Universitatea "Lucian Blaga" din Sibiu

"LUCIAN BLAGA" UNIVERSITY OF SIBIU

"VICTOR PAPILIAN" FACULTY OF MEDICINE

ABSTRACT OF Ph.D. THESIS

TREATMENT AND MONITORING OF ELDERLY PATIENT WITH FEMORAL NECK FRACTURE

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Personal research

Motivation and aim of Ph.D. thesis

The first part of doctoral research we aimed to highlight, especially, the risks of Healthcare Associated Infections (HAIs) to the elderly patients of the femoral neck fracture operated, ensuring simultaneously transfer of medical information from the hospital area, high-specialized, but extremely expensive to the primary care, where he will continue treatment after discharge, with less risk and lower costs.

In the second part of the work we have achieved a doctoral applied research, finalized by patenting a new technology for non-medical treatment of wounds resulting from surgery.

Following personal research i realized a ,, Pedicle surgical compress with passive pump systems for modulated unidirectional transfer of wound fluids", recognized worldwide as absolute novelty.

Incidence of healthcare-associated infections, in elderly patients with femoral neck fracture operated.

Introduction

In Romania there are few attempts to study, systematically, the incidence of Healthcare-Associated Infections (HAIs), particularly at the level of the special group of patients aged over 60 years, who underwent surgery for femoral neck fractures.

The Healthcare-Associated Infections (HAIs) were defined by CDC (Centers for Disease Control and Prevention) and NHSN (National Healthcare Safety Network) since 1988 as systemic or site side effects, arising from the presence of an infectious agent or their toxins in patients from healthcare facilities with beds for patients with acute diseases, without the need to prove that the infection was contracted or incubated when entering that unit.

The Concept of Healthcare-Associated Infections (HAIs) has replaced the old name, known under the name of Nosocomial Infections, which became obsolete. The Nosocomial Infections referred only to infections occurring in facilities with beds for patients with acute diseases, which were reported statistically only if they were proven to be contracted from those healthcare facilities.

The group of Healthcare-Associated Infections (HAIs) consists mostly of surgical site infections (SSIs), the group of bloodstream infections (BSIs), urinary tract infections (UTIs),

pneumonia (PNEUs) and gastrointestinal system infections (GIs), which are responsible for the substantial increase in costs related to hospitalization.

Working hypothesis

The research assumes that there is a relation between the number of hospitalization days, antibiotic prophylaxis or sex of patients and the occurrence of Healthcare-Associated Infections (HAIs), in case of elderly patients with femoral neck fracture operated.

Aim of the study

The study aims is to draw attention to the need to change the name as well as the way of reporting on the infections occurring in facilities with beds for patients with acute diseases, by amending the relevant legislation, so that the old name of "Nosocomial Infections" should be replaced with the actual name, internationally accepted, of: Healthcare-Associated Infections (HAIs).

The study offers an effective model of reporting and management of statistical data needed for management of health units for optimize cost-efficiency, while increasing the quality of medical care.

The analysis provides of supervisory organisms for medical services a means of indirect control on the state of hygiene or quality medicines and sanitary materials from health care facilities with beds for acute care.

Material and method

The research was conducted on a representative sample of **627** patients, aged over 60 years, diagnosed with femoral neck fractures, hospitalized in the Department of Orthopedics and Traumatology of Sibiu County Emergency Hospital.

Through an analytical study of follow-up have monitored the incidence of associated infections (HAIs) in the period 01.01.2008-31.12.2015, in the sample under investigation.

I will further use in the study the established international names, relating to Healthcare-Associated Infections (HAIs), taking into account the fact that no legislative amendments in the field were made.

The necessary data for the study were collected and processed from the medical charts of the patients hospitalized in the Department of Orthopedics and Traumatology of Sibiu County Emergency Hospital.

The processing of data in the diagrams inserted was performed in the program IBM Statistical Package for the Social Sciences (SPSS 21).

Eligibility criteria: Patients aged over 60 years, who underwent surgery for femoral neck fracture, hospitalized in the Department of Orthopedics and Traumatology of Sibiu County Emergency Hospital.

Exclusion criteria: Patients with femoral neck fracture who died preoperative within the period studied, patients treated functionally or patients who refused surgery.

We formed two groups of patients, depending on exposure to risk factors in-hospital. We calculated the arithmetic average (Average length of stay ALOS) for the entire period of hospitalization studied, which become therefore the central variable of the study. We classified the patients into two study groups, depending on the ALOS:

Group A, consisting of patients for which the exposure to risk factors during the hospitalization did not exceed 16 days, the equivalent of arithmetic average length of stay (ALOS), for the entire period covered by the study.

Group B, consisting of patients for which the period of exposure to risk factors during hospitalization exceeded 16 days. We followed up the incidence of Healthcare-Associated Infections (HAIs) during hospitalization, for both groups, and the results were compared.

Results

Distribution of cases in the period examined

We will further create an analytical table of cases with femoral neck fractures operated during the period 01.01.2008 – 31.12.2015.

Distribution of cases by years of study

Table 1.Annual distribution of cases with femoral neck fractures operated

Year		Cases with femoral neck fractures operated		
		No.		Percentage %
2008		62		9.90
2009		63		10.00
2010		63		10.00
2011		55		8.80
2012		86		13.7
2013		93		14.8
2014		94		15.00
2015		111		17.7
Total		627		100

The analysis of annual distribution of number of cases involving femoral neck fractures operated shows an annual increase during the period 2008 – 2010, a relative decrease in 2011, followed by a significant increase in 2012 - 2015.

Distribution of cases depending on the length of hospital stay

In the table bellow we have entered the data that emphasizes the distribution of cases studied, depending on the length of hospital stay and its percentage in the overall architecture, so that we have an overview over its distribution on each day, up to the maximum length of hospital stay registered.

Table 2. Distribution of cases depending on the length of hospital stay

No. of hospitalization days	No. of cases	Percentage %	Percentage validation%	Cumulative percentage %
3	2	0.3	0.3	0.3
4	7	1.1	1.1	1.4
5	8	1.3	1.3	2.7
6	17	2.7	2.7	5.4
7	19	3.0	3.0	8.5
8	35	5.6	5.6	14.0
9	45	7.2	7.2	21.2
10	38	6.1	6.1	27.3
11	47	7.5	7.5	34.8
12	39	6.2	6.2	41.0
13	27	4.3	4.3	45.3
14	38	6.1	6.1	51.4
15	26	4.1	4.1	55.5
16	28	4.5	4.5	60.0
17	24	3.8	3.8	63.8
18	32	5.1	5.1	68.9
19	24	3.8	3.8	72.7
20	20	3.2	3.2	75.9
21	28	4.5	4.5	80.4
22	31	4.9	4.9	85.3
23	21	3.3	3.3	88.7
24	12	1.9	1.9	90.6
25	14	2.2	2.2	92.8
26	7	1.1	1.1	93.9
27	5	0.8	0.8	94.7

	28	11	1.8	1.8	96.5
	29	3	0.5	0.5	97.0
	30	2	0.3	0.3	97.3
	31	3	0.5	0.5	97.8
	32	1	0.2	0.2	97.9
	34	2	0.3	0.3	98.2
	35	3	0.5	0.5	98.7
	37	1	0.2	0.2	98.9
	38	1	0.2	0.2	99.0
	41	2	0.3	0.3	99.4
	42	1	0.2	0.2	99.5
	44	1	0.2	0.2	99.7
	51	1	0.2	0.2	99.8
	71	1	0.2	0.2	100.0
	Total	627	100.0	100.0	

The graphical representation of the data was performed by a histogram, in which there are entered the number of hospitalization days, on the horizontal axis, and the number of cases, on the vertical axis, associated with Gaussian curve for the analysis of normal distribution.

