LECTURE NOTES OF THE ICB SEMINARS

STATISTICS AND CLINICAL PRACTICE

Warsaw, June 2002

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Background

The aim of the EDEN study is to evaluate the efficacy of acute psychiatric treatment in a day hospital setting in 5 European centers: Dresden, London, Wroclaw, Michalovce and Prague. The full title of the project is "Psychiatric day hospital treatment: An alternative to inpatient treatment, being cost effective and minimising post-treatment needs for care? An evaluative study in European areas with different care systems". For the study the acronym "EDEN" (European Day hospital Evalua tion) was established. Details about the project can be found on the Internet site http://www.edenstudy.com.

This research demonstrates the viability and applicability of acute day hospital treatment. The main conjecture is that day hospital treatment for acute psychiatric patients is as effective as conventional inpatient hospital care. In terms of outcome criteria, the following are being examined:

- observable parameters (such as psychopathology, level of functioning, and objective needs for care)
- subjective parameters (such as quality of life, satisfaction with treatment, subjective needs for care and effects on closest reference person)
- cost-effectiveness of inpatient and day hospital treatment (including both direct and indirect costs)

Comparison of psychiatric health care systems between Eastern and Western European countries is also a subject of interest.

The evaluation of the day hospital utilizes a randomized controlled trial design with repeated measures at the following time points:

* t₁: admission/ 3 days after admission; t₃: 1 week after admission;
* t₄: 4 weeks after admission; t₄: discharge;
* t₅: 3 months after discharge; t₆: 12 months after discharge.

During the realization of the project the data from clinical instruments are collected. The characteristics of the instruments are given in Table 1. Total number of variables obtained for each patient during the study is greater than 2200 (without SCAN data).
Table 1. Characteristics of the instruments used during EDEN study.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Time points</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Sociodemographic and Clinical History (CSCHI)</td>
<td>$t_1$, $t_2$, $t_3$, $t_4$, $t_5$ only if $t_1-t_4 &gt; 1$ week; $t_5$, $t_6$</td>
<td>Standardized documentation sheet of the individual patient’s sociodemographic data and psychiatric history [8]</td>
</tr>
<tr>
<td>Schedules for Clinical Assessment in Neuropsychiatry (SCAN 2.1)</td>
<td>$t_1$; $t_2$, $t_3$, $t_4$, $t_5$ only if $t_1-t_4 &gt; 1$ week; $t_5$, $t_6$</td>
<td>Standardized clinical interview for establishing ICD-10 diagnoses of mental disorders (developed under the auspices of the World Health Organization) [14]</td>
</tr>
<tr>
<td>Brief Psychiatric Rating Scale (BPRS)</td>
<td>$t_1$, $t_2$, $t_3$, $t_4$ only if $t_1-t_4$ is at least 6 weeks; $t_5$, $t_6$</td>
<td>Assessment of psychopathological symptoms [16]</td>
</tr>
<tr>
<td>Groningen Social Disabilities Schedule (GSDS)</td>
<td>$t_1$, $t_2$, $t_3$, $t_4$ only if $t_1-t_4$ is at least 6 weeks; $t_5$, $t_6$</td>
<td>Assessment of social disabilities in 8 major social roles [13]</td>
</tr>
<tr>
<td>Berliner Bedürfnisinventar (Berlin Needs for Care Inventory), Questionnaire for Clients</td>
<td>$t_1$, $t_2$, $t_6$</td>
<td>Evaluation of care needs of the patient [6]</td>
</tr>
<tr>
<td>Berliner Bedürfnisinventar (Berlin Needs for Care Inventory), Questionnaire for Carer</td>
<td>within 5 days; $t_6$, $t_7$</td>
<td>Evaluation of the need for care from the vantage point of professional carers in 16 areas of the patient’s needs [6]</td>
</tr>
<tr>
<td>The Manchester Short Assessment of Quality of Life (Mansa)</td>
<td>$t_1$, $t_2$, $t_3$, $t_4$, $t_5$</td>
<td>Assessment of subjective quality of life [11]</td>
</tr>
<tr>
<td>Clients’ Scale for Assessment of Treatment (CAT)</td>
<td>$t_1$ 3rd day after admission; $t_6$, $t_4$</td>
<td>Assessment of the patient’s satisfaction with the treatment [10]</td>
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<tr>
<td>The Helping Alliance Scale (HAS)</td>
<td>$t_5$, $t_6$</td>
<td>Assessment of the quality of the therapeutic relationship [12]</td>
</tr>
<tr>
<td>Client Service Receipt Inventory (CSRI)</td>
<td>$t_1$, $t_2$, $t_3$, $t_4$, $t_5$</td>
<td>Assessment of the individual patient’s direct and indirect health care costs [3,4]</td>
</tr>
<tr>
<td>Involvement Evaluation Questionnaire (IEQ, incl. GHQ-28)</td>
<td>$t_1$ within 1 week; $t_5$, $t_6$</td>
<td>Assessment of the (psychological, social and financial) burden on the patient’s closest reference person(s) [5,15]</td>
</tr>
</tbody>
</table>

