

1. Introduction

Pressure ulcers (PUs) are an avoidable risk of the first magnitude and constitute an indicator of the quality of care provided in health institutions (1). Recently, a new conceptual framework has been proposed for PU, incorporating physiological and biomechanical key components and their impact on damage thresholds. This model establishes a theoretical causal route in which these physiological and biomechanical components are classified as indirect and direct key causal factors. This framework provides the basis for understanding the critical determinants of the development of pressure ulcers and has the potential to influence and guide the practice for risk assessment (2). The intervention on the modifiable factors inevitably requires prevention strategies that some standardized skin care regimes try to implement, with results in the reduction of the incidence of PU, although there are inconsistent results about their cost effectiveness (3,4). However, in older people with a high risk of suffering from PU, high- and low-tech support surfaces can significantly reduce the incidence of PUs (5).

Non-pharmacological interventions for the prevention of PUs focus on the use of pressure relieving surfaces, repositioning and nutritional interventions, although there are inconclusive results regarding their impact on the prevention of PUs due to the poor quality of the studies. Thus, it is difficult to make strong recommendations on hydration, repositioning, standardized risk assessment, or multi-component interventions (5).

The recommendations on repositioning establish that the nurse takes into account the patient's factors when deciding on their frequency, although the existing background in this regard makes it very difficult to have specific criteria for this decision (6). Thus, a systematic review of the Cochrane obtained uncertain results due to the lack of statistical power of the studies and could not state precise recommendations on which repositioning strategy is most effective (7).

One option under study is the tailored repositioning (6), which proposes to assess the specific patients' factors, and those of their context to decide on repositioning strategies. Basic research is a way forward to better understanding the mechanisms of production of the PUs and translating them to tailored repositioning. The study by Lachenbruch et al. (8) evaluated the pressure and temperature subjected to shear forces in the sacral region, using a laser Doppler flowmeter system to measure the blood flow of the skin. However, the small sample size, together with the measurement technique and methods carried out to apply loads, limit their conclusions. Higer et al. (9) have used capacitive pressure measurement surfaces, although with short samples and in the pediatric population, without taking into account the contact area.

Therefore, it is necessary to advance in the understanding of how the pressure is distributed in bedridden subjects in different body areas and thus improve the knowledge about interventions that help to maximize the repositioning of patients at risk and reduce this important adverse event.

The aim of this study is to determine what degree of inclination of the human body with respect to a surface in bed, on lateral decubitus, generates more pressure in the trochanteric region. Additionally, to analyze the influence of factors such as gender, age and anthropometric characteristics in the variations of this pressure.

2. Material and methods

An analytical cross-sectional study with healthy volunteers was carried out at the Faculty of Health Sciences of the University of Malaga (Spain). Subjects older than 18 years of age with the ability to remain in standing position and in recumbency, who agreed to participate in the study were selected. Subjects with problems in lower extremities, or who did not tolerate the recumbency were excluded.

Characterization variables such as age, gender, and level of physical exercise (no activity, moderate activity, rigorous activity, a lot of activity or athlete) were collected. The main study variables were body mass index (BMI) (measured in kg/m^2), both lean mass (LM) and fat mass (FM) (measured in kilograms), and the pressure exerted by the trochanter in right lateral decubitus at 90° , 30° and 60° (measured in N/cm^2).

2.1. Data collection

The data were collected in a research laboratory at the Faculty of Health Sciences of the University of Malaga between February and April 2018. The measurement of the data of each subject had an average duration of approximately 10 minutes per person, following the following procedure:

1. Reading and signing of informed consent.
2. Measurement of weight and height. All subjects were weighed with their clothes on, without a coat and without shoes.
3. Bioelectrical impedance: Participants were asked to remain in supine position, with their arms and legs slightly apart (about 25 cm between the thighs), dressed, but without coat or shoes, and no metallic element in contact with the skin. Following, four emitting electrodes were placed in the midline of both the radial and cubital styloid apophysis, and in the intermaleolar midline of both feet. In addition, four sensing electrodes were placed approximately 5cm apart from the emitting electrodes and located in the metacarpophalangeal and metatarsophalangeal midlines.
4. The frequencies obtained from the impedance were recorded in the BodyCompMF Hexa software (10), together with gender, age, level of physical activity.

5. Pressure measurement was carried out with a capacitive surface, namely, the XSENSOR PX100: 64.160.02 which has high resolution sensors with a pressure range ranging around 0.1 to 3.87 psi and 0.07 to 2 0.7 N/cm²; a spatial resolution of 12.7 LM, with an accuracy of $\pm 10\%$ of full scale and frame rate sampling of 17. The total area of the capacitive surface is of 99.1 cm x 221 cm and its area of detection is 81.3 cm x 203.2 cm, with a thickness of 0.08 cm and 10,240 detection points.

