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3. Fassung

The evidence based status of psychodynamic psychotherapy in the treatment of psychosomatic disorders

Horst Kächele, Franz Porzsolt & Jörn von Wietersheim

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abstract
The lecture has to deal with four topics
First: We shall clarify what evidence-based status may sensible mean.
Second: We shall discuss the distinction among efficacy, effectiveness and efficiency and their impact on institutional aspects of outcome research Third:what are psychosomatic disorders? We shall endorse the view that there are many disorders in which sub-groups of patients are found that display significant psychological co-morbity.
Fourth We then shall raise typical EBM questions for two clinical situations.

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First: What is our understanding of EBM

The rise of Evidence-Based Medicine (EBM) has been one of the more remarkable phenomena of the British health scence during in 1990s. Initially EBM grew as a bottom-up approach to continuing medical education under the name of Clinical Epidemiology. CE was based upon emphasizing the potential of epidemiological information for guiding clinical practice. CE was widely regarded as a refreshing approach that blew away cobwebs and let in some light. CE mobilized the enthusiasm of people to come to grip with interpreting clinical data for themselves for use in their own clinical practice.

Let us remind you of the prophet´s of EBM, David Sackett´s introductionary statement:

"The practice of EBM is a process of life-long, self-directed learning in which caring for our own patients creates the need for clinically important information about diagnosis, prognosis. therapy and other clinical and health care issues., and in which we:

1. convert these information needs into answerable questions;
2. track down, with maximum efficiency, the best evidence with which to answer them (whether from the clinical examination, the diagnostic laboratory, from research evidence, or other sources);
3. critically appraise that evidence for its validity (closeness to the truth) and usefulness (clinical applicability);
4. apply the results of this appraisal in our clinical practice; and
5. evaluate our performance"

(Sackett et al. 1997), p.2)

The programme of EBM is a procedural conception, not a fact-based concept. As this seemed to happen to often, Sackett had to spell out in detail "What EBM is and what it is not" (Sackett et al. 1996).

It is not 'cook-book' medicine. Because it requires a bottom-up approach that integrates the best external evidence with individual clinical expertise and patient choice, it cannot result in slavish cook-book approaches to individual care. External clinical evidence can inform, but never can replace, individual clinical expertise and it is this expertise that decides whether the external

evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similar, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient´s clinical state, predicament[1], and preferences.

Let me clarified some of these issues.
First misunderstandings occur with the use of the notion of evidence. For example in German the expression "something is evident" means more self-evident, you do not need proof. The word "evidence" in English means proof, meaning that there are data available that are able to support a clinical statement.
EBM represent the continous effort to state which data support which conclusion - this is all, basically. Quality of these data and quality of the derived conclusions may be variable, even questionable.
A total misunderstanding - which politically sometimes is heavily used (Charlton & Miles 1998) - would be to name EBM a representative for that kind of medicine that only proven statement should be used in daily clinical practice. Even if one is committed to this new look in medicine, it would be foolish to deny that 50% of medical practices are based on soft evidence only.

David Sackett, the initiator of EBM, has investigated the decisions on a general medical ward. There he demonstrated that about 80 % of these decisions were based on hard scientific facts or on solid clinical experience. There is agreement that such a figure is unrepresentative for the whole field sof medicine; depending on the kind of the field and the status of its scientific development such figures are much lower. (are there figures available ? for psychiatry ?).

More important as the quality of the evidence is the question, whether a decision has been based on data at all and whether the necessary knowledge is available and whether the readiness for self-criticism is present.
The heart of EBM is the explicit and conscientious and most fitting application of the best available external evidence on a medical decision (Sackett). Mind you. the core of this statement resides with the expression. <best available>. What is meant by best available evidence. A simple reasoning could be that in the English language use evidence means proof and proofs in medicine are only

[1] complex, difficult situation

created by randomized studies providing the only control in the sense of experimental studies. This reading is a misapprehension. Our reading is different: evidence is not proof; evidence in EBM means the ethical obligation to support your clinical opinion by external facts thus providing evidence - the more reliable the better[2].

