Finding the ideal place for a psychotherapeutic intervention in a stepped care approach – a brief overview of the literature and preliminary results from the Project PREDICT

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Abstract

AIMS: To provide an overview over empirical evidence regarding stepped care approaches that include psychotherapies. To present own preliminary study results in alcohol dependent patients.

Methods: Publications were searched in the databases Medline, PsycINFO and the internet search engine Google Scholar. Inclusion criteria were psychosocial treatment and psychiatric disorders. Our own study consists of two steps. In step 1 patients receive anti-craving medication or placebo and Medical Management (MM). After a relapse to heavy drinking patients can step up and after randomization they either continue with the same treatment or they receive additional alcoholism specific psychotherapy (ASP).

Results: Evidence suggests that stepped care might be efficacious in patients with obsessive-compulsive behavior and depression. There is no evidence for efficacy in problem drinkers. Results of our own study show that the completer rate in MM alone is higher than in ASP with MM, but there are no significant differences concerning age, sex and disease severity between completer and non-completer in both study arms.

Conclusions: Further research with regard to stepped care in alcohol dependent patients is needed. An introduction of the psychotherapy at earlier stages might be sensible. Copyright © 2008 John Wiley & Sons, Ltd.

Key words: psychotherapeutic intervention, stepped care approach, alcoholism

Background

Sobell and Sobell (2000) define stepped care as an approach in which the initial treatment of choice is the least intrusive on patients life-style, is efficient regarding treatment resources and has a reasonable chance of being effective. Thus stepped care can optimize resource allocation. While many patients might already benefit from early minimal interventions, more intensive and expensive treatments or

multidimensional pharmacological and psychosocial treatment concepts are reserved for patients who do not benefit from brief interventions (Haaga, 2000; Newman, 2000). Stepped care can either mean a change in the treatment regime or providing an add-on treatment. This paper investigates the role of psychotherapy in stepped care approaches for psychiatric diseases in general and alcohol dependent patients in particular.

Objective

First, we summarize the empirical evidence regarding stepped care approaches including psychotherapeutic interventions from the literature. Second, we present preliminary results from the trial flow data of the six year, multi-centre, randomized clinical trial 'Efficacy of Additional Psychotherapy to Alcohol Dependent Non-responders to Anti-craving Medication'. This trial is a part of Project PREDICT trying to answer the question whether a brief alcoholism specific psychotherapy (ASP) is effective as an add-on intervention for non-responders to anti-craving medication in a stepped care model. We draw first conclusions about the value of a late stage psychosocial intervention in a stepped care approach for alcohol dependent patients.

Methods

Review

The review provides an overview of the evidence from the literature. The electronic databases Medline (Ovid), PsycINFO (EBSCO) and Google Scholar were searched for relevant publications. The search strategy consisted of a combination of textwords (using conjunction AND) to detect stepped care approaches ('stepped care' OR 'treatment tiering' OR 'adjunctive treatment') and references concerning psychotherapy ('psychotherapy' OR 'cognitive-behavioral therapy' OR 'motivational interviewing'). To avoid low retrieval rates the MeSH-thesaurus was not used. The reference lists of all relevant publications were searched for further publications. Studies were included if they investigated stepped care models in patients with psychiatric disorders. Trials with medical interventions alone, i.e. without psychotherapeutic treatment, and studies in patients with somatic disorders, e.g. hypertension, were excluded.

Project PREDICT

Preliminary results from the psychotherapy arm in Project PREDICT are presented (Mann et al., in press). This randomized, double blind trial was developed for patients with alcohol dependence and consists of two steps. Step 1, the 'individually adapted therapy of alcoholism', compares the efficacy of two anti-craving-medications (Acamprosate versus Naltrexone versus placebo). Step 2 investigates the 'efficacy of additional psychotherapy to alcoholic non-responders to anti-craving medication'. In Step 1 all patients are randomly allocated to the different medication and receive

Medical Management (MM), which is a brief intervention model based on motivational interviewing techniques (Bien et al., 1993). Patients relapsing to heavy drinking (defined as the consumption of 60 grams or more of alcohol per day for males and 48 grams or more for females) within the first year of Step 1 can proceed to Step 2. Included patients are randomly assigned to either continue with the former treatment or receive ASP as an add-on therapy. This is a manualized, disorder-specific, cognitive-behavioral psychotherapy for alcohol-dependent patients. This psychotherapeutic intervention is based on the Combined Behavioral Intervention designed for use in Project COMBINE (Miller et al., 2005).

An interim drop-out analysis was performed for those patients who were documented until April 2006. Association between relapse (as a dichotomous variable) and the characteristics sex, age, drinking days at baseline, heavy drinking days at baseline, daily alcohol consumption, number of inpatient detoxifications, number of inpatient long-term treatments, number of deliria, seizures, and previous suicide attempts were explored using multivariate logistic regression models. The research question whether adherence to medical management and ASP were associated with patient characteristics was tested with univariate *t*-(continuous outcomes) and chi-square-tests (dichotomous outcomes).

