Dependence Department, Health Local Agency (ASL) "Città di Milano", Milan, Italy, E.U.

Heroin Add & Rel Clin Probl 2003; 5(3): 19-34 **Research report**

"Vedette" study and "Tracking" project; Their integration and preliminary results

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Summary

Since the end of 2000, our Department has managed two independent research activities. The first, the VEdeTTe Study, is a national multicentric cohort study which aims to evaluate the efficacy of treatment provided by outpatient units (called Servizi Tossicodipendenze, "Ser.T." or SERTs) at national level. The second, Tracking Project, is a local form of research which was devised to "track" the careers of addicts and evaluate changes within therapeutic courses using ASI. As the Study and the Project had the same time frame, we thought it right that each should take account of the other, to yield a result capable of fulfilling the aims of both, and to exploit the potentialities of both research protocols. The preliminary results now available refer to a population consisting of subjects enrolled in 2001 and 2002, and this paper aims to investigate and describe any differences between the two main subgroups: cases of addiction to heroin and cocaine, where one or other was the primary drug abused.

Key words: Efficacy of treatment - Outpatient units - Cocaine abuse - Heroin abuse

Introduction

Research studies in the field of addiction show divergences from those held in other medical sciences, partly because of their complexity; in fact, a study on addiction requires a compulsory investigation on areas outside the medical one, and the study design often includes an exploration of the family, legal, psychological, health and

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substance abuse situations (1,9). This paper is part of an ongoing longitudinal study which is investigating a cohort population of Italian addicts.

DARP (2,13) and DATOS (4,5,12) studies are examples of cohort studies which investigate the long-term efficacy of addiction treatments, considering some specific aspects besides the strictly medical one. These kinds of studies will allow people working in the field of addiction to acquire a deeper knowledge of their own profession, and help them to make an evidence-based choice of the treatment to be provided (6,7,10).

Tracking Project is a funded clinical and epidemiological longitudinal study which aims to re-build the careers of addicts assisted at public outpatient units in Milan, and to provide a shared methodology of data collection and clinical monitoring in five outpatient units working in the city. The project started in December 2000 and will take three years to complete; its main target population is incident cases involving subjects seeking treatment during the study period. In the same period, the Region of Lombardy joined a national multicentric longitudinal cohort study – the VEdeTTe Study – which had the same target population and shared two of its objectives: to describe an addict population using a standardized protocol and to evaluate treatment programmes outcomes and mortality.

Because of a wide range of similarities between Tracking Project and VEdeTTe Study (which were planned independently), it was decided to merge them in Milan to satisfy the project and study needs of both.

This paper is a preliminary report describing the population enrolled in 2001 and 2002, and directing specific attention to the primary drug consumed by these subjects — heroin or cocaine.

Methods

From the onset, Tracking Project was planned to be implemented using a standardized questionnaire able to cover the overall situation of single patients and monitor their clinical evolution, but also able to provide analyses of the entire population. The Italian version of Addiction Severity Index (ASI) — fifth edition — (8) was chosen as study questionnaire because its characteristics allow the pursuit of objectives such as the definition of the level of patients' involvement by using composite scores (11); moreover, it is internationally validated. This last quality made it suitable for population comparisons with other studies, including those outside Italy (9).

The VEdeTTe Study, which is mainly an epidemiological study, has a protocol involving specific materials such as a questionnaire at enrolment time, a sheet to record clinical interventions and a follow-up questionnaire to be answered every two years.

A new questionnaire (called VEdeTTe-ASI) was created to satisfy both studies: it was constructed by adding all the ASI items that had not been previously considered to the standard VEdeTTe form. In this way we were able to respect the original VEdeTTe protocol while implementing our local project, which has a shorter follow-up period (every six-nine months) as internal protocol, and this was another reason for choosing

ASI as research instrument.

After a brief period of employees' training to acquire capability in submitting questionnaires, patients enrolment started, and is still ongoing.

Inclusion criteria for the enrolment of target populations were: incident cases (both true and false incident cases) treated at addiction units from the beginning of 2001 to the end of 2003, heroin or cocaine abuse as primary drug, Italian citizenship. Informed consent was requested from patients, and, in cases of refusal, a section of the questionnaire was filled in by the employee using data from clinical documents.