However there is one important operational maybe even post.modern principle with which we shall conclude this section

Figure : ABSENCE OF EVIDENCE DOES NOT IMPLY EVIDENCE OF ABSENCE

Absence of external evidence because no formalized studies have been performed does not justify the positive statement: no evidence on a given form intervention. They might be good reasons for not fulfilling this requirement.

To illustrate this issue I will detail just one example: The Grawe et al. 1994 (Grawe et al. 1994; engl 1998) meta-analysis based on RCT trials evidence judged a widespread method of relaxation - called autogenic training invented by I H Schultz (1932) - about the same time when Jacobson invented his method - as poorly efficacious.

. The problem of such statements is the difficult to calculate the half life time (Halbwert-Zeit) of the research findings (Kächele 1995). Already at the time when the Grawe book appeared, a major German controlled study - comparing

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[2]There are any number of issues in medicine that cannot be answered by a randomized controlled trial. For example:

the quality of a new diagnostic tool requires the parallel application of two tools, an old one and an new one.
In order to evaluate the validity of a prognostic factors this factor should be described at a early as possible time of the illness and the course of the illlness should be observed as long as possible
Comparing a surgical with a medical intervention randomization hardly is an appropriate tool, as any practioner knows that as well the complicance of the patients as the adherence of the doctors with the randomization gets smaller, the larger the risks of the treatments will be. In such case patients and doctors - consciously or unconsciously - performs a classical economical analysis, comparing costs of treatment and consequences of alternative actions this deciding on the basis of his or her personal experiences and available informations. Recently these new findings limitating the performance of RCT have been summarized in a symposium (Abel & Koch 1998).

cognitive-behavioral interventions with a control condition, namely the autogenic training demonstrated that the so called control conditions was as powerful as the highly praised cognitive-behavioral intervention for the treatment of itching (Ehlers & Gieler 1994; Ehlers im Druck)
Meanwhile a recent meta-analytic review has identifed 64 controlled studies, 50 of them demonstrating positive effects, and 14 zero or negative effects of AT on psychological disturbances (Stetter 1998)

Second: what kind of evidence by what kind of study

Since Klaus Grawe in his momumental monography attested the psychodynamic psychotherapies a modest, but reasonable efficacy on neurotic and personality disorders, but a poor efficacy on psychosomatic disorders (Graweet al. 1994; 1998) a debate has shaked the German academic psychodynamic community. The emotional aspects of this debate involved the quite offensive disqualification of all present acting chairs of the department of psychosomatic medicine at German medical faculties that for whatever reasons are all psychoanalytically oriented therapists.
To proper understand the issue at stake we have to consider that preferences in research perspetive might be involved.
Since the beginning of formalized psychotherapy research psychodynamic oriented clinicians and researchers did not share the prevailing notion that randomized-controlled trials, with the highest degree of internal validity, yet with a low degree of external validity, should be looked upon as providing "the highest level of evidence". This has been especially true for the continental-European branch. On the contrary the cognitive-behavioral scientific community from the outset favoured the controlled-experimental design resulting in a huge discrepany in terms of sheer numbers of RCT performed in the different treatment modalities on a variety of psychological disorders:

<u>Cognitive-Behavioral Therapies</u> 429 studies, mean 11,2 sessions 434 studies, mean 7, 9 weeks

Humanistic Therapies
70 studies, mean 16,1 sessions
76 studies, mean 11, 6 weeks
Psychodynamic Therapies
82 studies, mean 27,6 sessions
80 studies, mean 30,7 weeks

The vast differences reflect strong convictions of whar is therapeutically viable among the treatment orientations. Take the comparison of a surgical with a medical intervention where randomization hardly is an appropriate tool: any practioner in our field knows that as well the complicance of the patients as the adherence of the doctors with the randomization gets smaller, the larger the inconvenience of the treatments will be.

This has been demonstrated in a recent German study on the treatment of anxiety disorders where randomization totaly failed as the two treatments - inpatient three month versus outpatient one year - were preferred by totally diverse populations. Middle aged male patients out of job went to the inpatient treatment , mothers with children preferred the outpatient arm (Krauthauser u. Bassler 1997).