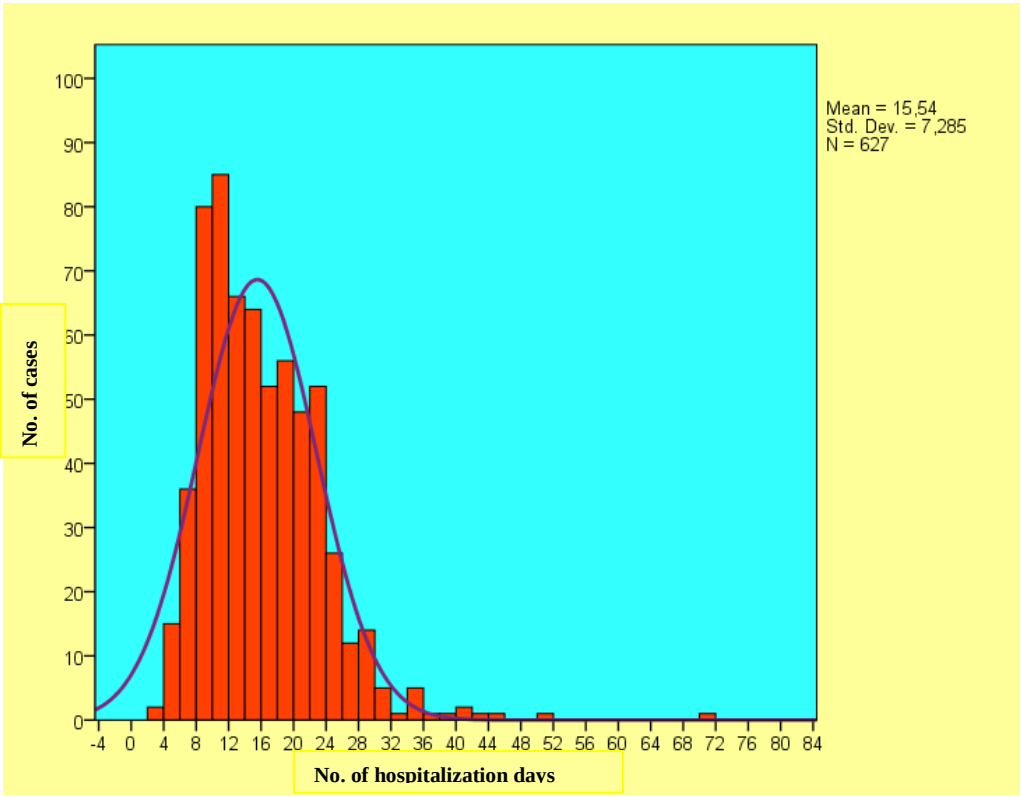

Figure 1. Histogram with the distribution of cases depending on the length of hospital stay

On first examination, the distribution curve is relatively asymmetric to the right, to the positive values and the scores around the mean are very concentrated, with leptocurticity aspect, although the distribution is unimodal (M=11).

The working hypothesis is to consider the distribution as a normal one and, therefore, the parametric tests will be applied.

The null hypothesis takes into account a non-Gaussian distribution, for which the nonparametric tests will be applied.

The extreme values of the distribution, although they are very few, change the aspect of the histogram, by inducing a positive asymmetry, being however important from a clinical point of view. The concentration of a large number of scores around the mean (M=15.4) generates a certain leptocurticity of the distribution, due to an administrative measure taken by the Government of Romania, which restricted the number of hospitalization days according to the Government Ordinance and lead to the cumulation of scores obtained before the implementation of legal provisions, with the scores obtained after a limited number for hospitalization days was imposed, as of 2012.

Finding the logarithm of the values obtained, in accordance with the universally accepted statistical rules, allowed the balancing of distribution according to Gauss-Laplace normal curve.

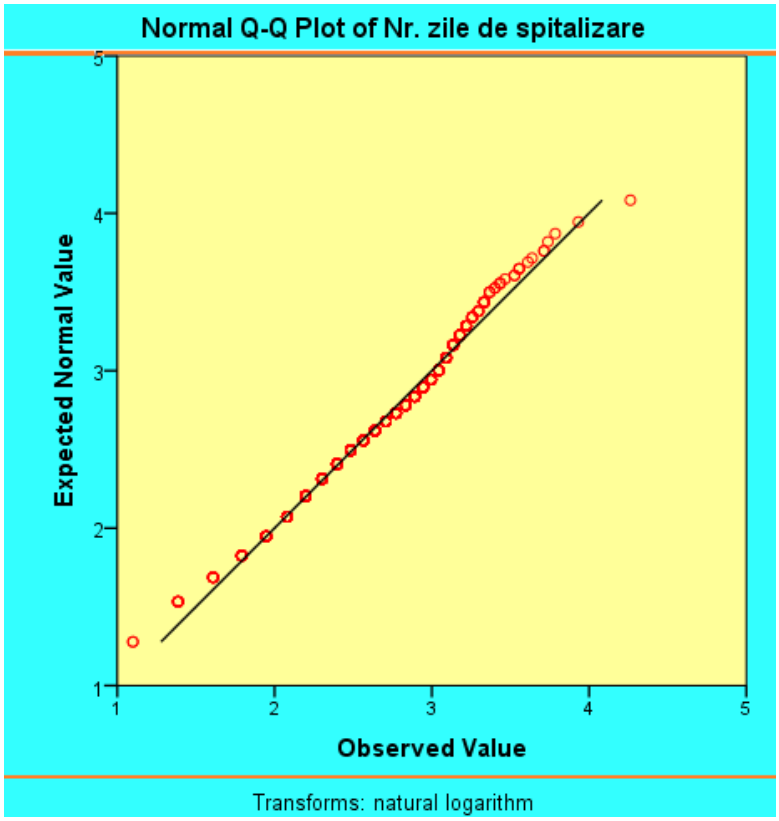

Figure 2. The normal Q–Q plot distribution for the cases studied, after finding the logarithm

The normal Q–Q plot test after finding the logarithm, shows a distribution of actual scores around normal values, represented by the oblique line in the chart, which corresponds to a normal distribution.

The Q–Q detrended plot test of empirical scores compared to normality, represented by the right line with the score z=0 for the mean and standard deviation 1, after finding the logarithm, shows that they fall within one standard deviation, corresponding to a normal distribution.

By finding the logarithm, the sample was subjected to a test for higher values, taking into account all the factors involved in the study, so that the sample should be very representative for the cases registered in the clinic, even if the administrative measures have unbalanced the distribution for a period of time.

