

IMPACT OF DIFFERENT PADS IN ELDERLY ASSISTED IN HOME CARE

Hypothesis / aims of study

The aim of this study is to assess, in a large cohort of incontinent elderly assisted in home care, the potential different impact of two kinds of pads in the prevention of skin complication.

Study design, materials and methods

The study was conducted among subjects ≥ 65 years old assisted at home, who suffered from severe UI and wearing pads provided by Local Health Unit. Each patient was followed up for 40 days – four examinations at home - by skilled nurses. The effectiveness of the diapers in preventing cutaneous lesions due to maceration was evaluated by the Braden scale score to predict ulcer risk and NPUAP classification system to assess the stage of skin pressure sores in the area covered by the diaper, as well as subjective nursing evaluations regarding moisture, maceration and desquamation was done. During follow-up the subjects have been asked if they've been simultaneously using other pads in addition to those provided by local health. Finally, to explore opinions (scores assigned to specific items) about the pads we have administered, at the end of the follow-up, a questionnaire to each subject or the caregiver who took care of him/her and to the homecare nurse. We randomly assigned the patients according to the health districts in which they lived, subdividing them into two arms: the A arm, in which patients were treated with the A diaper (innovative underwear belted-diaper with hook and loop fastening); the B arm, in which patients were treated with the B one (standard absorbent cellulose double-layer underwear brief-diaper with rubber bands and movable adhesive tapes).

The collected data were analysed by SPSS 17.0 and STATA 8.0. Fisher's, McNemar's, and Wilcoxon's two-sided tests of significance were used to compare two groups ($p \leq 0.05$). The exact test of symmetry for matched case-control data with discrete variables and multiple levels were used to test, for each arm, the null hypothesis of no symmetry in the distribution of Braden score at the first examination in comparison with the following II, III and IV examination, respectively.

Results

The total number of subjects who completed all four examinations was 377 (200 A arm, 177 B arm), 295 women (78.2%) and 82 men (21.8%). The mean age was $85.4.0 \pm 7.6$ years. In the A arm, an important decrease of subjects with wet skin was observed among the first and the second examination. This result was maintained even during the III and the IV examinations (Table 1). In the B arm, skin conditions remained unchanged over the four examinations. While the number of scratching lesions was stable in the B arm during all follow-ups, a statistically significant decrease of frequency was documented in the A arm. Regarding skin maceration, statistically significant differences were found between the two groups from the second examination on, with greater frequency in the B group. In the A arm, it has been recorded a decrease with statistically significant differences between the first and the third examination. The distribution of the Braden scale score by risk classes (high risk: < 13 ; medium risk: 13-16; low risk: > 16) did not statistically differ in the two arms (I examination: high risk: 25.2%, medium risk: 50.9%, low risk: 23.9; IV examination: high risk: 23.1%, medium risk: 50.7%, low risk: 26.2%). For the A arm significant differences between the first vs the fourth examination were observed (high risk: 23.5% vs 20.0%; medium risk: 52.0% vs 48.5%; low risk: 24.5% vs 31.5%). In the B arm, no statistically significant differences were found. Eighty-five (22.5%) patients had one or more ulcers in the area covered by the pad (45 in A; 40 in B). The prevalence in the two arms was respectively, 22.5% and 22.6% (no statistically significant differences). The incidence of subjects with new ulcers is 6.2% in the whole at-risk sample (namely, those who had no ulcers at the first examination) with no statistically significant differences between the two groups. At the II examination an average of 11.1% patients were using also additional pads which were neither A or B-type (12.5% A arm, 9.6% B arm, no statistically significant differences). In the A arm, the percentage of subjects who used also additional pads statistically decreased (5%) during follow-up, compared to the B arm.

The questionnaires which explored the opinions on pads have been filled in, at least partially, by the patients or by their relatives or caregiver for all the subjects and by 95 recruiting nurses (69 in the A and 26 in the B arm). The trend of each score is positively related with the A diaper for all the items. A diaper is considered better than the B one, both by the patients/caregivers and the nurses, for the aspects related to the quality of life of patients (dignity, privacy and comfort), the burden of care (less burden for caregiver, easy positioning, easy use of the fastening system) and the technical aspects (effectiveness, dry skin, safety against leakage, absorption capacity). These differences are summarized with the overall score of the product: 81.6% of the subjects and 63.8% of the nurses in the A arm express a "high" judgment, compared to, respectively, 6.9% and 11.5% in the B arm.

