retrospective data for standard of care.

TABLE 1

Patient # Initials	L	R	Size in Cm	Study Group I (Hydrogel Sheet*)	Study Group II (Thin Hydrocolloid**)	Rupture (Y,N)	Full / Partial
1 B.M.	X		6.4 x 4.8		X	Y	Full
2 F.F.		X	3.2 x 2.8	X		N	
3 E.C.	X		4.2 x 3.7		X	Y	Partial
4 E.C.		X	1.5 x 1.3		X	N	
5 P.G.	X		6.9 x 4.7	X		Y	Full
6 P.G.		X	3.6 x 1.5	X		N	
7 M.B.		X			X	N	
8 A.S.	X			X		N	
9 A.S.		X		X		Y	Partial
10 D.Z.	X				X	Y	Full
11 J.P.		X		X		N	
12 R.S.		X			X	N	
13 J.H.	X			X		Y	Partial
14 J.H.		X		X		N	

TABLE 2

	Study Group I	Study Group II	Standard of Care Group
# of Patients	5	5	17
# of Blisters	8	6	22
Intact blisters to resorption	5	3	3
Partial Thickness rupture	2	1	5
Full thickness rupture	1	2	14

Study Group I (hydrogel sheet): Of the five (5) patients with a total of 8 blisters, there were three (3) patients with five (5) heel blisters that remained intact for a 62.5% of the total. Two (2) of the three (3) ruptured blisters evaluated by the surgeon were determined as partial thickness and one (1) was a full thickness wound.

Study Group II (thin hydrocolloid): Of the five (5) patients with a total of six (6) blisters there were two (2) patients with three (3) heel blisters that remained intact for a 50% of the total. The surgeon determined that one (1) rupture was a partial thickness and two (2) were full thickness wounds.

At the time of the actual rupture of the blister, the treatment team made the decision as to the type of moist wound healing parameters to be used, which included advanced wound management. These parameters varied based upon the depth and appearance of the wound, and the patients health status.

Discussion: The initial review of available retrospective information referred to as **standard of care** determined the incidence of heel blisters in this institution to be 22/352 [~6%]. Deeper analysis of actual incidence showed that 16/22 [~72%] of the blisters were acquired from either the hospital or present at the time of transfer to the facility. (Eight of the residents living within the LTC facility had a below the knee amputation for various reasons prior to admission at the time of the chart review). With the aspects of MDS 2 which requires ALL wounds to be reported, the wound care team's decision was to attempt to prevent progression of this problem. It is important to attempt to prevent any problems from arising and to keep in mind that the goal is to take every precaution within reason to prevent development of wounds within the facility resident population.

At the onset of the study, the discussion centered around the question: "Is there a better way to prevent heel blisters from rupturing and subsequently allowing resorption of the blister fluid?" The philosophy of the general surgeon and podiatrist were similar in that using the standard of care protocol, blister formation was too great and there should be better protocols to reduce the incidence of blister formation. The nature of the physical properties of both of the dressings used in this study is somewhat similar yet significantly different. Examples of similarity include: they both prevent friction and shear. However, there is a considerable difference in cushioning and the degree of protection. They are different in that a review of the literature does show variation in amount of moisture absorbed, ease of handling, and the degree of inhibition of bacterial growth under the dressings. Hence, the decision to compare the two dressing materials.

Although this study is limited in the total number of heel blisters studied, the results presented here indicate that the hydrogel sheet * appears to be more effective than the thin hydrocolloid** in preventing blister rupture. Additional data is required to establish a statistical significant difference. The data does clearly show that both of the products involved in this study were superior in preventing blister rupture compared to the historical "standard of care" which had a total of 3/22 [13.5%] blisters resorbed. In contrast, the study protocol for the two dressings gave an 8/14 [57.1%] that did not rupture, but were resorbed. This data shows that the incidence of the blister resorption was approximately 4.2 times higher in those patients who had the hydrogel or hydrocolloid dressing compared to the thick pad and gauze. One could extrapolate this data to conclude that one could reduce the pressure ulcer formation by a factor of 4.2 or one fourth the number of ulcers. If one assumes that the same percentage patients went on to full rupture of the blisters and ulcer formation as historically data indicate, it follows that applying simple relatively inexpensive wound dressings to protect blisters from rupture, would result in an decreased incidence of ulcers and significant cost SAVINGS to the long term care facility.

Literature shows that a thin hydrocolloid dressing does assist in preventing blisters in heels of bed bound patients. This study demonstrates that there may be a number of different types of dressings that can give clinical similarity in that aspect. The results showed in Study Group II, 50% of the blisters remained intact when covered with a hydrocolloid or a factor of 3.8 times more effective than the standard of care. In Study Group I, 62.5% of the blisters remained intact when covered with the hydrogel or a factor of 4.6 times more effective than the standard of care. It becomes apparent that there could be significant cost savings in the care of these patients with the careful selection of the type or brand of products designated.

Conclusion: This protocol shows that a hydrogel sheet dressing* is a therapeutic alternative for preventing rupture of intact blisters. As shown in the data, the hydrogel* improved the standard of care by 4 times that established for the given LTCF. In addition, when compared to a known material (thin hydrocolloid**), the hydrogel sheet* shows potential to be a better material than those that are currently recommended in the literature as an alternative to gauze for preventing breakdown of heel blisters. Additional studies involving a larger patient population are needed to establish a statistical significant difference between these two dressings. However, they were both noted to be superior to the standard of care*** with the hydrogel sheet* exceeding the performance of the thin hydrocolloid** dressing by an additional 12%.

¹ Baharestani, M. "Pressure Ulcers in an Age of Managed Care: A Nursing Perspective". *Ostomy/Wound Management* May 1999, 45(5):18-45

² Stotts, N. "Risk of Pressure Ulcer Development in Surgical Patients: A Review of the Literature". *Advances in Woundcare*, April 1999: 127-136.

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