The questionnaire

VEdeTTe-ASI is a structured interview created by the VEdeTTe Study questionnaire and ASI 5th edition. It is divided into 10 sections numbered as follows: 1) preliminary information and registry data; 2) non-enrolled (specific for patients who do not agree to enter the study); 3-1) socio-demographic data; 3-2) education-employment data; 3-3) legal data; 4) alcohol and substance use; 5) overdose data; 6) previous treatment data; 7) health data; 8) psychiatric-psychological data. Table 1 reports numbers of items for every section and how many of them have been considered for the present paper. 47% of total items were used to perform analyses in this report; it was decided to give a descriptive statistic for the general population and then analyze data for two subgroups on the basis of the primary abuse substance (heroin or cocaine) to bring out any differences between those groups.

Table 1.
Description of questionnaire: numbers of items for each section and numbers of items used in the present paper

Section	*Nos. of items*	*Nos. of items used*
1	16	5
2	97	none
3-1	31	10
3-2	29	13
3-3	37	21
4	121	47
5	18	none
6	24	10
7	38	12
8	37	29
Tot. (excl. section 2)	311	147

Composite and other scores

Composite and other scores (such as employee's score and patient's self-evaluations) obtained by ASI were normalized to allow an internal comparison within each area and among areas: composite score (CS) is a value ranging between 0.00 and 1.00, employee evaluation (EMP) between 0 and 9 (a ten-level score), and both the patient's self-evaluations (perception of problematic situation – PAT1 - and treatment need – PAT2) between 0 and 4 (five-level scores).

Statistical analysis

Only descriptive statistics were performed on the total sample. Statistics between groups were performed using the X^2-test for categorical variables and the unpaired T-test for continuous variables. Other methods were not considered because of the limited sample actually available.

Results

In 2001 and 2002, 187 subjects were enrolled in the study: mean age (±SD) was 36.2±7.5 years and males represent 79.7% of the entire sample. Most of them (79.7%) underwent treatment as voluntary choice, and 17 (9.1%) subjects were under probation

Table 2.
Social characteristics

	No.	%
Marital status		
Unmarried	116	62.0
Married	27	14.4
Cohabiting	21	11.2
Separated/divorced	21	11.2
Widow/widover	2	1
Living status (in household)		
With partner and children	25	13.4
With partner	37	19.8
With children	1	0.5
With parents	67	35.8
With friends	10	5.3
Level of education		
None	3	1.6
Primary school	10	5.3
Secondary school	88	47.1
High school	75	40.1
University	11	5.9

or on parole. 116 subjects (62.0%) declared they had been treated previously at another public unit. Other social characteristics are listed in table 2.

Working status has been investigated using multiple items: current employment, employment during the last three years and the Hollingshead classification (as ASI item). Table 3 and fig. 1 summarize the previous and current working situation.

Table 3
Values for working status at time of enrolment and during the previous three years

Working status	*Current (%)*	*Last three years (%)*
Stable	86 (46.0)	105 (56.8)
Unstable	36 (19.3)	54 (28.9)
Student	5 (2.7)	6 (3.2)
Housewife, pensioner	4 (2.1)	1, (0.5)
Unemployed	56 (29.9)	19,(9.6)
Protected job	-	2 (1.0)