Table 1. Nursing evaluations on skin conditions/alterations by examination and arm (A; B)

	I examination*				II examination°				III examination [#]				IV examination ^s			
	A ⁽¹⁾		B ⁽²⁾		A ⁽¹⁾		B ⁽²⁾		A ⁽¹⁾		B ⁽²⁾		A ⁽¹⁾		B ⁽²⁾	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Wet skin	90	46.4	126	72.0	13	6.6	118	69.4	16	8.0	119	69.9	12	6.2	119	69.6
Scratching lesion	16	8.9	4	2.5	6	3.3	6	3.3	3	1.6	5	3.0	2	1.1	2	1.2
Maceration	7	3.9	11	6.6	2	1.1	11	6.6	1	0.5	15	8.8	0	0.0	14	8.4
Desquamation	0	0.0	6	3.7	0	0.0	2	1.2	0	0.0	6	3.6	0	0.0	3	1.9

Wet skin: $p \leq 0.05$; $p \leq 0.05$; $p \leq 0.05$; $p \leq 0.05$ (Fisher's exact test); ⁽¹⁾ I vs II examination: $p \leq 0.05$; I vs III examination: $p \leq 0.05$; I vs IV examination: $p \leq 0.05$ (McNemar's test). **Scratching lesion:** $p \leq 0.05$ (Fisher's exact test); ⁽¹⁾ I vs II examination: $p \leq 0.05$; I

vs III examination: $p \leq 0.05$; I vs IV examination: $p \leq 0.05$ (McNemar's test). **Maceration:** ° $p \leq 0.05$; # $p \leq 0.05$; § $p \leq 0.05$ (Fisher's exact test); ⁽¹⁾I vs III examination: $p \leq 0.05$ (McNemar's test). **Desquamation:** * $p \leq 0.05$ # $p \leq 0.05$ (Fisher's exact test)

Interpretation of results

The analysis of the Braden score distribution by test of symmetry shows how in the A arm the number of subjects whose status improved (score at the first lower than those in the other examinations) is greater than those whose status worsened (score at the first examination higher than those in other examinations) while in the B arm the distribution tends to remain substantially symmetrical. Similar results were observed for "moisture". Braden scale score and nursing evaluations show that the A diaper protects more effectively the patients' skin. In fact, while in the B group these same items remained unchanged in the course of the study, in the A group the same parameters evidenced better skin condition and a lower risk of ulcers. These results could be attributed to a true difference in quality between the two products, namely different performances in the containment of moisture. This aspect seems to be confirmed by the fact that the subjects enrolled in the A arm use were using additionally different pads with less frequency. Furthermore, the A diaper is considered better than the B one, both by the patients/caregivers and the nurses, for the aspects related to the quality of life of patients and the burden of care.

Concluding message

According to our results, the A diaper seems to be better in preventing risk factors for skin complications, as well as regards some aspects related to patients' quality of life and burden of care. Moreover, we have observed among patients who tried A diapers a less frequent use of additional pads, which are usually purchased out-of pocket. In a public health perspective, the appropriate choice (and the subsequent public prescription) of the most suitable kind of pad has to be based on all these aspects, not only on short-term economic criteria (1). Our results show that low-cost diaper may be a solution for many but not for all. Awareness and information about the availability of all kinds of incontinence aids is a prerequisite for the right choice by individuals, evaluating the best aid in the long-term patient's perspective (2).

References

1. International Continence Society. Fourth International Consultation on Incontinence. Incontinence. Committee 20, Management using continence products. 4th Edition, 2009. http://www.icsoffice.org/Publications/ICI_4/book.pdf (last accessed 12 July 2012).
2. Erekson, E., Meyer, S. A., Melick, C. & McLennan, M. T. (2008). Incontinence pads: recommending the best product-based wetback performance and price. International Urogynecology Journal 19, 1411-1414. doi: 10.1007/s00192-008-0645-4

Disclosures

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