6. The pressure exerted by the trochanter and captured by the capacitive surface was recorded in the aforementioned XSENSOR Pro V8 software, installed in a laptop dedicated exclusively to this procedure (Fig. 1).

Figure 1. Capacitive surface, anatomical position measurement and XSENSOR Pro V8 software.



7. The pressure exerted by the trochanter of the subject was measured while positioned in the right lateral decubitus and subjected, during the test, to three degrees of inclination with respect to the mattress: 90°, 60° and 30°. The exact measurement of the degree of inclination was performed using a goniometer.

2.2 Data analysis

The analysis was carried out descriptive statistics for the variables studied, with a confidence level of 95%, obtaining means and medians, interquartile ranges and standard deviations. The normality of the distributions was assessed by the Kolmogorov-Smirnov test. The difference of means by gender was evaluated by Student's t-test. For the non-parametric analysis, the Mann-Whitney's test and the Wilcoxon's test were used. In addition, non-parametric correlations between quantitative variables were calculated using Spearman's rho. The differences between the three positions were analyzed using repeated measures ANOVA. Likewise, a post-hoc analysis was carried out to assess the statistical power.

2.3 Ethical considerations

The study was authorized by the Ethics Committee of the University of Malaga and by the Research Ethics Committee of the Costa del Sol Health Agency. The ethical provisions contained in the Declaration of Helsinki were followed. All subjects signed the consent before their participation.

The devices used in measuring variables are approved for its use in humans, without risks for their health. The methods used for data collection were not invasive or generated pain.

3. Results

The final sample was constituted by 146 subjects (45 men and 101 women), whose average age was 30.36 years (SD 15.74). The mean BMI in men was 27.4 kg/m² (SD 4.71) and in women 24.6 kg/m² (SD 5.30). With respect to LM and FM, averages of 46.89 (SD 9.99) and 21.48 kg (SD 8.17) were obtained, respectively. By gender, the average of LM was in men of 58.71 kg and in women of 41.61 kg. Likewise, the average of FM in men was 21.90 kg and in women It was 21.29 kg.

The pressure exerted by the trochanter in the three body positions are detailed in Table 1, being 60° the position that generated more pressure.

Table 1. Trochanteric pressure distribution based on different degrees of inclination.

Degrees	Min	Max	Mean	SD
90° (N/cm ²)	0.48	0.84	0.59	0.05
60° (N/cm ²)	0.48	0.86	0.63	0.06
30° (N/cm ²)	0.51	0.84	0.62	0.05

Min = minimum, Max = maximum, SD = standard deviation, N/cm² = newton per square centimetre.

By gender, the pressure exerted by the trochanter on the capacitive surface, showed significant differences in the pressure range at the three degrees of inclination (Table 2).

Table 2. Trochanteric pressure distribution based on the degree of inclination, by gender.

	Male (n = 45)	Female (n = 101)	p
Degrees	Mean (SD)	Mean (SD)	
90° (N/cm ²)	0.61 (0.06)	0.58 (0.05)	0.026
60° (N/cm ²)	0.65 (0.08)	0.62 (0.05)	0.049
30° (N/cm ²)	0.64 (0.06)	0.60 (0.05)	0.036

p ≤ 0.05 = statistically significant, SD = Standard Deviation, N/cm² = newton per square centimetre.

This same analysis, adjusted by gender, showed how both groups generated more pressure in the trochanter zone when their inclination was 60°, with men being the ones that generated more pressure. Moreover, it was observed that the pressure values varied according to gender and anthropometric values (Table 3).

Table 3. Pressure at 90°, 60° and 30°, of inclination, associated to the different categories of BMI, differentiated by gender.

Gender		Normal	Overweight	Obesity	Total	P
		weight (n=84)	(n=33)	(n = 26)	(n = 146)	
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Male	90° (N/cm ²)	0.64 (0.07)	0.61 (0.05)	0.59 (0.04)	0.61 (0.06)	0.026
	60° (N/cm ²)	0.68 (0.09)	0.64 (0.08)	0.62 (0.03)	0.65 (0.08)	0.049
	30° (N/cm ²)	0.64 (0.07)	0.66 (0.06)	0.63 (0.04)	0.64 (0.06)	0.455
Female	90° (N/cm ²)	0.58 (0.04)	0.58 (0.05)	0.60 (0.04)	0.58 (0.05)	0.610
	60° (N/cm ²)	0.61 (0.05)	0.61 (0.05)	0.64 (0.05)	0.62 (0.05)	0.270
	30° (N/cm ²)	0.60 (0.04)	0.61 (0.06)	0.64 (0.05)	0.60 (0.05)	0.036

p ≤ 0.05 = statistically significant, SD = Standard Deviation, N/cm² = newton per square centimetre.