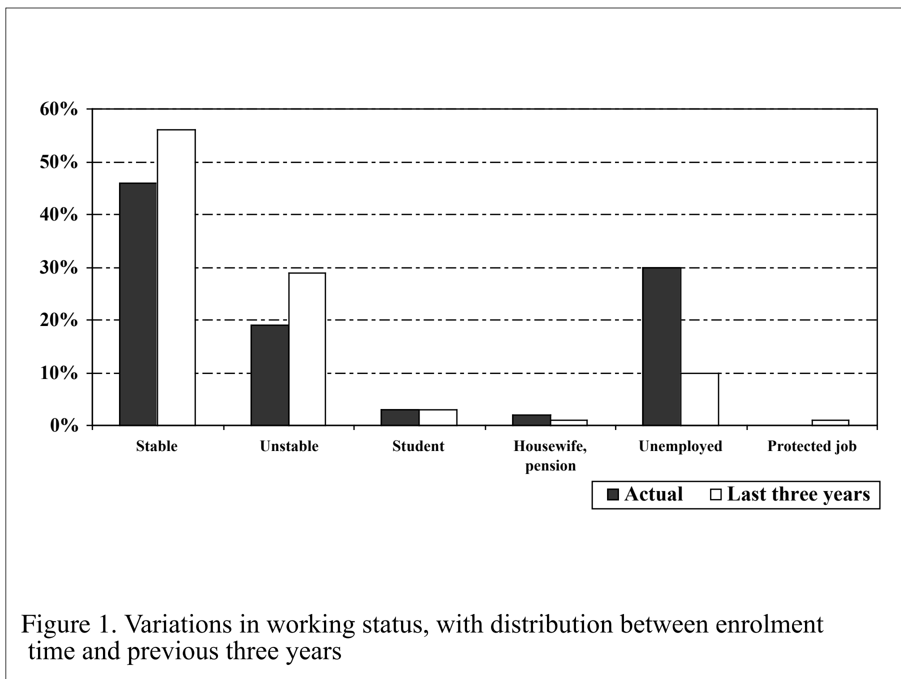

Figure 1. Variations in working status, with distribution between enrolment time and previous three years

The Hollingshead classification shows the prevalence of workers with or without a specialized job (64.4%) and clerks or traders (26.7%); 14 subjects (7.5%) assigned themselves to category 2 (manager).

The legal section indicates that 110 cases (58.8%) have had problems with the legal system, and 71 subjects have a lifetime prison record. 52 patients declared legal problems during the previous 12 months, and 31 had been in prison. Altogether, 533 crimes were recorded: the most frequent were those related to illicit drug offences (126), theft/shoplifting/receiving/bag-snatching (164), robbery (40) and aggression (33), while 74 crimes were classified under "other".

The drug section is the most interesting area, as it forms the core of the investigation: this section tries to explore the pattern of use of illicit drugs (and alcohol) and how they are used/abused. Firstly, the most abused primary drug was heroin (129 subjects; 69%), all the other cases were classified with cocaine as main drug (or, rather, the drug for which treatment was requested), but, in analyzing the ASI item about the problem drug(s) used, we observed that 6 cases (3.2%) declared no drug, 104 (55.6%) heroin,

Table 4.
Frequency of drug use in the previous 30 days: numbers of subject who declared they had used the drug, with mean value of use and maximum use recorded

Drug	*No. of Subjects*	*Mean use (mg.)*	*Max. (mg.)*
heroin	117	36.5	300
cocaine	97	13.6	300
amphetamines	4	0.1	3
ecstasy	5	0.2	20
cannabis	82	15.9	300
hallucinogens	4	0.8	90
benzodiazepines	17	4.4	176
other opiates	0	0.0	0
methadone	40	5.2	31
barbiturates	0	0.0	0
inhalants	1	0.0	4
alcohol (any use)	95	18.8	180
alcohol (intoxication)	13	1.0	30
more than one drug	41	6.7	150

42 (22.5%) cocaine, 1 (0.5%) ecstasy, 11 (5.8%) alcohol and drug(s) and 23 (12.3%) polydrug abuse.

Another item recorded was the number of times a drug had been used during the last 30 days, and the results are shown in table 4.

The reasons which drove subjects to request enrolment in a programme so as to receive treatment for their drug abuse problem are listed in table 5.

Some items investigate psychic area both directly and indirectly: generally items of this kind try to compare specific situations through time. The first group reports situations before and after the onset of drug use (table 6). As most of these conditions

Table 5.
Reasons for treatment: multiple answer question. Absolute numbers of choice and their percentage vs. the whole sample.

	No. (%)
Stop drug use	149 (79.7)
Reduce symptoms related to drug use	41 (21.9)
Reduce drug need	51 (27.3)
Reduce withdrawal symptoms	36 (19.3)
Maintain drug-free status	62 (33.2)
Psychological support	106 (56.7)
Social and work rehabilitation	84 (44.9)

Table 6.
Presence of psychic symptomatology before and after onset of drug use, and absolute and relative variations.

	Before onset	*After onset*	*D (D%)*
Anedonia	50 (26.7%)	137 (73.7%)	+87 (+47.0%)
Depression	73 (39.0%)	139 (74.3%)	+66 (+35.3%)
Self-injury	20 (10.7%)	36 (19.3%)	+16 (+8.6%)
Suicidal attempts	9 (4.8%)	28 (15.0%)	+19 (+10.2%)
Anxiety	106 (56.7%)	153 (81.8%)	+47 (+25.1%)
Acting-out	34 (18.2%)	50 (26.7%)	+16 (8.5%)
Hallucination/delirium	4 (2.1%)	35 (18.7%)	+31 (+16.6%)
Treatment as psychiatric outpatient	8 (4.3%)	19 (10.2%)	+11 (+5.9%)
Admission to psychiatric clinic	6 (3.2%)	15 (8.0%)	+9 (+4.8%)

Table 7.
Presence of psychic symptoms not related to drug use over lifetime and in the previious 30 days.