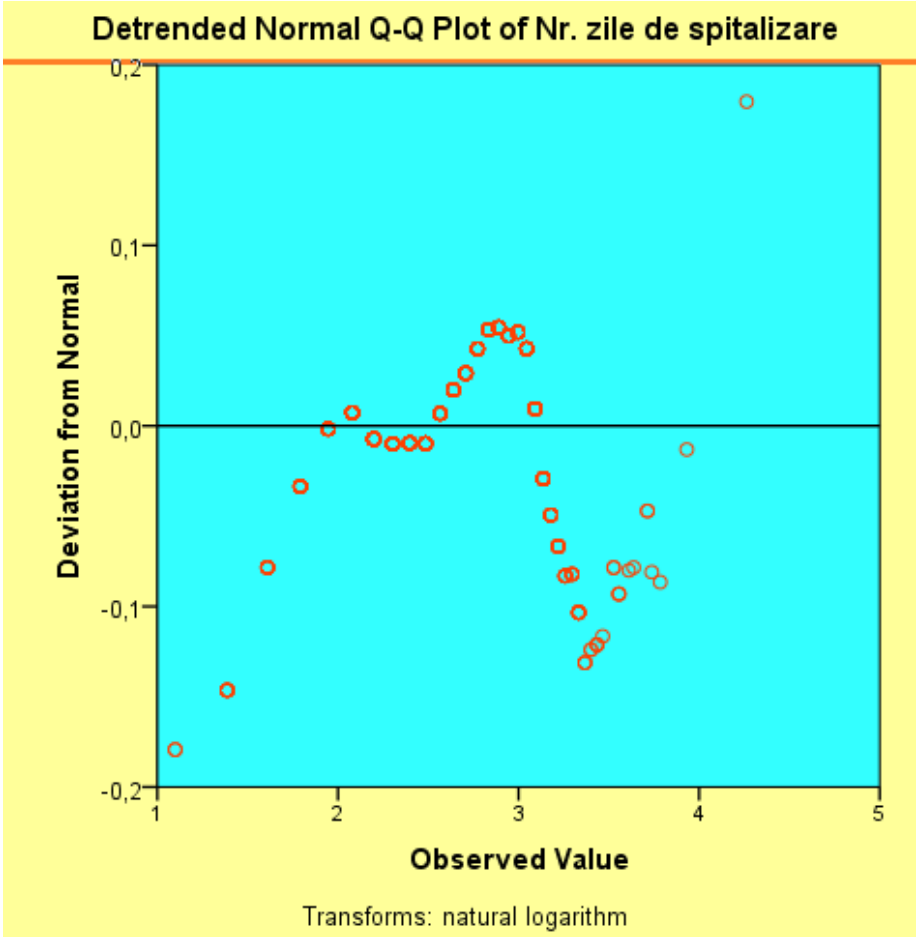

Figure 3. The chart with the dispersion of the scores examined, compared to normality, by detrended Q-Q plot test, after finding the logarithm.

The importance of these tests is given by the need to closely observe the influence of certain factors in the development of patients' health condition.

Following the application of normality tests, after finding the logarithm, the null hypothesis must be rejected and the working hypothesis can be analyzed. Then the descriptive

and inferential analysis will be performed by considering the distribution of scores within normal limits, according to the working hypothesis, for which the parametric tests will be applied.

Univariate analysis of average length of stay (ALOS)

Table 3. Statistical indicators of the average length of stay for the entire study period (ALOS)

Average length of stay		CI		Standard deviation	Standard error	Min	Max	Q25	Median	Q75
		-95%	*+95%*							
15.54		15.00	16.15	7.285	0.29	3.00	71.00	10.00	14.00	20.00

The median value emphasizes that 50% of patients in the study group were hospitalized less that 14 days (Me=14), while 25% of them were hospitalized more than 20 days (Q75=20).

The average length of stay was identified around the value of 15.54 days, with a distribution of scores (CI 95%), between 15.00 and 16.15 days (DS = 7.285 and Standard error = 0.29).

The confidence interval (CI 95%) is between 15.00 and 16.15 days, which demonstrates that the average in the population concerned falls, with a certainty of 95%, within this range.

Correlation between the number of hospitalization days versus patients' age

Table 4. Descriptive statistics on average length of stay (ALOS) depending on the age of patients

Age range	60-64	65-69	70-74	75-79	80-84	>85
Average length of stay	16.14	15.71	17.19	15.94	15.15	13.31
Standard error of the mean	1.04	0.94	0.84	0.57	0.49	0.64
Median	15.00	14.00	18.00	15.00	14.00	12.00
Standard deviation	7.80	7.87	8.82	6.92	6.06	6.44
Minimum	3.00	3.00	5.00	5.00	4.00	4.00
Maximum	38.00	41.00	71.00	44.00	35.00	41.00

According to the table 4, it is noted that the average length of stay varies from one age group to another, having minimum values in the age group between 60-69 years and maximum values in the age group between 70-74 years.

For the statistical analysis of the correlation between patients' age and the number of hospitalization days, we used the concept of regression to the mean, which studies the conduct of a variable, in our case, the number of hospitalization days, in relation to another variable, the age of patients.

The hypothesis under study refers to the existence of a correlation between patients' age and the number of hospitalization days.

The null hypothesis would demonstrate that there is no relation between patients' age and the number of hospitalization days.

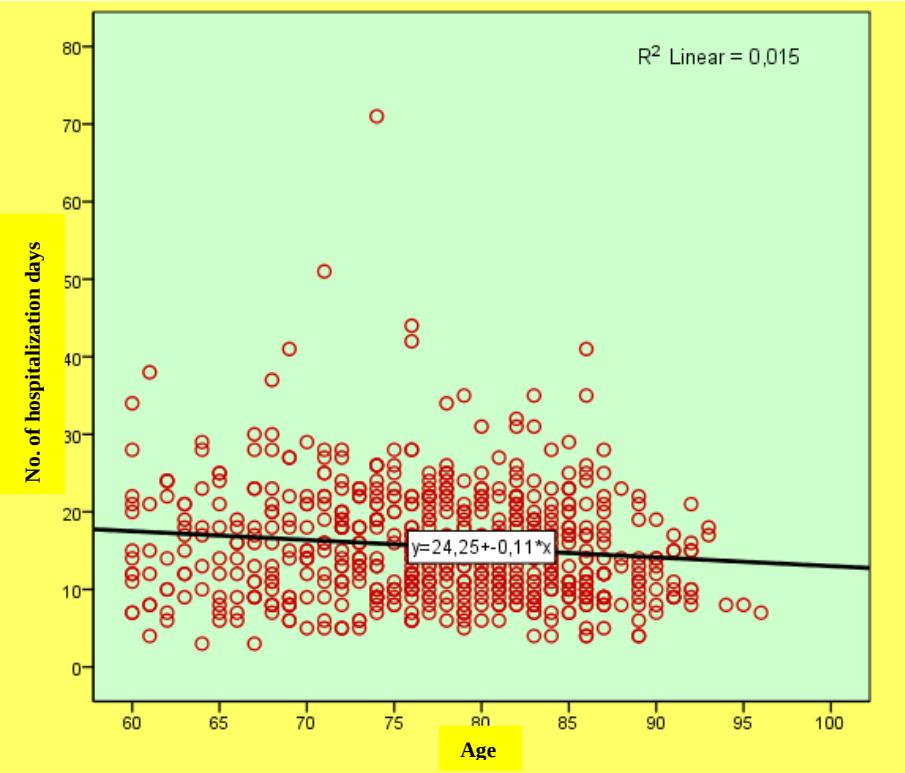

Figure 4. The regression line to correlate the number of hospitalization days with the age

As can been seen from the graph above, there is a negative relation, of mild intensity, but statistically significant, between patients' age and the number of hospitalization days. Therefore, paradoxically, the number of hospitalization days tends to decrease as patients' age increases.

Report of determination for linear regression, although small ($R^2 = 0.015$) is statistically significant, was confirmed by ANOVA test for linear regression.

To investigate the relation between patients' age, as independent variable and the number of hospitalization days, as dependent variable, we used the ANOVA regression test which provides an analysis relating to the variance in the number of hospitalization days depending on the regression and residue factor, represented by F-ratio and Sig.

To verify if the slope of the regression line is 0, in which case there would not be a correlation between patients' age and the number of hospitalization days and the null hypothesis could not be rejected, it must be checked the F-test whose value must be high and the Sig. value corresponding to F must be lower than 0.05. In this case, we have a F-test=8.576 and an associated Sig. value of 0.004. In conclusion, ANOVA test shows that the null hypothesis should be rejected and the hypothesis that there is a linear relationship between two variables statistically significant can be considered.

Table 5. ANOVA test for relation between age and hospitalization days

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	449.717	1	449.717	8.576	.004[b]
	Residual	32775.827	625	52.441		
	Total	33225.544	626			

a. Dependent Variable: No. of hospitalization days

b. Predictors: (Constant), Age range

Distribution of cases depending on the average length of stay (ALOS)

In the next phase of the study will make an analysis of cases according to the average length of stay. Therefore, the patients who were hospitalized for a period shorter than the average length of stay (ALOS) were included in group A, and the patients who were hospitalized for a period longer than ALOS were included in group B.

The average length of stay represents the most important variable of the study, due to the impact on all parameters resulting from statistical calculation and positioning all the patients according to it.