Results

Review

Very few stepped care studies for psychiatric disorders are reported from the literature. Theoretical stepped care models were developed for back pain (Von Korff and Moore, 2001), problem drinking (Breslin et al., 1997; Sobell and Sobell, 2000) migraine (Sculpher et al., 2002), anxiety (Newman, 2000), panic disorder (Otto et al., 2000), eating disorders (Wilson et al., 2000) and depression (Lin et al., 2000). Empirical studies are scarcer than theoretical considerations. Three relevant studies concerning psychiatric conditions are presented in Table 1.

Stepped care seems to be a useful approach in patients with obsessive-compulsive behavior and in patients with depression (Araya et al., 2003; Tolin et al., 2005). Yet there is no advantage concerning the effectiveness of stepped care compared to standard treatment in the therapy of problem drinking (Breslin

Table 1. Results of retrieved studies including psychotherapeutic interventions

Author	Year	Indication	Number of patients	Control group	Model of stepped care	Place of psychotherapeutical intervention	Main outcomes
Tolin et al.	2005	Obsessive-compulsive disorder	11	No	Change of modality first: bibliotherapy second: brief education third: cognitive-behavioral therapy	At the end	Every fifth responded to Step 1. Of the remaining almost 30% responded to Step 2. Of the remaining who finally receive psychotherapy almost 70% met responder criteria. The depression score in patients receiving stepped care decreases significantly more than in patients receiving usual care. There are no significant changes in percent days abstinent due to the supplemental cognitive-behavioral and motivational intervention.
Araya et al.	2003	Major depression	240 women	Yes (treatment as usual)	Change of modality first: psychoeducation second: pharmacotherapy	At the beginning	
Breslin et al.	1998	Problem drinking ¹	136	Yes (standard treatment: four individual sessions and two aftercare phone contacts)	Add-on First: standard treatment Second: standard treatment and cognitive-behavioral and motivational program	At the end	

¹Participants were problem drinkers and not severely dependent on alcohol (≥ 25 on the Alcohol Dependence Scale; Skinner and Allen (1982)).

et al., 1998). To date there is no evidence supporting the efficacy or effectiveness of stepped care approaches in the treatment of patients with alcohol dependence.

Project PREDICT

Of 173 patients relapsing to heavy drinking within the first year of the first step of project PREDICT 97 patients were included in Step 2. From 76 patients who were not included 55.3% refused participation and 19.7% already dropped out in Step 1. In the remaining 25% of cases there were other reasons for exclusion, e.g. concomitant diseases, incompatible medication or plan of a long-term psychotherapy. Multivariate analyses showed that relapsing patients had a more intensive treatment history (number of inpatient detoxifications 4.7 versus 1.9; $p = 0.031$) and a higher rate of physical complications, i.e. delirium, (22.6% versus 7.8%; $p = 0.049$), than non-relapsing patients. From the included patients 48 were randomized to continue their treatment. The completer rate in this arm was 50%. From the 49 patients receiving medication plus MM plus ASP the completer rate of MM alone was 50%, of ASP alone 40% and of both treatment conditions together approximately 30%. Completer and non-completer in both study-arms did not differ significantly concerning age, sex and disease severity ($p > 0.05$). Of 49 patients randomized to ASP plus MM plus medication, one-third already completed ASP (36.7%), but also one-third did not start ASP at all (34.7%).

Conclusions

Empirical findings on stepped care approaches including psychotherapeutic interventions, especially concerning alcohol-related disorders, are scarce. To date, there is no evidence for efficacy or effectiveness of stepped care approaches in patients with alcohol dependence. One study in problem drinkers could not prove superiority of stepped care over standard treatment with regard to the percentage of days abstinent. However, our literature search did not fully meet all the QUOROM-requirements (Moher et al., 1999). Therefore, unpublished studies could not be retrieved and included.

Project PREDICT is the first study that can contribute to the value of stepped care models for patients with alcohol dependence and the role of psychotherapy within such an approach. Our preliminary drop-out analysis found that the drop-out rate in the ASP is higher than in MM condition. But there are no

significant differences between completer and non-completer sample concerning age, sex and disease severity in both conditions. Most of the high drop-out rate in ASP must be attributed to the high proportion of patients who did not start the psychotherapeutic intervention. Possible explanations could be that there is an insufficient confidence in psychotherapy in general in this sample. Patients might be frustrated by the relapse. They also might prefer minimal interventions like MM or find the add-on of psychotherapy too time-consuming. The altogether high drop-out rates are similar to other trials (Anton et al., 2006). This high drop-out rate might be due to the negative selection of patients with regard to physical complications. The relapsed patients have significantly more inpatient detoxifications and a higher number of deliria than the not-relapsed patients. Therefore, the relapsed sample is altogether more severely diseased. The latter supports that stepped care might have the important drawback that patients requiring quick and intensive care are at first mildly treated. This might cause harm to the patients or frustration and also create higher costs. Therefore, the identification of predictors for the need of intensive care and finally the development of screening tools for that purpose might be an important direction for further research.

The preliminary data from project PREDICT suggest that it might be necessary to examine the effectiveness of a psychosocial intervention for alcohol dependent patients in models that introduce this intervention at an earlier stage of a treatment course. Perhaps this can also lead to a higher motivation or confidence in patients to initiate or adhere to psychotherapy.

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Declaration of interest statement

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