	Lifetime	*Last 30 days*
Severe depression	64 (34.2)	27 (14.4)
Severe anxiety	101 (54.0)	70 (37.4)
Hallucinations	5 (2.7)	5 (2.7)
Problematic understanding	15 (8.0)	12 (6.4)
Problematic control of violent behaviours	29 (15.5)	9 (4.8)
Serious suicidal ideas	26 (13.9)	9 (4.8)
Suicidal attempts	15 (8.0)	3 (1.6)
Drug prescription for psychic problems	39 (20.9)	24 (12.8)

could be directly related to drugs effects, another item investigated the lifetime presence of such symptoms and their presence during the last 30 days not linked with drug consumption (table 7).

The last psychic item is a control item filled in by the interviewer regarding the patient's situation during questionnaire submission. It investigated the presence of depression (observed in 26 cases; 13.9%), hostility (2 cases, 1.1%), anxiety (48 cases; 27.5%), thought disturbances (4 cases; 2.1%), memory and concentration problems (15 cases; 8%) and suicidal ideas (3 cases; 1.6%).

CS, EMP, PAT1 and PAT2 values for each area have been normalized and compared in figure. 2. These values belong to significantly different contexts (CS values refers to the last 30 days, the EMP ones have a lifetime scope, while the PAT1 and PAT2 ones are subjective evaluations made by patients), but, if analyzed together, they could take on clinical and research dimensions.

Group analysis

Comparison of cases according to the primary drug abused (heroin or cocaine) showed that each subgroup under study has some specific characteristics.

First of all, CS displayed significant differences in the work, legal and drug abuse areas (figure 3). Patients' and employees' evaluations showed significant differences only for the areas shown in figure. 4.

Most cocaine patients had never been previously treated at a public unit (87.9% vs. 50.4%; $p<0.001$), and had never undergone any kind of treatment (70.7% vs. 38.0%; $p<0.001$). Contact was voluntary for 86.8% of heroin cases (vs. 63.8% for cocaine), while probation or parole was higher for cocaine users (15.5% vs. 6.2%; $p<0.01$). 10.5% of cocaine users had been in prison during the previous 30 days (vs. 1.6%). No differences were found in marital or living (household) status, while level of education was significantly higher for heroin users ($p<0.05$), as was their Hollingshead classification

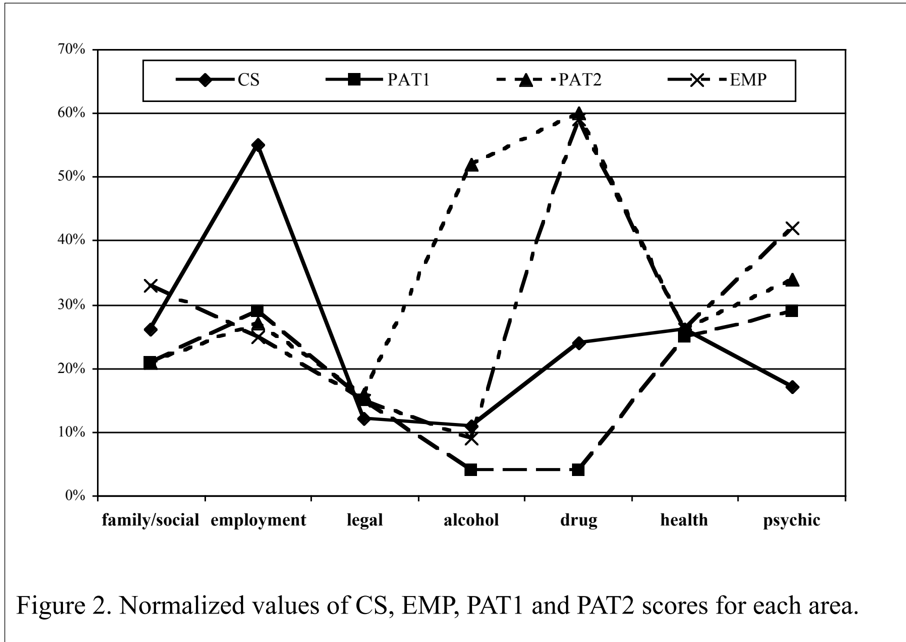

Figure 2. Normalized values of CS, EMP, PAT1 and PAT2 scores for each area.