Fact is that the psychodynamic psychoanalytic scientific community has not demonstrated great excitement on the methodology of RCT which is represented in the relatively small numbers of psychodynamic RCT that mainly have been performed in the anglo-american language community. On the contrary it has to a significant degree from early on demonstrated a steady propensity for follow-up studies[3] .The German speciality - in-patient rehabilitative psychotherapy - has repeatly provided impressive programm evaluations; the latest one documents process and outcome and follow-up over 4000 psychosomatic patients in behavioral and psychodynamic oriented rehabilitations clinics.(Nübling et al. 1999).

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[3] (Breyer et al. 1997; Dührssen u. Jorswieck 1965; Fenichel 1930), about pre-post evaluations (Bräutigam et al. 1980; Grande et al. 1997; Kordy et al. 1983; Kordy et al. 1988; Kordy et al. 1989; Rad et al. 1998; Rudolf 1991a; Rudolf 1991b; Sandell et al. 1997; Sandell et al. 1998; Senf 1995; Senf et al. 1984)].

The nation-wide multi-center study on eating-disorders - TR-EAT ((Kächele u. für die Studiengruppe MZ 1999) has provided a substantial base on nearly< 1200 patients for investigating a rich facets of issues (Hannöver et al. in press).

Following Ken Howard there are three questions regarding the results of a treatment

1.	**Can this treatment be shown to work? EFFICACY (Phase III)**
2.	**Does this treatment work in practice? -- EFFECTIVENESS (Phase IV)**
3.	**Is this treatment working for this patient? -- EFFICIENCY (Phase V)**

The first two questions are treatment-focused (e.G., main effects) while the latter is patient-focused. There is no necessary logical connection among the answers to these questions (a treatment could be shown to not be efficacious, yet it could be effective; a treatment could be ineffective and efficient for a particular case). The issue of what kind of external evidence we would really need for working in the frame of EBM to us shold be dealt with somewhat differently that it is usually dealt with. Studies with high level of internal validity but low levels of external validity are not likely to be very helpful for making clinical decisons.

The NIMH Collabortaive Study on the Treatment of Depression was huge in internal demonstrated that two psychotherapeutic treatments were roughly equivalent to imipramine (Elkin 1994). So far the good message. From the point of effectiveness the study demonstrated that twelve sessions for the treatment of major deprsssion for a sizeable part of patients are not enough as demosntrated by the number of relapeses in the follow-up period (Shea et al. 1992).

We have to keep in mind that the research methodologies for these questions are distinct:

1. Efficacy	--	Experiment
2. Effectiveness	--	Quasi-experiment Systematic naturalistic observation
3. Efficiency	--	outcome monitoring

Thus the title of this presentation that has been given to me contains conceptual pitfals as I have tried to demonstrate.
I did not select it nor did I protest to it. You may gather from my arguments that I am not convinced that the usual hierarchy of external evidence attributing a prime position to RCT based knowledge clinically does make sense. Instead my favours are clearly directed to effectiveness and efficiency approaches which in my mind will be more useful for a clinican´s decison making process

Psychotherapy research has not yet made great progress to spell out a research model that directly would provide evidence necessary to predict if a particular patient is most likely to utilize best a available treatment. The intention of this efficiency, patient-focused research is to even directly provide information concerning available clinical services (Howard et al. 1994).

Third: what are psychosomatic disorders?