In the table 6 are reproduced, synthetically, the actual and percentage scores of the two groups, made up according to the central variable of the research.

Table 6. Distribution of cases by study groups depending on the average length of stay (ALOS)

Study group	No.	%
Group A → length of stay ≤ 16 days	376	60.0%
Group B → length of stay > 16 days	251	40.0
Total	627	

In the group A were included 376 subjects (60% of cases), which were admitted less than 16 days, and in group B were included 251 subjects who were hospitalized for more than 16 days (40% of cases).

Group B is smaller, in absolute value, than group A, by 125 patients and, in relative value, by 20%. The total number of patients included in the study was 627, for a period of 8 years, which allowed the carrying out of relevant statistical observations.

Incidence of Healthcare-Associated Infections (HAIs)

The Healthcare-Associated Infections were analyzed in terms of unidirectional descriptive statistics and the data were included in tables and graphs.

The analysis of incidence of HAIs on the entire sample of patients studied, shows that the Healthcare-Associated Infections are 4.6%, at a confidence level of 0.05 (CI 95%). The relative values of HAIs (4.6%) are between the minimum value of 3.0 % and the maximum value of 6.4 %, with the possibility that, in the actual population concerned, these values should be included in 95% of cases, in the specified confidence interval.

Table 7. Incidence of HAIs on the total number of cases

		No. of cases	Percentage %	Valid percentage %	Cumulative percentage %	CI	
						-95%	+95%
	Without HAIs	598	95.4	95.4	95.4	93.6	97.0
	HAIs	29	4.6	4.6	100.0	3.0	6.4
	Total	627	100.0	100.0		100.0	100.0

Incidence of HAIs depending on sex of patients

From a clinical and statistical point of view, it is important to know the distribution of HAIs depending on the sex of patients to allow the objective analysis of the data, in order to prevent and fight against them. The working hypothesis is the existence of a relation, between the sex of patients and the incidence of HAIs.

Table 8. Incidence of HAIs depending on sex of patients

Sex		No. of cases	Percentage%	Validated percentage %	Cumulative percentage %
Men	**Without HAIs**	178	92.2	92.2	92.2
	HAIs	15	7.8	7.8	100.0
	Total	193	100.0	100.0	

Women	**Without HAIs**	420	96.8	96.8	96.8
	HAIs	14	3.2	3.2	100.0
	Total	434	100.0	100.0	

The null hypothesis would demonstrate that there is no relation between the two variables.

The distribution depending on the sex of patients shows that the number of cases with HAIs, in absolute values, is higher in men than in women, although the percentage of women in the total number of cases is higher (ratio 2.3:1). Data analysis reveals that the percentage of men in the group share of HAIs is 7.8% and in the group of women HAIs share is only 3.2%.

The analysis of correlation between the incidence of HAIs and the sex of patients shows that there is a relation between the two variables, the Pearson's index, r=0.10 at a Sig. significance level, p=0.012, significantly lower than 0.05. In this situation, the null hypothesis can be rejected and the working hypothesis will be taken into consideration.

Table 9. Pearson test on the correlation between the incidence of HAIs and the sex of subjects

		Total HAIs	Sex
Total HAIs	Pearson Correlation	1	-.100*
	Sig. (2-tailed)		.012
	N	627	627
Sex	Pearson Correlation	-.100*	1
	Sig. (2-tailed)	.012	
	N	627	627

*. Correlation is significant at the 0.05 level (2-tailed).

The correlation index is negative, therefore, it results that the incidence of HAIs is in an inverse relation in regard to the variable relating to the sex of patients. In this context, the variable relating to the sex of patients has lower scores, therefore it is in a relation of covariance with the increase of incidence of HAIs. Knowing that the male patients are fewer, it results that the incidence of HAIs is higher among them.

The incidence of HAIs depending on study groups

Working hypothesis: there is a direct connection between the study group and the incidence of HAIs, being higher in group B, where the length of hospital stay exceeds 16 days.

Null hypothesis: There is no connection between the study group and the incidence of HAIs.

The table 10 the incidence of HAIs is higher in group B compared to group A, both in absolute values and in relative, percentage values. Taking into account the fact that group A is

higher than group B, the ratio between the relative values of the incidence of HAIs in the two groups is approximately 7:1.

The statistical processing revealed an association between belonging to the research group, low or high number of hospitalization days and HAIs. It is noted that there is a higher incidence of Healthcare-Associated Infections in case of patients in group B (over 16 days of hospitalization).

Table 10. Incidence of HAIs depending on study group

	Group A		**Group B**	
	Incidence observed	**Percentage %**	**Incidence observed**	**Percentage %**
Without HAIs	371	98.7	227	90.4
HAIs	5	1.3	24	9.6
Total	376	100.0	251	100.0

To test the hypotheses, we used the analysis of Spearman's ranks which, although nonparametric, may also be applied to data with parametric distribution, but which have a high degree of abnormality in a certain direction. As for the study, being necessary to correct the deviations from normality by finding the logarithm, it is necessary to apply the Spearman's rank test, which disregards the values of variables and which takes into account their rank or position in the hierarchy of scores.

Table 11. Analysis of Spearman's correlation between the study groups and incidence of HAIs

			Study groups	Total HAIs
Spearman's rho	Study groups	Correlation Coefficient	1.000	.192**
		Sig. (2-tailed)	.	.000
		N	627	627
	Total HAIs	Correlation Coefficient	.192**	1.000
		Sig. (2-tailed)	.000	.
		N	627	627

**. Correlation is significant at the 0.01 level (2-tailed).

The analysis of the data in the table 11 shows a value of Spearman's rank correlation index of ρ=0.192, at a Sig. significance level p=0.001.

As the Spearman's correlation index is positive, it results that the patients who are part of group B are more exposed to the risk of acquiring HAIs in hospital.

Antibiotic prophylaxis – univariate analysis

The table 12 shows the scores for antibiotic prophylaxis administered in the Department of Orthopedics and Traumatology for all cases entered into the study..

Table12. Distribution of cases depending on antibiotic prophylaxis

		Without antibiotic prophylaxis	Antibiotic prophylaxis	Total	CI	
					-95%	+95%
	No. of cases	27	600	627	2.7	6.1
	Percentage %	4.3%	95.7%	100.0%	93.9	97.3

The univariate descriptive analysis shows that 600 patients received antibiotic prophylaxis (95.7%) of cases and 27 patients (4.3%) did not require antibiotic prophylaxis, at a confidence interval of 95%.

The confidence interval shows that in the population concerned there is a chance that the real values of patients with antibiotic prophylaxis will be within the range of 93.9% - 97.3% of cases. Similarly, the patients without antibiotic prophylaxis will be within the range of 2.7% - 6.1%.

The correctness as regards the implementation of antibiotic treatment and measures to prevent and fight against Healthcare-Associated Infections can be measured by checking their incidence.

Therefore, at a representative study sample, consisting of 627 patients, selected from the Department of Orthopedics and Traumatology, the average of incidence of HAIs is only 4.6%, at a confidence interval of 95%, with a minimum of 3% and a maximum of 6.4%.

It results that in the real population concerned, the average of incidence of HAIs will be, with a probability of 95%, between 3.0% and 6.4%.

Antibiotic prophylaxis by study groups – bivariate analysis

The following table presents a report on antibiotic prophylaxis depending on the study group and the scores obtained are presented both in absolute and relative values. In group A,

4.5% of patients are without antibiotic prophylaxis and in group B, 4.0% are without antibiotic prophylaxis.

Table 13. Distribution of cases depending on antibiotic prophylaxis and study groups

Study groups		Without antibiotic prophylaxis	Antibiotic prophylaxis	Total
Group A	**No. of cases**	17	359	376
	Percentage %	4.5%	95.5%	100.0%
Total	**No. of cases**	17	359	376
	Percentage %	4.5%	95.5%	100.0%
Group B	**No. of cases**	10	241	251
	Percentage %	4.0%	96.0%	100.0%
Total	**No. of cases**	10	241	251
	Percentage %	4.0%	96.0%	100.0%

The analysis of antibiotic prophylaxis by groups is bivariate and is based on the following assumptions:

Working hypothesis - antibiotic prophylaxis is interrelated with the distribution of cases depending on the study group.