The analysis based on FM did not show significant differences by gender. In women, at 30° a greater pressure was found outside the range of FM, compared to those in the range (Table 4). Finally, in the analysis based on LM, non-significant variations in pressure figures were found according to gender.

Table 4. Pressure variations according to gender, fat mass and muscle mass, in different degrees of position.

Mean (SD) LM			Mean (SD) FM		
In rank	Out of rank	P	In rank	Out of rank	P
(n=30)	(n=15)		(n=33)	(n=12)	

Male	90° (N/cm ²)	0.62 (0.07)	0.61 (0.05)	0.553	0.62 (0.05)	0.61 (0.08)	0.533
	60° (N/cm ²)	0.66 (0.08)	0.63 (0.07)	0.605	0.66 (0.07)	0.63 (0.09)	0.714
	30° (N/cm ²)	0.64 (0.07)	0.64 (0.04)	0.088	0.65 (0.06)	0.62 (0.06)	0.598
		In rank	Out of rank		In rank	Out of rank	
		(n=81)	(n=20)		(n=79)	(n=22)	
Female	90° (N/cm ²)	0.59 (0.04)	0.58 (0.05)	0.241	0.58 (0.04)	0.59 (0.05)	0.195
	60° (N/cm ²)	0.62 (0.05)	0.61 (0.04)	0.721	0.61 (0.05)	0.64 (0.05)	0.435
	30° (N/cm ²)	0.6 (0.04)	0.62 (0.06)	0.040	0.6 (0.05)	0.62 (0.05)	0.971

SD = Standard Deviation, LM = Lean Mass, FM = Fat Mass, p ≤ 0.05 = statistically significant, N/cm² = newton per square centimetre

4. Discussion

The objective of this study was to determine what degree of inclination of the human body with respect to a surface in bed, on lateral decubitus, generates more pressure in the trochanteric region. Additionally, to analyze the influence of factors such as gender, age and anthropometric characteristics in the variations of this pressure. According to the results obtained, the pressure in the anatomical area evaluated varies according to gender and anthropometric patterns.

Since the sample was composed entirely by Spanish population (mostly women), the body composition figures can be compared with the reference values of the Spanish population (11) that are available longitudinally, from breastfeeding to old age. These results show how differences in adipose tissue from infancy, through childhood and until the beginning of adolescence are less distinguishable, but, over the years, men accumulate more subcutaneous fat in the trunk than on the extremities. Conversely, women accumulate fat in the trunk and extremities up to 40 years, but from that age,

they accumulate adipose tissue in the skin folds and in the trunk region. Ventral subcutaneous fat is higher in males, which results in an increase in abdominal FM as men's BMI rises, which, on the contrary, does not always happen in the women (12). Likewise, women have greater redistribution of fat and tend to deposit it in peripheral areas (breasts, gluteal area, thighs and hips), while in men it tends to deposit in central areas, such as the abdomen and back (12).

Both anthropometric variations and the different distribution of body fat by gender have a direct influence on the pressure exerted on a specific degree of inclination. According to the model of Coleman et al. (2) for the development of PUs, this finding belongs to the mechanical boundary conditions (type of loading, magnitude and duration of mechanical load). Thus, the relationship between the BMI and the degree of inclination is the one that would explain the generation of different pressure values. The use of a capacitive surface pressure measurements ensures an objective measurement of the pressure distribution (13), and it constitutes a methodological strength of our study.

A systematic review (7) analyzing experimental studies to detect changes in the different pressure levels of the trochanteric area reported lack of statistical power to detect significant differences. Furthermore, evidence in this area is limited, with few clinical trials and poor sample sizes, yielding high risk of bias. In our case, the post-hoc power analysis showed the absence of type II error. Specifically, this analysis found that, with the sample used in our study, the power was greater than 85% in men and 99.8% in women. Our study has found significant differences in pressure levels in the trochanteric area both at 30° and 60°, distributed unevenly between men and women.

The adherence of nurses to individualized repositioning is an issue that may be addressed by using an application to support decision-making, although there is no evidence on its impact on the incidence of Pus, and the factors used to guide decisions

in this application do not include the level of precision of the variables used in our study (6).

