Shared Decision Making and Long-Term Outcome in Schizophrenia Treatment

Johannes Hamann, M.D.;
Rudolf Cohen, Ph.D.; Stefan Leucht, M.D.;
Raymonde Busch, Dipl.Math.; and Werner Kissling, M.D.

Objective: Compliance with antipsychotic medication is a major issue in schizophrenia treatment, and noncompliance with antipsychotic treatment is closely related to relapse and rehospitalization. An enhanced involvement of patients with schizophrenia in treatment decisions ("shared decision making") is expected to improve long-term compliance and reduce rehospitalizations. The aim of the present analysis was to study whether shared decision making (SDM) in antipsychotic drug choice would influence long-term outcome.

Method: From February 2003 to January 2004, psychiatric state hospital inpatients with a diagnosis of schizophrenia (ICD-10; N = 107) were recruited for the trial using a cluster-randomized controlled design. An SDM program on antipsychotic drug choice consisting of a decision aid and a planning talk between patient and physician was compared with routine care with respect to long-term compliance and rehospitalizations (6-month and 18-month follow-up).

Results: On the whole, we found high rates of noncompliance and rehospitalization. There were no differences between intervention and control groups in the univariate analyses. However, when controlling for confounding factors in a multivariate analysis, there was a positive trend (p = .08) that patients in the SDM intervention had fewer rehospitalizations. Additionally, a higher desire of the patient for autonomy and better knowledge at discharge were associated with higher hospitalization rates.

Conclusion: The intervention studied showed a positive trend but no clear beneficial effect on long-term outcomes. A more thorough implementation of SDM (e.g., iterative administration of decision aid) might yield larger effects. Those patients with higher participation preferences are at higher risk for poor treatment outcomes and therefore require special attention. Strategies to match these patients' needs might improve compliance and long-term outcomes.

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Long-term compliance with antipsychotic agents in the treatment of schizophrenia is often poor, leading to suboptimal treatment results and high rehospitalization rates.[1] The model of shared decision making (SDM) is thought to be a new and promising approach for improving patients' involvement in medical decisions and their adherence to treatment regimes derived from shared decisions.

Although SDM has been developed within somatic medicine and to date there is only sparse evidence on the feasibility and efficacy of SDM for psychiatric settings,[2] the model of SDM or similar approaches are urgently advocated by treatment guidelines for schizophrenia (e.g., for antipsychotic drug choice[3–5]). These recommendations fit well with the fact that most patients wish to be involved in medical decisions concerning their treatment,[6] but the actual education of patients on treatment options and inclusion of patients in treatment decisions are still unsatisfactory.[7]

For SDM, neither the physician alone nor the patient alone is responsible for medical decisions, but rather both share information and responsibility.[8] The model explicitly goes beyond informed consent; thus it aims at

decreasing the informational and power asymmetry between doctors and patients by increasing patients' information and control over all treatment decisions that affect their well-being.[9]

Innovative ways of implementing SDM have been developed to facilitate SDM in clinical settings, among which are decision aids (media displays of pros and cons of treatment options to help patients in finding their own preferences)[10] as well as communication skills training for physicians.

In a preceding analysis,[11] we have shown that the administration of a decision aid on antipsychotic drug choice to inpatients with acute exacerbation of schizophrenia was feasible for many patients and improved perceived involvement in medical decisions, knowledge about the disease, and drug attitudes.

In the present article, we display data on the effect of this intervention (decision aid) on patients' long-term compliance and rehospitalization rates.

METHOD

Study Design and Baseline Measures

Detailed data on the intervention and short-term effects have been reported elsewhere.[11] Briefly stated, inpatients (male/female, aged 18–65 years, no exclusion criteria) with a diagnosis of schizophrenia (International Classification of Diseases, 10th Edition) were randomly included in a decision aid program or received usual care (randomization of the wards).

A printed decision aid was developed for the study in cooperation with a number of psychiatrists, psychiatric nurses, and former patients. The final version of the decision aid was a 16-page booklet covering the pros and cons of oral versus depot formulation, first- versus second-generation antipsychotics, psychoeducation, and type of socio-therapeutic intervention. These booklets were presented to the patients of the intervention group by the head nurse of the ward as soon as the psychiatrist in charge considered them able to cooperate. The nurses had been trained in assisting the patient to work through the booklet and in answering any requests for information. In the decision aid, the patients were asked to write down their experiences with previous antipsychotic medication and to indicate their preferences regarding the different options on each topic.