Problems and Methods

1. Randomization

Samples are drawn from the patients' populations admitted during the first 18 months of the project for inpatient ward or day-hospital. Recruitment of samples is carried out according to defined inclusion and exclusion criteria. Patients who fail to meet criteria are informed about the research project and those who consent to take part are randomly and independently allocated to treatment in either a day hospital or an inpatient setting. At the beginning of the
study a minimum target size of sample of admitted patients was derived as ca. 230 for each center.

A part of analyses is devoted to examination of randomization's validity at the beginning of treatment. For patients from both wards observable and subjective parameters are compared. Randomization correctly carried out should imply no differences between patients from both settings at admission. Compared variables have various types: nominal, ordinal and interval as well. This diversity extracts distinct methods for comparison of the two samples. In classical case of comparison two samples from normally distributed population t-test [17] is used. Considerable part of variables reveals statistically significant deviation from normality (confirmed by Shapiro-Wilk test). For those variables nonparametric tests for two independent samples (e.g. Mann-Whitney test) are used.

2. Instruments

Instruments used in the study differ in their structure. Some of them (CSCHL, CSRI) are utilized just for collecting sociodemographic or economic data. Considerable part of instruments consists of items assessed on fixed, appropriate scale. For these questionnaires (BPRS, GSIS, GHQ, HAS, CAT, MANSACA) items are very often not analyzed separately, but some pre-calculations on a given group are made. For instance, to assess psychopathology, (BPRS) mean-score over all 24-items is computed. Questionnaires consist of questions or items with various kind of answer: dichotomous, polychotomous, multiple-choice, categorical, interval and open questions. For some purposes variables of interval type are categorized before analyzing. Statistical analyses, that concern even one task, require often variables from few instruments to be taken into account.

3. Comparison of settings and centers

On admission research assistants collect information about patient's clinical history and rates his/her psychopathology. Patients are asked also about their social functioning and their quality of life. General needs and sources of help are assessed both subjectively and objectively. These measures are taken on admission (t1), at discharge (t4), and both 3 months (t3) and 1 year after discharge (t6). In addition, the patients assessment of their treatment is collected at 3 days, 1 week, and 4 weeks into their treatment. Patients assessment of the helping alliance is collected at t3 and t6. Effects upon the patients closest reference person - specified by a first degree relative - are assessed at t1, t3, t5 and t6. Assessment of the cost of all health care received by the patient is carried out at t1, t4, t3 and t6.

At this stage of the study comparison between day-hospital and inpatient care is based on patients treatment and his/her health.

Instruments used for collecting patients' data have different structure because they are used for different purposes. A relatively large number of instruments, repeated measures, connections between instruments, and different types of variables cause that nonstandard methods of statistical analysis need to be involved.

Some of instruments require pre-calculation for obtaining mean-score or number of positive answered questions. Only data prepared in this way are further analyzed. Obtained variables are of different type: categorical or interval. Only a part of them satisfy assumptions for classical methods as analysis of variance. Significant number of interval variables are not normally distributed.

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4. Trainings and assessment of reliability

An essential part of mental health studies are trainings connected with assessment of agreement. Before the beginning of the study a training program was developed for those, who would be conducting the interviews. In the EDEN study ratings of videotaped interviews for Brief Psychiatric Rating Scale (BPRS) and ratings from written case vignettes for The Groningen Social Disabilities Schedule (GSDS-II) were considered.

BPRS consists of 24-items assessed with scale from 1 to 7. The mean score is a measure of psychopathology. The consistency of scores produced by different raters is the major standard for evaluating rating scales such as BPRS or GSDS. With this end in view inter-rater reliability is evaluated. Standard methods as Cohen's kappa [1] or simple Intraclass Correlation Coefficient ICC cannot be used because patients have been assessed by different number of raters per patient. For BPRS unbiased ICC for not equal number of raters proposed by Bartko and Carpenter [2] was used.