Nevertheless, it is necessary to corroborate our findings in the clinical context, since a limitation of our study is that it was conducted in healthy volunteers. These results should be tested in bedridden patients with acute and chronic conditions, and in immobilized patients in the community setting. Another limitation of the study is that the measurements were made in periods of time shorter than those usually used in clinical practice for repositioning patients, since the purpose was exclusively to identify the changes in the pressure exerted. It would be necessary to evaluate these variations in pressure during periods of time similar to those commonly used in clinical practice and not only in trochanteric areas, but in other risk areas. Finally, the composition of the sample included many young and female subjects, so that in future studies a wider spectrum of subjects should be included, especially those patients with risk factors identified in the literature for the development of PUs.

5. Conclusions

The measurement with capacitive surface has shown that there are differences in the pressures of the trochanteric zone (risk zone of PUs) depending on anthropometric factors and by gender, in different body positions.

With respect to the influence of anthropometric characteristics, only significant differences were found due to the BMI at 30°. The relationship indicated that obese people exerted a higher pressure in the trochanter area at 30° of body inclination than overweight, normal weight and underweight people, respectively.

From the clinical point of view, these findings invite to consider a possible differentiation in the repositioning interventions of the patients, according to gender and BMI, as a preventive strategy for PUs.

ACKNOWLEDGEMENTS

The present study has been carried out thanks to the collaboration of voluntary subjects, as well as to the faculty of health sciences, which granted its laboratories to carry out this field work.

REFERENCES

- [1] National Institute for Health and Care Excellence. Pressure ulcers: prevention. Guidelin 179. 2014.
- [2] Coleman S, Nixon J, Keen J, Wilson L, McGinnis E, Dealey C, et al. A new pressure ulcer conceptual framework. *J Adv Nurs* . 2014; 70 (10): 2222-34.
- [3] Lichterfeld-Kottner A, Hahnel E, Blume- Peytavi U, Kottner J. Systematic mapping review about costs and economic evaluations of skin conditions and diseases in the aged. *J Tissue Viability*. 2017; 26: 6 -19.
- [4] Palfreyman SJ, Stone PW. A systematic review of economic evaluations assessing interventions aimed at preventing or treating pressure ulcers. *Int J Nurs Stud*. 2015; 52: 769-88.
- [5] Lozano-Montoya I, Vélez- Díaz- Pallarés M, Abraha I, Cherubini A, Soiza RL, O'Mahony D, et al. Nonpharmacologic Interventions to Prevent Pressure Ulcers in Older Patients: An Overview of Systematic Reviews (The Software ENgine for the Assessment and optimization of drug and non-drug Therapy in

Older peRsons [SENATOR] Definition of Optimal Evidence-Based Non-drug Therapies in Older People [ONTOP] Series). *J Am Med Dir Assoc*. 2016; 17 (4): 370.e 1-10.

[6] From Meyer D, Van Hecke A, Verhaeghe S, Beeckman D. PROTECT - Trial: A cluster RCT to study the effectiveness of a repositioning aid and tailored repositioning to increase repositioning compliance. *J Adv Nurs* . 2018.

[7] Gillespie BM, Chaboyer WP, McInnes E, Kent B, Whitty JA, Thalib L. Repositioning for pressure ulcer prevention in adults. *Cochrane Database of Systematic Reviews* 2014, Issue 4. Art. No .: CD009958. DOI: 10.1002 / 14651858.CD009958.pub2.

[8] Lachenbruch C, Tzen YT, Brienza DM, Karg PE, Lachenbruch PA. The relative contributions of interface pressure, shear stress, and temperature on tissue ischemia: a cross-sectional pilot study. *Ostomy Wound Manage*. 2013; 59 (3): 25-34.

[9] Higer S, James T. Interface pressure mapping pilot study to select surfaces that effectively redistribute pediatric occipital pressure. *J Tissue Viability*. 2016; 25 (1): 41-9.

[10] Bodycomp MF Hexa Software [Internet]. 2013 Available at:

http://www.akern.com/images/documents/Hexa%20Software%20ITA%20rev%201%20nov_2013.pdf.

[11] Pérez Miguelsanz M^{to}J, Cabrera Parra W, Varela Moreiras G, Garaulet M. Distribution REGIONAL fat body: Use of techniques of image as a tool of diagnosis nutrition. *Hospital Nutrition* 2010; 25 (2): 207-23.

[12] Rodríguez Camacho PM. Reference values of body composition for the adult Spanish population, obtained by anthropometry, tetrapolar electrical impedance (BIA) and infrared interactance. University of Complutense of Madrid; 2017. Available at: <https://eprints.ucm.es/43420/>

[13] Lippoldt J, Pernicka E, Staudinger T. Interface pressure at different degrees of backrest elevation with various types of pressure-redistribution surfaces. *Am J Crit Care*. March 2014; 23 (2): 119-26. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/24585160>