Patients met their physicians within 24 hours after having worked through the decision aid. The aim of these meetings, i.e., "planning talks," was to reach an agreement between patient and psychiatrist on further treatment according to the preferences indicated by the patient in the booklet. For a more detailed discussion, the psychiatrist and the patients had various charts available with quasi-quantitative information on the most common antipsychotics and their side effects.

Patients in the control group were treated "as usual," thus they did not receive the decision aid and there was no arrangement for an extra planning talk.

Patients and physicians in both groups filled in several questionnaires/rating forms related to patient involvement/satisfaction and psychopathology including the following scales for physicians (before discharge): the Positive and Negative Syndrome Scale for Schizophrenia (PANSS)[12] and the Working Alliance Inventory (WAI, therapist form)[13]; and for patients (before discharge, except API: after study entry): the decision-making preference subscale of the Autonomy Preference Index (API),[14] the Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness (COMRADE),[15] patients' overall satisfaction with care (ZUF8),[16] the Medication Adherence Rating Scale (MARS),[17] and patients' knowledge of disease and treatment (7-item multiple choice).

Short-term results indicated that the intervention improved patients' perceived involvement (COMRADE score shortly after the intervention, but not at discharge) and patients' knowledge. There was also a trend for more positive attitudes toward antipsychotic treatment. In addition, it boosted the uptake of psychoeducation and socio-therapeutic measures.[11]

Outcome Measures/Follow-Up

For the follow-up, patients and their outpatient psychiatrists were contacted 6 and 18 months after discharge from hospital.

Rehospitalizations due to schizophrenia were recorded for the periods 0–6 months and 6–18 months after discharge from hospital. We defined rehospitalization within 18 months after discharge as the main outcome measure. This variable was dichotomized into scores of 1 (rehospitalization occurred within 18 months after discharge) and 0 (no rehospitalization occurred within 18 months after discharge).

In addition, at 6 and 18 months after discharge, patients' compliance, global functioning (Global Assessment of Functioning scale), and severity of illness (Clinical Global Impressions scale) were assessed.

We also recorded how often the main antipsychotic (excluding those low potency drugs that were used mainly for sedation) was switched within 6 months after discharge.

In order to rate compliance with medication, patients were requested to fill in a questionnaire on their compliance (MARS). The MARS is a previously validated[17] 10-item questionnaire derived from the Drug Attitude Inventory (DAI) and the MAQ (Medication Adherence Questionnaire). Physicians were requested to rate compliance of their patients on a 4-point scale ranging from "poor compliance" to "very good compliance."[18] Physicians were requested to make unannounced measurements of plasma levels of the prescribed antipsychotics at 6

months and 18 months after discharge (to which patients had signed informed consent during the index hospitalization). For the 6-month follow-up, 22 plasma level measurements were available, and for the 18-month follow-up, 14 plasma level measurements were available.

For the analysis, the estimates of compliance by patients and physicians as well as results of the plasma levels were dichotomized into good and poor compliance as follows: doctors' ratings of 1 and 2 (very good and good compliance) were counted as good compliance, and ratings 3 and 4 (modest and poor compliance) were rated as poor compliance.

MARS ratings below the median score of 8 were considered to indicate poor compliance; ratings of 8 or above were considered to indicate good compliance. Plasma level results were also dichotomized into good compliance (for all patients with an average level of the substances prescribed) and poor compliance (for those patients without any substances showing up on measurement). Patients with very low levels (N = 2) were classified as "unclear."

A "conservative" algorithm was applied in order to obtain an overall measure of compliance for every patient and point in time. Overall compliance was considered "good" if patients and physicians agreed in their (positive) estimates. In all other cases (incongruence of ratings, both rating poor compliance), compliance was rated as "poor." Results were corrected in the direction toward the results of the plasma level evaluation if plasma levels indicated compliance or noncompliance different from that derived from self-rating/physicians' rating (in 2 cases). For patients with missing data, the data available were used to determine compliance.

The study was approved by the ethics committee of the Technische Universität, Munich, Germany. Recruitment took place between February 2003 and January 2004 in 2 German state hospitals (Haar and Agatharied).

Statistical Analysis

In a first step, the intervention (SDM) and control groups were compared with respect to several outcome variables using univariate analyses (t and χ^2 tests). For the rehospitalization rate, exploratory correlations with possible confounding variables were calculated using Pearson's correlation.