For GSDS assessment of role, behavior is carried out by giving ratings from 0 to 3 or 9, for each of the eight roles, and for each of the dimensions per role. For three roles it is necessary to assign the individual to a certain category, prior to making assessments. This feature and the fact that patients has been assessed by different number of raters did not allowed to apply classical methods for computing inter-observer reliability. It was proposed to take a mean of kappas obtained from each pair of raters. In the first step data were categorized. Three classes were considered:

i. rating 0 is treated as 0 - lack of disability,
ii. ratings 1, 2, 3 are treated as one class - disability,
iii. rating 9 is treated as 9 - not applicable.

Ratings for dimensions were compared if and only if category was there same. For each item Cohen's kappa coefficients were calculated for all pairs of raters. Concordance for each item was defined as the mean of corresponding coefficients.

Results

At this stage of the study (i.e. in the half-time of the project) data regard to 641 admitted patients. The sample consists in 60.4% of woman and in 39.6% of men. The mean age of patients admitted on wards is 40.9 (95% CI: 39.6 - 42.2) and to day-hospital 37.82 (95% CI: 36.2 - 39.2).

For process of assessment of correctness of randomization, marital status, living situation, psychopathology, main mental disorder (ICD-10), number of previous episodes etc. were also compared between both subgroups. Results allow to presume that randomization proceeds correctly.

Concordance for BPRS training is acceptable. The single unbiased ICC equals 0.786.

Kappa values for GSDS vary (according to Landis and Koch [9]) from moderate to almost perfect agreement, with scores ranging between 0.523 and 0.942. Mean score is substantial and equals 0.735 (95% CI: 0.689 - 0.781).

Conclusions

A variety of instruments, types of variables and different aspects of the study, requires a modification of well known methods. The aim of the study - comparison of psychiatric day-hospital and inpatient care in 5 centers-causes that parallel group design is used. For the
assessment of inter-rater reliability it was necessary to develop new methods based on standard coefficients evaluating agreement [7].

References


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Lecture Notes of the ICB Seminars

Statistics and Clinical Practice

Warsaw, June 2002

Edited by L. Bobrowski
J. Doroszewski
N. Victor

Warsaw 2002
The International Centre of Biocybernetics (ICB) of the Polish Academy of Sciences was established in Warsaw in June 1988.

The ICB is a multi-national association of the Academies of Science and organizations interested in biocybernetics and health care through science and technology. The ICB acts in accordance with the Agreement about the establishment of the ICB as signed by its Parties. Membership to the ICB is opened, new members are admitted by applying in writing to the Secretary of President of Polish Academy of Sciences and signing the Agreement.

In 1991 the ICB was appointed and in 1996 reappointed as WHO Collaborating Centre for Research and Training in Biocybernetics and Biomedical Engineering.

MAIN TASK FOR THE ICB. The main objectives of the ICB are: exchange of scientific experience and the improvement of professional qualifications, and facilitation of research and application in the field of biocybernetics and biomedical engineering.

To achieve these aims, the ICB will undertake the following activities:

- organization of scientific meetings in the form of seminars, summer schools and conferences as well as other meetings aimed at the exchange of information and of experience;
- facilitation and encouragement of research and development;
- acquisition and dissemination of relevant information, including publication of scientific materials connected with ICB activities.

SCIENTIFIC COUNCIL. The Scientific Council of the ICB is appointed by the Parties.

The members of the Scientific Council are distinguished specialists in the field of biocybernetics or biomedical engineering delegated by the Parties. Other persons up to a maximum of 50% of those directly appointed may be invited "ad personam" to become members on the proposal of the Scientific Council. Members would serve for a period of three years, unless specifically reappointed or reinvited for another term.

SCIENTIFIC ACTIVITY. The ICB organizes seminars and special meetings in the following main directions of biocybernetics and biomedical engineering: biosystems, biomeasurements, artificial organs, biomechanics and bioinformatics.

The scientific program of seminars includes the recent results of fundamental researches of physiological processes as well the problems of new technology and design of biological devices and systems for therapy, life support, clinical diagnosis and information processing.

Since 1988 the ICB has organized 64 seminars and workshops.

The duration of seminars varied from 5 to 10 days. The number of participants per seminar varied from 40 to 100 persons. All together 4000 scientists from 41 countries took part in ICB activities.

PUBLICATIONS. Journal "Biocybernetics and Biomedical Engineering" is the official journal of the ICB. The full texts of lecturers delivered at the ICB Seminars are published in "Lecture Notes of the ICB Seminars". Lecturers are kindly requested to supply their texts before the date of the seminar.

OTHERS. Lecturers of the Seminars from countries which signed the Agreement are delegated by their Organizations. Other lecturers are invited by the Director of the ICB. The Seminars take place in the ICB headquarters, lecturers and some participants of the Seminars are accommodated in the ICB guest rooms.