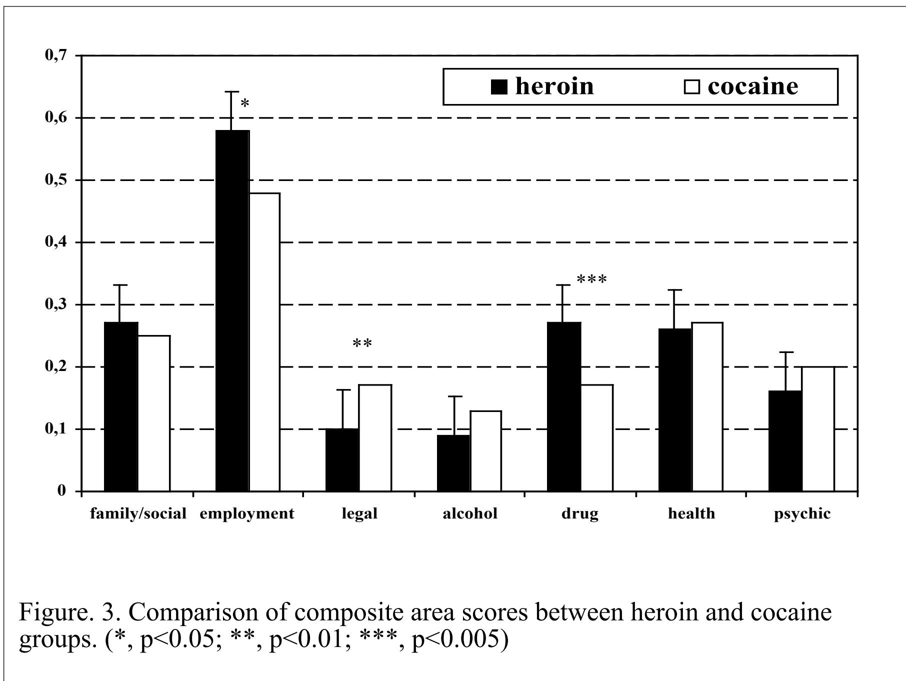

Figure. 3. Comparison of composite area scores between heroin and cocaine groups. (*, $p<0.05$; **, $p<0.01$; ***, $p<0.005$)

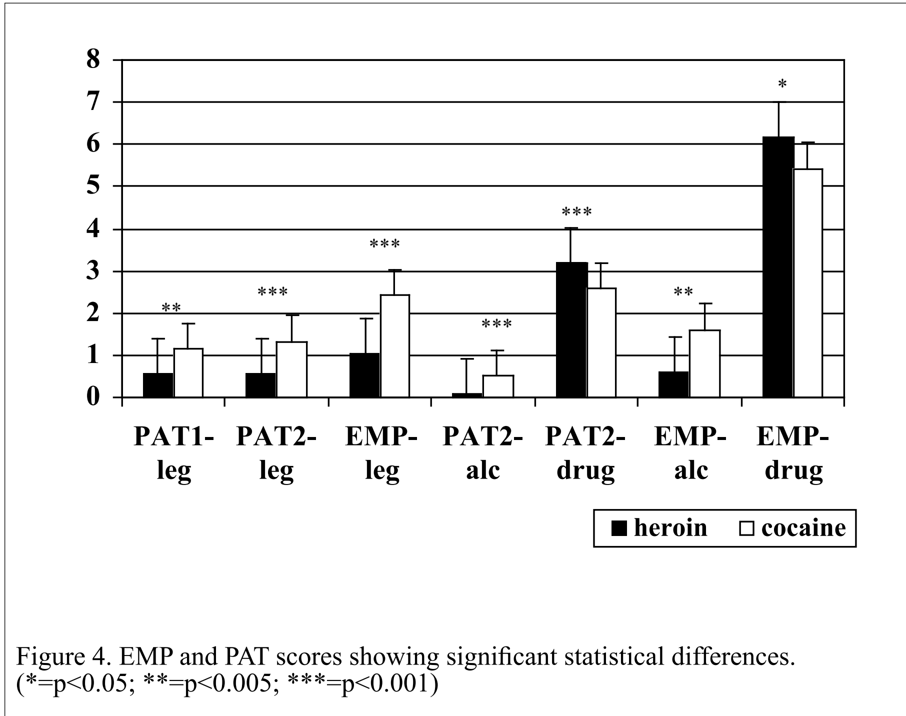

Figure 4. EMP and PAT scores showing significant statistical differences. (*=p<0.05; **=p<0.005; ***=p<0.001)