There is considerable dispute among all of us what kind of disturbances should we consider as "psychosomatic disorders" At the 15 European Conference on Psychosomatic Research Lipowski was very succint about the misuse of the term "psychosomatic disorders":

"The concept of psychogenesis and, consequently, the psychogenic connotation of the term 'psychosomatic' can finally and exclicitly be discarded as being incompatible with the modern views on the etiology of the disease. It would be a fallcy to maintain that the chief task of psaychosomatic medicine is to prove psychogenesis of ever more disease. In the case of the most prevalent diseases today, the chronic ones, no single factor can be considered the cause, but rather a complex interaction of contributory factors that are neither necessary nor sufficient appears to be responsible for their occurence...the term 'psychosomatic' should be cleaned of all etiological connotations. Moreover, the use of the term 'psychosomatic disorders 'should be avoided.(Lipowski 1986)

It seems that the field has not followed this admonition; rather an expansion took place. The German standard textbook of psychosomatic medicine (Uexküll 1997) works through a list of specific disorders in the field of internal medicine as well covers quite a number of psychosomatic disturbances in other fields.:

cardiovascular syndrome
hyperventilation syndrome
psychogenic syncopes
gastro-intestinal syndromes
pain
Headache
Anorexia nervosa
Bulimia Nervosa
Sleep disorders
Coronary heart disease
Essential Hypertension
Bronchial Asthma
Duodenal Ulcer

Ulcerative Colitis
Crohn´s Disease
Low Back Pain syndromes
Diabetes Mellitus
Cancer risk and survival
etc

Skipping through the therapeutic recommendations one rarely encounters clear cut recommendations for psychodynamic therapy. Sometimes as for somatoform pain disorders one might find an enthusiastic advertisement:

> Psychoanalytic oriented therapies are widespread in the treatment of chronic pain in Germany but there are still few evaluations especially for long term therapies.(Egle et al. 1992)

Two studies (Basset u. Pilowsky 1985; Pilowsky u. Barron 1990) that both display significant methodological weaknesses point to negative (Pilowsky & Barret) or to unsatisfactory effects. However in the meantime the authors of that aforementioned quotation have performed a controlled study on somatoform pain disorder comparing treatment as usual (TAS) in a pain clinic with a psychodynamic group therapy lasting for 100 sessins lus the pain treatment. On a two year follow - up the finding of an effect size of ES 1.12 in favor of the psychodynamic interventions group (Bürkle-Storz 2000).

For the topic of gastro-intestinal syndromes one finds reference to two formally controlled study of psychodynamic psychotherapy on the irritable bowel syndrom with a Cochrane level of two [Svedlund, 1983 #10168; [Guthrie, 1993 #10179] (see (Egle et al. 1999)
The study by Svedlund has been praised in the reknown Handbook of Psychotherapy and Behavior Change (1994) as one of the early and best controlled trials "that randomly assigned 101 IBS patients to receive standard medical care alone or to receive the medical care plus10 one hourly sessions (spread over three months) of psychotherapy. The therapy was described as "dynamically oriented short term individual psychotherapy" but was focused on teaching new coping strategies for stressful problems as well as on an educational behavioral analysis.... Thus the therapy is very much akin to to any

of the cognitive stress coping techniques. Replications were performed by a number of researchers." (Blanchard 1994)

What is important in these studies is that they provide a different perspective. Epidemiological studies studying community samples have shown that 70 -80 % of people meeting the inclusion criteria for IBS had not consulted a physician. Moreover although symptomatically indistingishable from IBS patients who had sought medical attention, those with IBS symptoms who had not sought help were relatively normal on psychological tests while those who had sought help showed test results typical of a so called "neurotic" or "chronic illness" population (Drossmann et al. 1988). This finding is consistent with many other replicated findings that among a treatment seeking IBS population there are a sizeable majority who will meet the diagnostic criteria for one or more anxiety disorders (usually generalized anxiety disorder or social phobia) or mood disorders (dysthymia or major depressive disorders).

The problem we have to deal with is a basic issue: Does it make sense to ask whether a given diagnostic category is indicative for psychotherapy, let alone for psychodynamic psychotherapy ?
Lambert & Bergin (1994) apportioned the percentage of variance attributed to various therapist, client, and treatment factors and reached the conclusion that client variables are most strongly associated with outcome, followed by the quality of the therapeutic relationship (therapeutic alliance, facilitative relationship, etc.). The estimates of the diagnosis contributing to the outcome has been estimated to be seldom more than 15 %. The use of specific procedures and models (e.g., CT, IPT, etc.) accounts for less than 10% of the total outcome in their analysis.

