Anxiety of patients regarding informed consent to administration of intravenous iodinated contrast material

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Purpose

1. To evaluate the relation between the state anxiety level in patients before the delivery of informed consent with patients after that.
2. To evaluate the relation between the trait anxiety level in patients before the delivery of informed consent with patients after that.
3. To evaluate the relation between the state and the trait anxiety levels in patients before the delivery of informed consent with patients after that.
4. To access relations between psychometric tests and sociodemographic characteristics.

Methods and Materials

In accordance to institutional guidelines, the approval of this study was obtained from the review board and the consent to participation was obtained from each patient selected.

Patients

From April 2009 to June 2009, 161 patients that were referred to Computerized Tomography (CT) exams were selected by convenience sampling. The exclusion of patients that weren't legally habilitated, illiterate or physically habilitated was made. The sample was divided in a control group and an experimental group. The control group was composed by 82 patients and the experimental group was composed by 71 patients. There were 47 men and 35 women in the control group with a mean age of 52.84 years, ranging from 18 to 82 years of age. The experimental group was composed by 47 men and 32 women, with a mean age of 53.76 years, ranging from 22 to 88 years of age.

Variables

In this study, the independent variable was the informed consent delivered to the patient, since it was immutable and needs to be delivered to every patient that may need an intravenous injection of iodinated contrast material. The dependent variable evaluated was anxiety, which may be altered by the informed consent.

Instruments
To prosecute our study, we created a sociodemographic interview. This interview included general data from patient such as gender, age, residence, marital status, salary, knows the exam, previous CT exam, scholar degree and work status.

The state-trait anxiety inventory (STAI), form Y, validated for Portuguese population, was use to prosecute the psychometric evaluation of the patients selected. This instrument is essential when the anxiety intensity needs to be verified and is composed by STAI Y-1 that measures the SA and STAI Y-2 that measures TA.

Procedures

From each selected patient we obtained the informed consent to participation on this study. This authorization was signed by the patient and by the investigator and allows data utilization only for this study purpose, obligating to preserve confidentiality.

After the granted authorization, the patient was invited to answer the investigator questions that are contained in the sociodemographic interview in a private room prepared to this purpose.

In control group STAI was applied before the delivery of the informed consent to intravenous administration of iodinated contrast material. In experimental group STAI was applied after the delivery of the informed consent to intravenous administration of iodinated contrast material. To maintain the minimum interference from the investigator, the patient self-answers, in the private room, first to STAI Y-1 and then to STAI Y-2.

To each patients consent to participation, sociodemographic interview and STAI was attributed a sequential number. After the direct data collection, the informed consent for participation was stored in a safe place and separated from the sociodemographic interview and STAI.

Results

Psychometric values

In the control group, the value for state anxiety (SA) was 1.843±0.212 and the value for trait anxiety (TA) was 1.885±0.158. In the experimental group, the value for SA was 2.713±0.169 and the value for TA was 1.967±0.219. We can verify that the difference in SA between the two groups was 0.87±0.043 while the difference in TA between the two groups was 0.082±0.061

Internal consistency
The internal consistency of State-Trait Anxiety Inventory (STAI) was measured by the Cronbach's Alpha. So, for STAI Y-1 (that measures SA) the Cronbach's Alpha value was 0.932 and for STAI Y-2 (that measures TA) the Cronbach's Alpha was 0.721.

Normality test

Using the Kolmogorov-Smirnov test we verified that, for a 95% confidence level, only the values for TA in experimental group presents a normal distribution. This implies the use of non-parametric tests.

State anxiety and Informed consent

At a 95% confidence level we verify that the difference between SA means is contained in the interval -0.929 and -0.810. The results for $t$ student test reveal that there exists significant differences between variables so that the value of the test ($t$-value) is -28.701 ($df=159$ e 2-tail $P=0.000$). We can also verify that the negative sign of $t$ student test shows that mean SA of control group is inferior to experimental group.

Trait anxiety and Informed Consent

At a 95% confidence level we verify that the difference between TA means is contained in the interval -0.141 and -0.022. The results for $t$ student test reveal that there exists significant differences between variables so that the value of the test ($t$-value) is -2.722 ($df=159$ e 2-tail $P=0.007$). We can also verify that the negative sign of $t$ student test shows that mean TA of control group is inferior to experimental group.

State and Trait anxiety

The correlation between data obtained with STAI Y-1 and STAI Y-2 was made using Spearman's Rho. At a 95% confidence level we can verify the existence of correlations statically significant based in a non-normal approximation. So, to control group, the value of this test was 0.409 ($P=0.000$) and to experimental group, the value of this test was 0.321 ($P=0.004$).

Psychometric tests and sociodemographic characteristics
The correlation between data obtained with STAI and sociodemographic characteristics was made using Spearman's Rho and, at a 95% confidence interval, we didn't find any significant correlation. The table 1 contains test values and significance values.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control group</th>
<th>Experimental group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$P$</td>
<td>TA $P$</td>
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<tr>
<td>Age</td>
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<td>0.571</td>
</tr>
<tr>
<td>Gender</td>
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<td>0.375</td>
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<td>Residence</td>
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<td>Marital status</td>
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<td>Salary</td>
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<td>Knows the exam</td>
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<td>0.442</td>
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<td>Previous CT exam</td>
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<td>Scholar degree</td>
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<td>Work status</td>
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</tr>
</tbody>
</table>

Correlation is significant at the 0.05 level.

**Table 1 Correlation between psychometric tests and sociodemographic characteristics**

**Conclusion**

In accordance to the significance values and the difference between the values of the t student test, we can conclude that state anxiety (SA) has a high intergroup difference and is bigger in the experimental group, so we can infer that informed consent increases SA.

In the same way, we can infer that informed consent increases trait anxiety (TA). But, despite a significant intergroup difference, the intergroup difference between mean values of psychometric tests is small.
Also, about the correlation between SA and TA, we can conclude that trait anxiety influences each patient state anxiety.

Finally, we can conclude that sociodemographic characteristics do not influence SA or TA.

References


Ross L, Thomsen B, Boesen E, Johansen C (2004) In a randomized controlled trial, missing data led to biased results regarding anxiety. Journal of Clinical Epidemiology 57: 1131-1137

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