The effect of the intervention on rehospitalizations was then analyzed using multivariate analysis to account for confounding variables. Therefore, a logistic regression model was applied to predict rehospitalization within 18 months after discharge. The following variables were entered into the logistic regression model: group allocation, PANSS total score at discharge, duration of illness, perceived involvement (COMRADE), participation preferences (API), knowledge, compliance at discharge (MARS), satisfaction with treatment at discharge (ZUF8),

and therapeutic alliance (WAI). A p value < .05 was considered significant.

RESULTS

Patient Characteristics

A total of 107 patients were included in the original study and agreed to being followed up. Of these, 51 (48%) were female. Mean age was 38.0 years (SD = 11.4), mean duration of illness was 9.2 years (SD = 8.5), and the mean number of hospitalizations due to schizophrenia (including the present stay) was 5.6 (SD = 5.7). Thirty-five patients (33%) had been admitted involuntarily to the hospital.

Sixteen patients (15%) were lost to follow-up at 6 months and 30 (28%) at 18 months. Another 4 patients withdrew their consent, and 2 patients died within 18 months after discharge. Thus at 6 months, follow-up data on 86 patients (80%) were available; and at 18 months, follow-up data on 71 patients (66%) were available.

There were no significant differences between the intervention and control groups in terms of dropout rates at 6 and 18 months. Additionally, there were no differences between dropouts of the intervention or control groups with respect to patients' age, gender, duration of illness, or PANSS score at discharge (6- and 18-month data, t tests and χ^2 tests; all p > .05).

Patients who dropped out of the trial (6- and 18-month data) also showed no difference to patients continuing the trial with respect to patients' age, gender, duration of illness, or PANSS score at discharge (6- and 18-month data, t tests and χ^2 tests; all p > .05).

Rehospitalization Rates and Compliance Ratings

Sixteen patients (22%) were rehospitalized within 6 months after discharge and another 33 (42%) between months 6 and 18 after discharge. Together, 39 patients (49% of those 79 patients for which any data on hospitalization were available) were hospitalized within 18 months after discharge.

Overall compliance was "good" for 42 (49%) of the patients at 6 months and 40 (59%) at 18 months.

Poor compliance at 6 months after discharge was associated with rehospitalizations between 6 and 18 months after discharge (χ^2 = 4.23, p = .04).

Effects of the Intervention

Using univariate analyses, there were no significant differences between the intervention and control groups for any outcome measure (Table 1).

In the preceding analysis,[11] we had demonstrated that in the short term the intervention had an influence on several parameters (perceived involvement, knowledge of disease) and as Figure 1 shows, there were distinctive cross-correlations between the individual factors. Thus, higher participation preferences correlated with lower satisfaction

Table 1. Differences Between Intervention and Control Groups[a]

Characteristic	Intervention	Control	p Value
Patients hospitalized within 6 mo after discharge, N/N (%)	8/36 (22)	8/37 (22)	p > .05[d]
Patients hospitalized within 18 mo after discharge, N/N (%)	20/38 (53)	19/41 (46)	p > .05[d]
Patients showing good compliance at 6 mo, N/N (%)	16/39 (41)	26/47 (55)	p > .05[d]
Patients showing good compliance at 18 mo, N/N (%)	18/30 (60)	22/38 (58)	p > .05[d]
CGI score at 18 months, mean ± SD[b]	4.0 ± 1.5	4.1 ± 1.4	p > .05[e]
GAF score at 18 months, mean ± SD[c]	54.7 ± 16.5	51.0 ± 18.5	p > .05[e]
Patients with drug switches (main antipsychotic) within 6 mo after discharge, N/N (%)	12/36 (33)	16/40 (40)	p > .05[d]