In order to overcome this issue we should refrain from the idea that we could meaningfully answer the question posed to the lecture.
AE Meyer introduced the taxonomic perspectives first for neurotic clientel in his 1971 handbook article (1971); much he later also suggested it for psychosomatics (Meyer 1994) .We should at least discontinue the assumption that we are talking about homogeneous groups when applying a somatic diagnostic criteria; this would be a useful strategy. Instead a concept that focuses on well-defined subgroups is more likely to be a rewarding object for treatment evaluation

Which subgroups of all so called psychosomatic disorders then are good candidates for psychodynamic psychotherapy ?

We first discuss as prototype a disease where there is agreement that practically all are afflicted with severe psychopathology:

a) Anorexia Nervosa:
There is general agreement that all patients afflicted with this disorder needs psychological intervention - this is not implying that all get into treatment; a variety of treatment mainly - behavioral-cognitive but also psychodynamic interventions have been demonstrated their usefulness in non-randomized pre-post designs; there are to date practically no properly controlled RCT for reasons easy to understand. (Herzog u. Hartmann 1997; Jacobi et al. 1997).
The conclusions from one of the long term studies is quite laconic: "The course of anotrexia nervosa is protracted" (Strober et al. 1997).

b) Bulimia Nervosa
A large body of RCT cognitive-behavioral studies comparing to psychodynamic studies does not show systematic difference in outcome [Hartmann, 1962 #10183; Jacobi et al.1997); however Fairbairn recently has again demonstrated advantage of CBT against IPT.
The true critical issues not answered by these RCT design have been studied carefully in longitudinal observational studies both for a BCT treatment compound [Fichter, 1999 #10174] and for psychodynamic therapy by the German multicenter study TREAT [Kächele, in press #10175]. Both studies demonstrate quite similar long time results for bulimia.
Even this kind of LOS ist still a far cry from the evidence a clinican might want to really know about in detail. In the Psychodynamic German Eating Disorder Study 80% of al patients have been in treatment before the index treatment and 80% % of patients have been in another treatment with the 2.5 years follow up period (Metzger et al. eingereicht) Based on our data from the Eating Disorder Study we have developed a decision tree model that helps to use a variety of clinical parameters for treatment decisions for bulimic patients (in press).

Figure: Predicting patients´rating of outcome

It seems to us that this kind of information is more useful in providing treatment recommendations that just asking for effect sizes. It woud be hard to explain to a patient what the difference of an effect size 0.90 and 1.20 to her would mean!
The evidence related information a clinician would like to know would comprise the following items:
an adaequate knowledge on the natural course of disorder, secondly on an adeaquate knowlede of a proper time when to intervene and when not
the proper form who long an intervention most likely will be useful
what format of treatment - out patient, inptient, intermittent etc
the generic kind of treatment is from all what we know seems the least important

The kind of details that the widespread research on anorexie and bulimia has provided to a certain extent, could be retrieved only to a small degree on any other psychosomatic subgroup.

Let take up for a contrast Crohn disease.
In terms of levels of evidence the German Multi- Center study on psychodynamic interventions in Crohn disease (Jantschek 1998; Wietersheim et al. 2000)
has generated the following findings.
a) There was no general psychopathology of patients, but patients in acute relapse show higher level of depression and anxiety
b) There was no significant difference between treatment and control groups in relation to the course of the disease
c) From the view of the patients´ the participants of the treatment group reported positive results of the pysychodynamic psychotherapy; compared to the control group they report larger changes in the psychological situation, better handling of interpersonal conflict and better capacity for relation. All in all a much better state of mind (Keller 1993; Wietersheim 1999)

The same findings results from some other controlled studies (Schwarz u. Blanchard 1991) und (Milne et al. 1986) This might result in the following

EBM - based recommendation for the treatment of Crohn disease: Patients with additional psychopathology and poor coping and stressful life situation might profit from an psychodynamic intervention. In fact this would be exactly the same recommendation that could be inferred from the available CBT or stress managment studies.
What is lacking in terms of our own critique are longitudinal observational studies with patients with and without psychotherapy; only then covering a life span fundamental difference of coping failures with adaequate support systems might be discovered that are so familiar to the clinician (Kordy u. Normann 1992).