Null hypothesis – there is no relation between antibiotic prophylaxis and study group.

Table 14. Pearson correlation between study group and antibiotic prophylaxis

		Study groups	Antibiotic prophylaxis
Study group	Pearson Correlation	1	.013
	Sig. (2-tailed)		.746
	N	627	627
Antibiotic prophylaxis	Pearson Correlation	.013	1
	Sig. (2-tailed)	.746	
	N	627	627

The results demonstrated that there is no association between antibiotic prophylaxis and study group, being accepted the null hypothesis, Pearson correlation coefficient is close to 0 (r=0.13) and the significance level Sig. is higher than 0.05 (p=0.746).

Antibiotic prophylaxis depending on the sex of patients and the study group

The table bellow presents a bivariate analysis of the relation between antibiotic prophylaxis, sex of patients and study group.

Table 15. Distribution of cases depending on study group, sex of subjects and antibiotic prophylaxis

Study groups					Total
			Without antibiotic prohylaxis	Antibiotic prohylaxis	
Group A	**Men**	**No. of cases**	8	109	117
		Percentage %	6.8%	93.2%	100.0%
	Women	**No. of cases**	9	250	259
		Percentage %	3.5%	96.5%	100.0%
	Total	**No. of cases**	17	359	376
		Percentage %	4.5%	95.5%	100.0%
Group B	**Men**	**No. of cases**	3	73	76
		Percentage %	3.9%	96.1%	100.0%
	Women	**No. of cases**	7	168	175
		Percentage %	4.0%	96.0%	100.0%
	Total	**No. of cases**	10	241	251
		Percentage %	4.0%	96.0%	100.0%

Working hypothesis – there is a relation between sex of patients, study group and antibiotic prophylaxis.

Null hypothesis – there is no relation between sex of patients, study group and antibiotic prophylaxis.

To verify the existence of an association between two or more variables introduced in the analysis, it will be performed a bidirectional correlation that highlights the existence of any connection, either positively or negatively.

In order to perform a correlative analysis between the above variables, we used Pearson test for parametric data, taking into consideration that the scores obtained by finding the logarithm comply with Gauss-Laplace distribution.

Analyzing the association between antibiotic prophylaxis and study groups, it is noted that Pearson correlation index r=0.013 is very close to zero and the significance level Sig. is p= 0.746, higher than the acceptable statistical level of 0.05.

By analyzing the correlation between antibiotic prophylaxis and sex of patients in the study is found the Pearson correlation are r = 0.046, at a significance level Sig. greater than 0.05, p = 0.252.

Table 16. Correlative analysis between antibiotic prophylaxis, study groups and sex of patients

		Antibiotic prophylaxis	Study groups	Sex
Antibiotic prophylaxis	Pearson Correlation	1	.013	.046
	Sig. (2-tailed)		.746	.252
	N	627	627	.627
Study groups	Pearson Correlation	.013	1	.009
	Sig. (2-tailed)	.746		.824
	N	627	627	627
Sex	Pearson Correlation	.046	.009	1
	Sig. (2-tailed)	.252	.824	
	N	627	627	627

In conclusion, there is no correlation between antibiotic prophylaxis and study group or between antibiotic prophylaxis and sex of patients, therefore, the null hypothesis cannot be rejected.

Discussions

The results obtained from this study may be different from the official statistical reports, due to data collection method regarding the infections from healthcare facilities with beds in Romania, where only the nosocomial infections are reported, as defined by the Order of the Ministry of Health no. 916/2006, which allows the registration of infections only if it is proved that they occurred after hospital admission or after incubation in such unit and they were not on incubation period, during the onset or clinical evolution before hospital admission.

These new methods of reporting data has been much closer to reality, ensuring observing the phenomenon infections occurring in health facilities with beds on a statistical scale much higher.

Introduction of a new type of reporting, regarding the infections occurred in healthcare facilities with beds, will also cause a change in the allocation of financial, logistical and human resources in order to prevent and fight against them.

Healthcare-Associated Infections (HAIs), encountered in patients of the study, had a significantly higher incidence in case of patients hospitalized for more than 16 days.

For the future, further studies are required regarding ALOS, in order to bring information on venous thromboembolism, caused by prolonged stay in hospital. The decrease of ALOS must also be studied from the point of view of the risk of death, caused by an insufficient period of hospitalization to heal the sick people, even under proper primary healthcare services.

The study was conducted in one healthcare establishment and it requires adjustments in case of further investigations throughout the country, so the data can be used adequate by the decisions makers in public health policies.

Conclusions

The concept of Healthcare-Associated Infections (HAIs) must be implemented in the Romanian legislation, by aligning to the practices of European and American CDC (Centers for Disease Control and Prevention).

The implementation must be carried out as soon as possible to allow the decision makers to identify the public health problems caused by HAIs and to finance programs in order to prevent and fight against them, in healthcare facilities with beds.

Healthcare-Associated Infections (HAIs) in elderly patients who underwent surgery for femoral neck fractures require multidisciplinary approaches for prevention and treatment. In order to decrease the number of Healthcare-Associated Infections (HAIs), it is necessary to reduce the average length of stay (ALOS), by transfer to primary healthcare services, where the risks are much smaller and the costs are lower.

The increase of the average length of stay (ALOS) causes the occurrence of Healthcare-Associated Infections (HAIs), even if the antibiotic prophylaxis was performed adequately.

Reducing the number of hospital stays can be done efficiently in the second quartile area of ALOS, where the number of patients is higher and influences the whole health management..

To reduce the incidence of HAIs, the hospital managers and the chiefs of departments should ensure purification systems that are efficient, effective disinfection of showers and toilets.

Perspectives

Following the results obtained, we interceded with the Ministry of Health and the President of Romania to change the way of reporting the infections occurring in facilities with beds.

We sent several written submissions to the Ministry of Health and President of Romania to amend the Decree no. 916/2006, which relates to nosocomial infections and which allows to report only the infections that were proven to be contracted in hospital.

In June 2016 it was published a draft of the decree issued by the Minister that aligns the reporting rules, for infections occurring in healthcare facilities with beds, with the international rules, also their name being changed.

Through these new approaches to Healthcare-Associated Infections (HAIs), it will be easier to identify all types of bacterial or viral strains that are found in healthcare facilities with beds, there is a possibility of direct investments made in the departments where there is statistically an increase in their incidence.

Through the extensive reporting of infections occurring in healthcare facilities with beds, a large amount of information in this area will be stored and new opportunities will open up for increasingly elaborate statistical studies, having an increased impact on the health of the population.

Stimulation of tissue regeneration in wounds through systems of unidirectional passive pumps included in surgical compresses

Introduction

The wounds affect 1.5% of world population, having a major impact on quality of life. In order to supply the functions of the injured tissues there are used various devices of covering and protection that have developed during the history, to achieve healing as soon as possible.

Medical devices used for the protection of wounds are of different types and shapes, using woven, non-woven or knitted materials which have been the subject of multiple patents, known as surgical compresses.

Purpose of the research

The purpose of the research is to obtain new medical devices ensuring an adequate isolation of wound from the external environment, taking over the role of the healthy tissue and fast wound healing. The medical devices obtained must provide an aseptic and antiseptic environment, but at the same time, they must maintain an optimum humidity level in the wound.

Applied research and patenting the invention

The personal research led to the invention of a new technical solution, patent application no. A00248, at OSIM Bucharest (State Office for Inventions and Trademarks), on 25.03.2013, under the title: "Pediculate surgical compress with systems of passive pumps for modulated unidirectional transfer of fluids from wounds" published in the Official Industrial Property Bulletin (BOPI), nr. 10 / 2013.