[a]The total N amounts for the intervention and control groups vary from measure to measure, due to missing information.
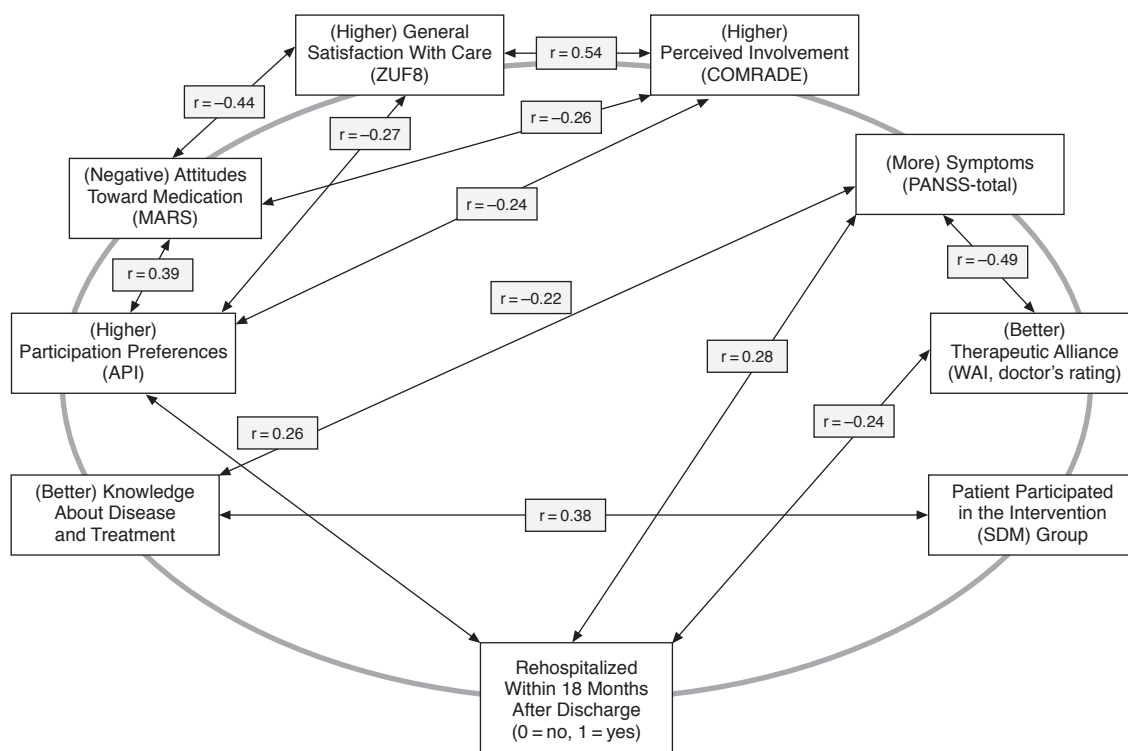[b]Intervention group, N = 35; control group, N = 40.
[c]Intervention group, N = 30; control group, N = 37.
[d]χ^2 test.
[e]t test.
Abbreviations: CGI = Clinical Global Impressions scale, GAF = Global Assessment of Functioning scale.

Figure 1. Cross-Correlations Between the Single Factors[a]

[a]All cross-correlations that were statistically significant (p < .05) are displayed.
Abbreviations: API = Autonomy Preference Index, COMRADE = Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness, MARS = Medication Adherence Rating Scale, PANSS = Positive and Negative Syndrome Scale, SDM = shared decision making, WAI = Working Alliance Inventory, ZUF8 = patients' overall satisfaction with care.

scores (general satisfaction with care, perceived involvement), lower self-reported compliance, and higher rehospitalization rates. Higher PANSS scores correlated with poorer WAI scores, poorer knowledge, and rehospitalization. Poorer WAI scores additionally correlated with rehospitalization. Finally, general satisfaction, drug attitudes, and perceived involvement all showed positive correlations with one another.

To account for these inter-correlations, we performed a multivariate analysis (logistic regression), with rehospitalization rate within 18 months as the dependent variable. Rehospitalization rate was chosen as the most objective and, in terms of impact on patients' lives, most important variable.

Using backwards stepwise regression, the model predicted 18% of the variance (Nagelkerke r = 0.43) with

higher participation preferences (OR = 1.06, p = .03) and better knowledge (OR = 1.23, p = .03) significantly predicting rehospitalization. Having received the SDM intervention showed a positive trend (OR = 0.19, p = .08) in the direction of fewer hospitalizations.

Doctor-patient relationship (WAI) and PANSS scores did not prove to be independent significant prognostic factors.

DISCUSSION

Long-term compliance with antipsychotic medication was poor for up to 50% of the patients, and nearly half of the patients were rehospitalized within 18 months after discharge. The shared decision-making program, consisting of a decision aid and a planning talk during hospitalization, showed a positive trend for reducing rehospitalization rates in the multivariate analysis but had no clear effect on the other outcome parameters including compliance. An additional finding was that patients expressing a higher desire for autonomy and those being better informed about their disease were more likely to be rehospitalized.