The evidence-related information any clinician working with Crohn patients would like to know would comprise the following:
an adaequate knowledge on the natural course of disorder (Adler 1993).
an aedaequate knowlede how to identify patients at an early stage which could benefits from a psychodynamic intervention (the identification of psychological mindedness as a good prognostic sign for succes in psychodynamic therapy (Piper et al. 1999); other criteria valuable for all kind of psychological interventions could be high level of depression, anxiety and low levels of coping skills and low social support
what we sorely miss are specific instruments to identify goals and goal attainment; there is little agreement on this highly individualized measurement devices.
It is a good sign that the German Society for Gastroenterology has officially included so called psychosomatic aspects in their guidelines. However they are not specific as to what kind of psychotherapy they would recommend. We think that in the face of the well know problem of differential indication (Kächele u. Kordy 1996) this has been a wise decision.

In contrast to these aforementioned fields of intervention which have provided some systematic support, how should we handle the reports by Fonagy & Moran (Moran u. Fonagy 1987, 1990 #10173; Moran et al. 1991). In their treatment of growth-retarded diabetic children, they were able to report three successful replications of their A-B design. They initially tested a boy of eight, a boy of twelve, and finally a girl of twelve. A contingent relationship between psychoanalytic therapy and growth was demonstrated each time. For the clinician this data base may be small or large depending on his or her judgment.

He might wait until more controlled research has corroborated these finding, or he or she may use his or her individual clinical expertise and take into account the patient choice.

I refrain from telling you moving stories of individuals that came to intensive psychoanalytic treatment after a long odyssee first for their psychosomatic conditions, later to turn out to suffer from a severe borderline pathology complicated by f.e. Crohn disease - it would be truely exciting to find a methodology that could bring together this kind of narrative evidence into this scientific arena.

Closing remarks

so called psychosomatic disorders are a mixed group in terms of their affinity to psychological intervention (Meyer 1994). There is a vast heterogeneity in terms of patients´ own motivational status for psychological intervention. Psychosomatic disturbances are part and parcel of many conditions as documented by psychometric instruments like the SCL-90. Psychodynamic therapies may be not the front line approach for illness-related psycholigical sufferings as far as this would be a coping intervention; patients´concept of illness and the concept of most of their physicians´ favours more non-intrspective, handling approaches; to the degree that concepts like the therapeutic alliance are spreading in all kinds of interventions, - sometimes disgoused as compliance - this distinction might become less pervasive; to the degree that more severe psychopathology is involved the more the usual criteria of psychotherapy research may be applied for adaequate judgment of what kind of intervention for what kind of patient. In Germany inpatient psychotherapy especially for patients with diffuse psychosomatic conditions has shown repeatedly to be highly effective on rather large samples. However the ingredients of these compound treatments are hard to disentangle. The mixtures of symptomatic approaches, group psychotherapies and body-related work have become standard in most behavioral and psychodynamic treatments setting. There is an urgent need for serious research initiatives that is focused on questions such as

for which patients does inpatient psychotherapy promise specific advantages (in comparison to outpatient treatment)
how much do individual components of inpatient psychotherapy programs contribute to treatment effects and for whcih patients

how much do environmental factors (milieu factors) influence the therapeutic outcome (Kordy u. Kächele 1997).

There is an accepted tendency in the field of psychotherapy research to move away from comparative studies focusing on disorders; instead dose-effect models have achieved a momentum (Howard et al. 1986). This is in vein with the findings of the Consumer Reports (Seligman 1995) findings where patients satisfaction with treatment was highly correlated with amount of treatment. Individual patients need and seek out individualized treatments, even sometimes psychodynamic psychotherapy is well suited to provide.

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Asthma

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Morbus Crohn

Bulimia Nervosa (Herzog et al. 1992; Herzog et al. 1997)

Anorexia Nervosa

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