The invention describes a surgical compress whose structure contains several pedicles (figure 5), provided with systems of passive pumpsfor modulated unidirectional transfer of fluids from wounds. This new device maintains an optimum moist environment in the wound, ensures the reduction of adhesion points and performs local asepsis and antisepsis.

The structural unit of the new device consists of a pedicle obtained from the stitches of the half cardigan knit, which has attached, at the bottom, by knitting, a ring-modulator of transport the fluids from the wound, made of double stitches of the knit.

The pediculate structure offers aseptic and antiseptic properties to the surgical compress, through the difference of osmotic pressure between the pediculate face applied on the wound and the external side.

The difference of osmotic pressure between the two sides of the surgical compress is carried out by means of a system of unidirectional passive pumps included in the pediculate structure which generates superficial tension powers, called surface phenomena, around the pedicle fibers and capillarity phenomena inside the fibers, eliminating the fluids to the outside.

The fluids reach the capillary lumen through membrane's pores, in phenomena related to baromembranes, called direct osmosis processes, caused by the enormous surface tension forces exerted on the pedicle.

Through the above-described osmotic pumps, the wound fluids are forced to enter the capillary lumen, where the pressure is lower than the forces around the fibers in the pedicle. In the capillary lumen, fluids are subject to capillary phenomena and ascend to the level of the outer layer of the compress.

Ascending way of fluids is led through the ring-modulator (figure 6), which impregnates with the fluids taken from the pedicle, by diffusion and increases its volume due to the hydrophilic microscopic structure. By increasing the volume, the ring-modulator compresses the fibers which form the pedicle and blocks the transport of fluids towards the surface of the compress. At the same time, the fluids from the ring-modulator undergo an evaporation process, which determine the reduction of its volume, the circulation from pedicle to outside is unblocked and the cycle repeats.

The heat pumps provide the evaporation processes involved in unidirectional transport of fluids, from the wound to the outside, by exerting a negative pressure on the capillaries.

The energy required for heat pumps involved in the evaporation processes is produced by the human body and air convection from the outside controls the evaporation rate.

The association between pedicle shape and ring-modulator generates the modulation of transfer of fluids from the wound to the outside and it is provided an optimum moist environment for tissue regeneration and it is avoided the formation of crusts. Through the same mechanism it is blocked, biomechanically, the access of germs to the wound and the existing germs are already eliminated towards the surface of compress.

In the first stage the pedicles rapidly absorb the exudates from the wound until the maximum capacity is reached, rapidly releasing the excess of fluids in the area, which are toxic in large quantities, by proteinases involved in the autolysis of health tissues from the wound's extremity.

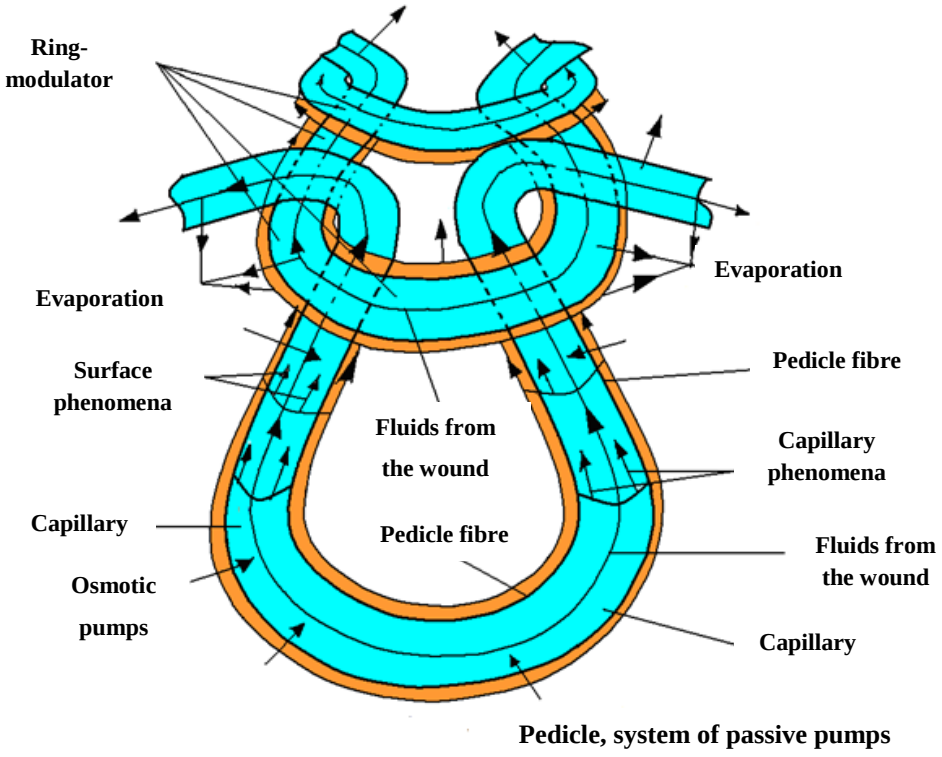

Fig.5. Pedicle structure

In the second stage, the fluids activate the transport modulating system by impregnation of ring-modulator and blocking the transport of liquids to the surface, maintaining an optimum moist environment necessary for tissue regeneration processes. (figure 6)

The wet environment, kept within optimum limits, stimulates tissue regeneration because it provides autolytic debridement of wound's necrotic extremities and migration of epithelial cells into the wound.

The pediculate surgical compress forms, at wound's level, an active interface, biologically speaking, by maintaining an optimum wet environment and transferring protective powers to the external layer, located at distance.

By using surgical compresses, the tasks of teguments are taken over by them, ensuring an environment suitable for their regeneration.

The surgical compress ensures an optimum wet environment and, at the same time, it creates a positive osmotic pressure that is superior to the pressure of the external environment, blocking the access of microbes to the wound.

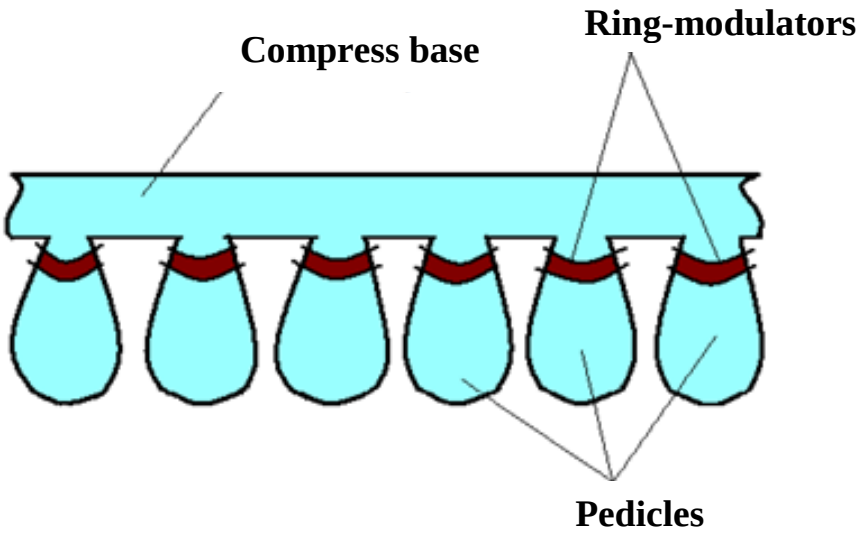

Figure 6. Schematic view of pedicles

The positive osmotic pressure is generated through active mechanisms that manage to maintain themselves throughout the secretory phase from the wound. By maintaining some active mechanism of positive osmotic pressure, the germs from the wound are eliminated towards the surface of surgical compress, ensuring an antiseptic environment.

The pediculate surgical compress behaves as a biomembrane which replaces, for a while, the functions of undamaged tissue and allows regeneration mechanisms to act quickly and effectively to heal the wound.