(p<0.05). Unemployment growth was high in both groups when their current status was compared with that during the previous three years, rising from 9.3% to 30.2% for the heroin subgroup and from 10.3% to 29.3% for the cocaine subgroup, respectively.

On a lifetime basis, legal problems were similar (30.2 vs. 34.5; heroin vs. cocaine), but in the previous 12 months the cocaine group had a higher involvement (20.9% vs. 43.1%; p<0.05), followed by more frequent imprisonment during the same period (20.0% vs. 41.5%; p<0.05).

Alcohol and substance (ab)use have been investigated by crossing two different items: the primary drug abused and the drug(s) which represent(s) the main problem (ASI item). Results are shown in table 8. Alcohol consumption is higher in the cocaine group, even when considering the average number of times alcohol was used in the preceding 30 days — 21.62 times vs. 23.27 (any use), and 1.81 vs. 3.19 (intoxication), respectively.

The reasons which drove subjects to request enrolment in a programme for treatment of their problem drug use show significant differences between groups (table 9).

Psychic symptomatology by groups shows that cocaine users suffer severer impairment than heroin addicts. The presence of disturbances before and after the onset of drug use is shown in table 10 and their differences in figure 5. The presence of any psychiatric problem not linked with drug abuse both during patients' lifetime and dur-

Table 8.
Comparison between heroin and cocaine groups vs the main problem drug(s) declared by patients

	Primary drug	
	Heroin	Cocaine
	N (%)	N (%)
Main problem		
None	2 (1.6)	4 (6.9)
Heroin	104 (80.6)	
Cocaine	1 (0.8)	41 (70.7)
Amphetamines	1 (0.8)	
Alcohol and drugs	4 (3.1)	7 (12.1)
More than 1 drug	17 (13.2)	6 (10.3)

Table 9
Differences in reasons for treatment between groups.

	Heroin	Cocaine	p
Stop drug use	115 (89.1%)	34 (58.6%)	<0.001
Reduce symptoms related to drug use	27 (20.9%)	14 (24.1%)	ns
Reduce drug need	39 (30.2%)	12 (20.7%)	ns
Reduce withdrawal symptoms	31 (24.0%)	5 (8.6%)	<0.05
Maintain drug-free status	45 (34.9%)	17 (29.3%)	ns
Psychological support	70 (54.3%)	36 (62.1%)	ns
Social and work rehabilitation	56 (43.4%)	28 (48.3%)	ns

ing the last 30 days reveals no significant differences between groups and is similar to that for the whole sample. Interviewers' reports about patients' situation when the questionnaires were submitted showed that depression and anxiety had a significantly higher incidence in the heroin group — 17.8% vs. 5.2% ($p<0.05$) and 30.2% vs. 15.5% ($p<0.05$), respectively.

Discussion

The introduction of the VEdeTTe-ASI questionnaire within the clinical work of public outpatient clinics for addiction treatment was the most difficult step: as each clinic based its work on its own history, experience and protocols, this new shared protocol initially aroused suspicion and diffidence: by now we can say that it is being used as a standard clinical tool. It is important to stress this aspect, because employees

Table 10. Presence of psychic symptomatology by groups before and after onset of drug use				
	Heroin		Cocaine	
	Before onset	After onset	Before onset	After onset
Anedonia	39 (30.2%)	100 (77.5%)	11 (19%)	37 (63.8%)
Depression	55 (42.6%)	98 (76.0%)	18 (31.0%)	41 (70.7%)
Self-injury	13 (10.1%)	21 (16.3%)	7 (12.1)	15 (25.9%)
Suicidal attempts	5 (3.9%)	16 (12.4%)	4 (6.9%)	12 (20.7%)
Anxiety	74 (57.4%)	105 (81.4%)	32 (55.2%)	48 (82.8%)
Acting-out	21 (16.3%)	28 (21.7%)	13 (22.4%)	22 (37.9%)
Hallucination/delirium	3 (2.3%)	15 (11.6%)	1(1.7%)	20 (34.5%)
Treatment as psychiatric outpatient	6 (4.7%)	8 (6.2%)	2 (3.4%)	11 (19.0%)
Admission to psychiatric clinic	4 (3.1%)	4 (3.1%)	2 (3.4%)	11 (19.0%)

