LET'S HEAL®

Let's Comfort®

TIELLE® PLUS

LEVEL ONE - RCT STUDY

Evaluating a superabsorbent hydropolymer dressing for exudating venous leg ulcers

Schulze, H.J., Lane, C., Charles, H., Ballard, K., Hampton, S., Moll, I. J Wound Care 2001, 10(1):511-518.

KEY POINTS

- A multicentre, prospective, randomised, controlled clinical trial in exudating venous leg ulcers (n=113 patients), comparing **TIELLE® Plus** with an alginate dressing (Kaltostat).
- **TIELLE® Plus** had a significantly longer wear time compared to the alginate dressing, in moderate to heavily exudating wounds.
- **TIELLE® Plus** was superior to alginates in terms of patient and investigator acceptability, rated as prevention of leakage, comfort, cosmetic acceptability and control of odour
- Treatment with **TIELLE® Plus** was more cost-effective than the alginate dressing

STUDY OBJECTIVE

To evaluate and compare the performance of **TIELLE® Plus** with an alginate dressing (Kaltostat) in terms of their ability to manage exudate, patient/investigator acceptability and cost-effectiveness.

METHODS

This is a multicentre, prospective, randomised, controlled, open-label clinical trial involving 113 patients, stratified into moderate or heavily exudating leg ulcers.

6 centers involved; 4 in the UK & 2 in Germany.

3 treatment groups were followed for a maximum of 4 weeks

- Group A: **TIELLE® Plus** (n=54 patients)
- Group B: Kaltostat + Opsite Flexigrid film (n=22 patients)
- Group C: Kaltostat + Topper-8 swabs (n= 37 patients)

NB: initially the comparator dressing was Kaltostat + film covering, however investigators believed that the film secondary dressing was causing erythema & maceration, thus protocol was amended & remaining patients were treated with Kaltostat + swabs.

Dressings were changed when clinically required

- Leakage
- Strikethrough had occurred or was imminent
- Infection was suspected
- Patient complained of pain
- Dressing displacement / dressing in situ for a maximum of 7 days

RESULTS

The mean wear time for Group A (**TIELLE® Plus**) was 3.91 days compared to 2.98 days for Group B and 3.16 days for Group C. The increased wear time for **TIELLE® Plus** was statistically significant (p=0.005).

Most dressing changes were due to leakage, with a much higher proportion of moderate /severe leakage associated with both alginate groups. Group B was also associated with more instances of maceration, which led to an amendment in the protocol followed.

Clinician / Patient acceptability

CLINICIAN ACCEPTABILITY				
CRITERIA	MEAN SCORE			STATISTICAL SIGNIFICANCE
	TIELLE® PLUS	ALGINATE+FILM	ALGINATE+SWAB	
EASE OF APPLICATION	4.65	3.14	4.51	p<0.001
EASE OF REMOVAL	4.39	3.91	3.97	p<0.001
ABILITY TO HANDLE EXUDATE	4.24	2.09	3.86	p<0.001
CONTROL OF ODOUR DURING USE	4.24	2.95	4.24	p<0.001
STAYING IN PLACE	4.67	3.82	4.2	p<0.001

Summary of data regarding investigator evaluations (5=good & 1=poor)

PATIENT ACCEPTABILITY				
CRITERIA	MEAN SCORE			STATISTICAL SIGNIFICANCE
	TIELLE® PLUS	ALGINATE+FILM	ALGINATE+SWAB	
OVERALL COMFORT	4.27	3.37	3.74	p<0.079
PREVENTION OF LEAKAGE	4.41	2.32	3.87	p<0.017
CONTROL OF ODOUR	4.45	3.05	3.96	p<0.001
COSMETIC ACCEPTABILITY	4.48	3.53	3.70	p<0.001
COMPARISON WITH PREVIOUS DRESSING	3.93	2.79	3.56	p<0.02

Summary of data regarding investigator evaluations (5=good & 1=poor)

TIELLE® Plus was more cost-effective than either of the alginate groups. Cost of treatment over a 28-day period incorporating redressing frequency, district nurse and dressing costs, were as follows:

- **TIELLE® Plus £125.73**
- Kaltostat + Opsite Flexigrid £174.09
- Kaltostat + Topper swabs £142.03

Costs reflect 2001 prices, which were appropriate at time of publication

CONCLUSIONS

TIELLE® Plus was found in this VLU study to have a significantly longer wear time compared to either alginate group.

Both patients and investigators rated **TIELLE® Plus** as superior to the alginate dressing with in almost all the evaluated criteria.

TIELLE® Plus was found to be more cost effective, based on the reduced number of dressing changes required, nursing time and overall cost of the dressing

SYS/GLO/548/0611