Dermal tolerance testing for pediculate surgical compress

The dermal tolerance is an important parameter in order to test the biocompatibility of surgical compresses, before placing them on the market.

For the initial phase there were carried out some tests in vivo on laboratory animals, complying with the EC directive No. 2010/63 relating to experiments on animals, particularly the three Rs (Reduction – Replacement – Refinement) and the law 471/2002 on approval of Government Ordinance no. 37/2002 on the protection of animals used for scientific or other experimental purposes. The tests were performed at the Public Health Institute of Iaşi.

Testing the irritation and/or sensitization potential

The product that is being tested: "Pediculate surgical compress with systems of passive pumps for modulated unidirectional transfer of fluids from wounds"

Product identification: Aspect: compress having the shape of a parallelepiped, made of pediculate cylindrical knit, white, homogenous all over.

Composition: cotton yarn 100%, 60/1 knitted.

Two groups of experimental animals have been formed, having the skin shaved on an area of 2 x 2 cm:

The Group A exposed, consisting of five rats, to which an aqueous solution was applied on a daily basis, in which fabric parts were sank in, for five days.

The Group B, witness batch, consisting of five rats, to which distilled water was applied on a daily basis.

The cutaneous reactions were assessed daily, one hour after application and the following day, before the next application. The experiment was repeated for 7 consecutive days. The cutaneous reaction was evaluated by monitoring the occurrence of erythema, edema or local infiltration. There have been monitored other changes of the skin of experimental animals, such as fissures, ulcerations or change of color, roughness or elasticity.

During the tests we followed the occurrence of severe irritant reactions, characterized by the formation of some hemorrhagic points followed by scars, intense pigmentation of the skin or poor hairiness growth of experimental animals. Sensitivity to pain was assessed by palpation of the area tested.

To obtain appropriate results, it was measured the intensity of sensitization, characterized by frequency and the speed of development of the cutaneous reaction, in response to the irritant effects of the substance tested.

The assessment of the cutaneous reaction followed :

1. Minimum focal hypersensitivity,
2. Expressed erythema with edema phenomena,
3. Expressed erythema with a moderate infiltration,
4. Accentuated erythema, edema and infiltration.

Test results:

The repeated application of aqueous solution, in which there have been sunk in fragments from the product that is being tested, on the shaved skin of the rats, did not cause irritant effects and did not lead to allergic or sensitization reactions.

Patch-test

Two batches of experimental animals were formed, having the back skin shaved on an area of 2 x 2 cm;

The Group C exposed, consisting of five laboratory rats, to which a portion of a compress described above was applied by means of a band-aid strip,

The Group D, witness batch, consisting of five laboratory rats, to which a simple piece of band-aid was applied.

After 24 hours, the band-aid strips have been removed and the appearance of the skin was microscopically examined.

Patch-test results:

The Patch-test did not find any irritant and / or sensitizing properties on the rats tested.

Testing the physical and chemical properties

Characterization of the knitted material used for the surgical compress was made in terms of:

a) raw materials;
b) structurally, of structural parameters;
c) technologically.

Materials and methods

a) The knitted fabric was produced using ring yarns, 100% cotton, yarn count Nm 60/1. The cotton yarns are not toxic, are easily accepted by the body and do not cause discomfort for the patient. Cotton is a natural fiber used very often in non-implantable medical uses such as dressings and bandages.

b) The knitted structure is half cardigan, produced with single jersey evolution and tuck stitches.

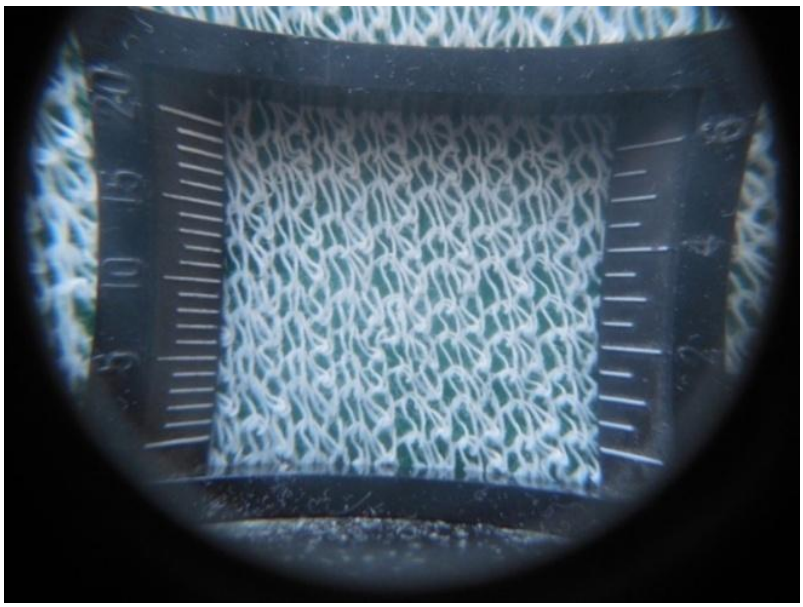

Figure 7. Aspect of the half cardigan fabric at a minimum strain, in the transverse direction, under magnifying glass

The appearance of the knitted fabric shows that the structure strongly contracts in the transverse direction, which increases its elasticity and extensibility.

The table presented below shows the values determined for the structural parameters of the pediculate surgical compresses. The density of the knit vertically were determined for normal and double stitches. The stitch densities were measured: horizontal density (Do) and vertical density (Dv). The vertical stitch density determined for the wales with normal and tuck stitches. Because the knitted fabric is tubular, the weight was determined per unit length M/400 mm (it was considered a unit length of 400 mm for the dressing), thus expressing the mass of dressing. The dressing thickness (gt) varies due to the manner in which it the knitted tube is folded, the number of layers being different from the extremities to the middle area. For this reason, the thickness of the dressing was expressed through an average interval, corresponding to a number of 4 layers, respectively 6 layers (maximum thickness).

Table 17. Determined values for structural parameters

Raw material	Density (stitches / 50 mm)			Mass/400 mm tub (g)	Thickness of the dressing (mm)
	Do	Dvn	Dvd		
Cotton, 100%, Nm 60/1	46	32	16	5.01 ±5%	2.74÷3.71

Methods for characterizing the behavior of the surgical compress

Characterization of the behavior of the surgical compresses, from a textile point of view, was performed in compliance with the standard SR EN 13726, part 1:2002, 2:2003 and 4:2003, equivalent EN 13726. This standard relates to the testing methods for primary dressings in contact with the wound. To these tests it was also added the determination of porosity of the knit in layers, taking into consideration the correlation between porosity and other physical or mechanical properties of the knit.

All the experimental determinations were performed at the Faculty of Textiles, Leather and Industrial Management from the "Gheorghe Asachi" Technical University of Iasi.

Determination of the absorption capacity

The absorption capacity of the surgical compress was determined by the method defined by SR EN 13726-1:,,Test methods for primary wound dressings". The standard defines the following necessary notions:

- primary wound dressing – material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound;
- fluid affinity of a wound dressing – ability to absorb fluid from or donate fluid to a simulated wound;
- fluid handling capacity – sum of the fluid absorbed and the fluid transpired through the dressing;
- free swell absorptive capacity – total absorptive capacity in the presence of excess test liquid and in the absence of any applied load;

Description of the method

The absorption capacity of the compress was determined without load.

A test solution of sodium chloride (142 mmol of sodium ions) and calcium chloride (2.5 mmol of calcium ions) was used to simulate the human serum, or the exudate of a wound. The preparation involved dissolving 8.298 grams of sodium chloride and 0.368 grams of calcium chloride dehydrate in deionized water up to 1 liter.

10 samples of knitted fabric (multi-layer) were collected, with a surface of 5 x 5^2. The samples were conditioned at a standard temperature and humidity (21±2° C, respectively 60±15% RH) in a vessel with silica gel. Previously, the samples were weighted.