Limitations and Strength of the Study

There are certainly limitations to our study, including the relatively low sample size, a considerable proportion of patients dropping out of the study because they were lost to follow-up, a onetime intervention without iteration or "booster sessions," and the well-known difficulty of measuring compliance of outpatients. On the other hand, we were able to combine information from 3 sources (self-report, physicians' estimates, and plasma levels) in order to assess patients' compliance, and dropout rates seem reasonable in the context of a naturalistic study in a routine care outpatient setting.

Discussion of the Results

Prior to the study, it was unknown what effects SDM would have when applied to schizophrenia treatment. The opinions of the psychiatrists participating in the trial ranged from high expectations of improvement of compliance to fears of a worsening of compliance and the therapeutic alliance. What the study has shown is that the intervention—a single trigger intervention consisting of a decision aid and a planning talk—has a positive short-term effect on "soft" parameters such as perceived involvement, drug attitudes, and knowledge as well as on treatment decisions,[11] some of them known to be associated with long-term compliance.

Although there was no clear positive influence of the intervention on long-term outcome measures, a positive trend toward reduced rehospitalization rates was found. This trend, however, became clear only in the multivariate analysis when we controlled for confounding factors.

The intervention studied was aimed at triggering patients' involvement and thereby intended to alter therapeutic decisions as well as patients' behavior toward therapeutic decision making. Results of the inpatient phase already showed a decline of perceived involvement from the beginning of the intervention until discharge, a result that implies that the effects are only of short duration and that patients as well as psychiatrists tend to revert to old (paternalistic) habits. Thus the observed trend toward better outcome for the intervention group might not be due to increased commitment or compliance of the patients but rather is a result of other treatments chosen. As described in the previous analysis, the intervention boosted the uptake of psychoeducation and socio-therapeutic measures. However, the poor transition between inpatient and outpatient care and the poor overall outcome with regard to maintenance of therapy and drug intake might have outweighed small effects of the intervention. Additionally, a closer look at the 2 factors that had significant influence on rehospitalization is necessary.

Thus, patients expressing a higher desire for autonomy during inpatient treatment are at higher risk of being rehospitalized within 18 months after discharge than patients expressing lower desire for participation. In addition, patients expressing higher participation preferences were shown to be less satisfied with care and involvement in medical decisions. For those patients, a mismatch between their expectations in regard to their doctor's behavior and the actual care received obviously existed. Therefore, these patients (being more autonomous and more disappointed by their doctors) might be more likely to discontinue medication and, in the long run, to be rehospitalized due to relapses. Obviously this mismatch between expectation and actual care was not resolved by our intervention, which might quite possibly be a result of the standardized procedure of the study (onetime only intervention) and conceivably of the physicians' return to paternalistic habits shortly after the intervention was over.

Additionally, those patients who were better informed about their disease and treatment options showed poorer outcomes with respect to rehospitalization. This result not only seems paradoxical (since one might expect the better informed patients to have better prognosis) but also contradicts approaches like psychoeducation. It might, however, be explained by the finding that psychoeducational interventions consisting of information provision only do not lead to compliance improvements.[19]

On the other hand, patients expressing higher participation preferences and being better educated about their disease might recognize warning signs of beginning psychotic episodes earlier than other patients. This might thereby lead to earlier and more rehospitalizations.

For all those patients, SDM might be a good option. Those with high participation preferences probably can be won by a more participatory approach, and those with

good knowledge about the disease might be good partners in negotiating different treatment options.

In the present study, the SDM intervention obviously was not efficacious enough to overcome these other influences. With more intensive interventions (e.g., iterative approaches or SDM training for patients) the SDM approach might yield clearer effects.

CONCLUSION

The intervention studied showed no clear beneficial effect on long-term outcomes. However, the trend toward fewer rehospitalizations shows the potential of SDM to improve long-term outcomes. A more thorough implementation of SDM (e.g., iterative administration of decision aid) might yield larger effects. Factors related to patient participation have been shown to be associated with long-term outcomes, making it necessary to focus on the area of participation preferences.

Further research in the area of SDM should therefore concentrate on the following issues:

- A more thorough implementation of SDM behavior by the use of iterative interventions (e.g., use of the decision aid for every important decision or every week).
- More efforts made to reach optimum matches of patients' preferences for decision making (reliable assessment strategies of patients' preferences must be developed and implemented).[20]
- Development of SDM training programs for patients[21] that can be included into psychoeducational programs.

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