The test solution was also conditioned at 37±1°C. To determine the absorption capacity, an amount of the test solution 40 times the mass of each knitted sample was introduced in Petri dishes with a diameter of 90 mm.

After additional conditioning for 30 minutes, the knitted samples were sunk into the solution for 30 seconds, then they were weighed.

The absorption capacity (CA) is expressed as the ratio of the average mass of the solution on 100 cm^2, representing the average size of a wound.

Results

With regard to the determination of the absorption capacity of the dressing, there have been carried out 5 determinations were carried out for the 4-layer dressing, respectively for the 6-layer dressing.

The following conclusions can be drawn from these experimental values:

1. the compress has an extremely high absorption capacity, which is due to the high porosity of the knitted material and the voluminosity of the dressing in layers.

2. the number of layers does not influence significantly the absorption capacity of the dressing for both 4 layers and 6 layers, the fabric can absorb an amount of solution approximately 10 times higher than the mass of the samples. However, the use of dressing in 6 layers allows the absorption of a higher quantity of serum / exudates; therefore, it is recommended to increase the number of layers a larger quantity of fluid from the wound's area must be removed.

The values determined for the mass of samples M_1, mass of the solution M_{sol} and mass of samples M_2 after immersion in the solution for 30 seconds and the value of the absorption capacity (AC) are shown in the table below.

Table 18. Experimental values for determining the absorption capacity of the compress

		M1 (g)	Msol (g)	M2 (g)	CA	
					Sample	/100cm2
1	4 layers	0.7078	28.312	8.2312	7.3232	29.2928
2		0.6249	24.996	7.6140		
3		0.8088	32.352	9.0034		
4		0.7096	28.384	8.4468		
5		0.7656	30.624	6.9371		
6	6 layers	1.0392	41.568	12.5277	10.3326	41.3304
7		1.0319	41.276	11.8890		
8		0.9928	39.712	11.6403		
9		1.0435	41.7400	11.7060		
10		0.8295	33.1800	8.8370		

The experimental data show an increased absorption capacity for the patented surgical compresses.

Determination of the permeability to vapors

To establish the compress' permeability to vapors, it was used a method equivalent to the method suggested in the standard SR EN 13726, Part 2: 2003, using a device PERMTEST (Czech Republic), equivalent to ISO 11092, which operates under Skin Model, according to the principle of dual calibration.

Description of the method

The device has a measuring head with sensor, covered by a membrane that allows the passage of water vapors through the sample. The following values are determined:

- relative permeability of the sample;
- permeability of the sample;

For determinations it was used a solution of distilled water, with 0.1% liquid detergent.

Results

The determined values show a good vapors' permeability, due to the high porosity of the multi-layer structure and structure of the pedicle, which ensures the transfer of humidity from the level of wound to the outside.

According to the recommendations, three determinations were made for permeability to vapors and relative permeability, the experimental values being shown in the following table.

Table 19. Experimental values for permeability to vapors

	R_{et} (m^2Pa/W)	P_{wv} (%)	Mean		Stand. Dev.		CV	
			R_{et}	P_{wv}	R_{et}	P_{wv}	R_{et}	P_{wv}
1	12.6	29.6	1.5	28	2.6	2.8	19.5	10.1
2	12.8	29.4						
3	17.2	23.8						
4	11.2	29.0						

Determination of mechanical reaction

The mechanical properties of the knitted fabric from the compress was assessed according to the standard SR EN 13726, part 4:2003, Non-active medical devices. Test methods for primary wound dressings. Part 4: Conformability.

The standard defines the following terms:

- conformability – ability to adapt to the human body shape and movements;
- extensibility – the force necessary for stretching the compress to a preset extension;
- permanent extension – increasing the length of the material after stretching and relaxation, expressed as a percentage in relation to the original length.

Description of the method

The samples are relaxed and marked on a length of 100 mm. In order to reflect the mechanical behavior of the compress, the samples had the same width and length as the dressing. The width of the compress is 8.5±2 mm.

The testing was conducted with a HOUNSFIELD tensile testing machine, using adapted clamps. The samples were placed so as to include the length L1 of 100 mm marked.

The test involves stretching the sample up to 20%, at a speed of 300±10 mm/min. It is registered the force necessary for stretching the material with a precision of 0.1 N. The extension is maintained for 60 seconds, after which the sample is relaxed for a period of 300±15 s. It is measured the distance between the two lines (L2).

As regards the pedicle compress, the conformability was determined only in the direction of the rows.

Results

Because the distance between the clamps was set at 100 mm, the absolute elongation that is necessary is 20 mm. Table below shows the experimental values registered for the tensile

force at 20%, relative elongation, and, for the remaining elongations, after the relaxation of the sample.

Table 20. Determining the conformability characteristics

	Force (N) - at 20% elongation				Elongation (mm) After relaxation	Mean (mm)	Stand. Dev.	CV (%)
	Values		Stand. Dev.	CV (%)				
1	15.35	12.66	4.13	32.59	103	102.4	1.14	1.11
2	14.15				101			
3	7.65				104			
4	9				102			
5	17.15				102			

The average extensibility of the knit in the longitudinal direction is El=1.49 N.cm.

By the nature of knit's structure, the compress has a very good extensibility in the longitudinal direction, the permanent elongation is AP=2.4%. In the transverse direction, the extensibility of the knit is much higher, mainly due to the specific geometry of the knitted structure and also due to the contraction registered during finishing.

Determination of the porosity

Porosity is a physical characteristic of textile materials, expressing the volume of areas free from fibers / yarns from a textile structure in relation to the total volume of the material. Porosity is an extremely important property that controls the behavior of the material in the wounds. In terms of knitted fabrics, their specific geometry determines a very high porosity.

Description of the method

The method used to determine the porosity of the compress is the pycnometer method. This method involves the determination of M1 mass of a material sample of 2 x 2 cm^2, of known thickness δ and placing them in a vessel with toluene, with density γ_l, vessel with known mass M_2. The toluene removes the air between the fibers, allowing the determination of fibers' volume.

Results

The experimental values determined for the multi-layered fabric for the surgical compress (maximum number of layers), considered in a relaxed state, are shown in the table below.

Table 21. Experimental values for the determination of the porosity by pycnometer method

	M_m (g)	M/m^2 (g)	δ (mm)	M1 (g)	M2 (g)	γ_a (g/cm^3)	γ_r (g/cm^3)	P (%)
1	0.138	345	3.78	81.858	81.988	0.09126984	0.92035385	90.0831792
2	0.145	362.5	3.94	81.988	82.126	0.09200508	0.91097826	89.9004093
3	0.149	372.5	3.87	82.126	82.271	0.09625323	0.89091724	89.1961649

It may be noted that the knit has an extremely high porosity (about 90%), that justifies the data obtained for the tests laid down in Standard SR EN 13726.

Discussions

The pediculate surgical compresses are part of medical devices intended to absorb the fluids from the wounds and to ensure an appropriate barrier between the wound and the external environment.

Through the tubular form, the patented surgical compresses do not allow the lints to reach the wound, which ensures the prevention of surgical site infections, both deep and superficial infections. These considerations of the inventor will form another line of study after the completion of the doctoral studies, which will have to deal with Healthcare-Associated Infections (HAIs), in terms of using the new surgical compresses. Therefore, it should be established if the incidence of surgical infections and the average length of stay decrease due to the patented pediculate surgical compresses that cannot be unraveled and the modulated and unidirectional absorption.

The knitted tubular structure and the inwardly folded edges allow the insertion of surgical compresses into deep surgical wounds without destructuring.

In order to improve the surgical techniques and to adapt the structure of compresses to the requirements of orthopedic surgeons, new studies are needed to enable the networking between them and the researchers in the field of medical devices responsible for the implementation of the invention.

Conclusions

Use of pediculate surgical compresses represents the ideal solution in order to increase the tissue regeneration capacity by systems of unidirectional passive transport and by modulated absorption of fluids from wounds.