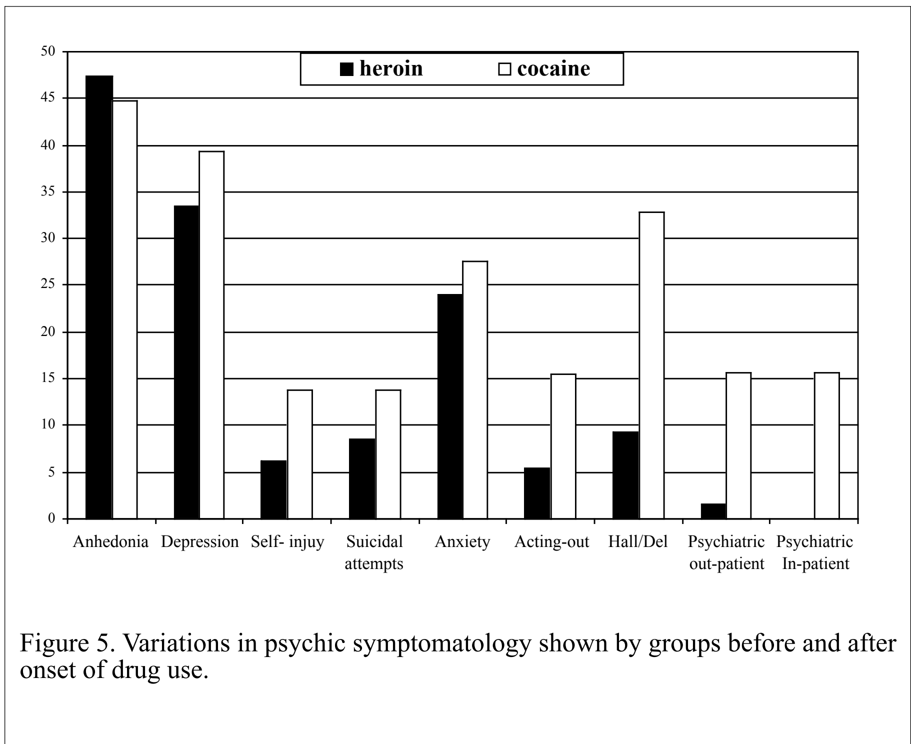

Figure 5. Variations in psychic symptomatology shown by groups before and after onset of drug use.

have come to recognize the clinical utility of the questionnaire, so that it is now felt to be not merely an instrument for research but a tool which allows them to approach patients in a standardized way, improving the quality of submissions and the completeness of data collection. Moreover, VEdeTTe-ASI is able to meet European standards for data collection (3).

Results from the whole sample show data for age, gender, education and living and working status very similar to those of the general population being served by the Italian national health service. As expected, unemployment proved to be higher at enrolment time than during the previous three years (+20.3%), suggesting that addiction is an important factor in the impairment of work activity.

Legal problems, imprisonment and crimes show that most patients (58.8%) have entered into conflict with the legal system, even if the kinds of crimes committed seem to be mainly related to small-scale crime.

Substance abuse was the section made surprising by the detailed nature of the data collected: in fact, the national standard protocol of data collection does not allow such a rich spectrum of variables, so making it difficult to describe the pattern of use and abuse of single drugs or the results of the simultaneous consumption of two or several drugs. Table 4 suggests that more than half of all patients (52.8%) had used cocaine during the previous 30 days, while 31% declared cocaine to be the primary drug they had been abusing; the table also shows that 41 patients had consumed more than one drug at the same time, so making it reasonable to hypothesize some cocaine use among these subjects too. As only cocaine and heroin were considered as the primary drug being abused, any other kind of drug use can be considered as concomitant to the primary one, and this suggests that poly-(ab)use may be very frequent among patients enrolled in the protocol. In 34 cases (18.1%) there was an awareness that the main problem of abuse was polydrug or drug(s)+alcohol consumption.

The reasons for enrolling in a treatment programme were investigated by a multiple choice question. The need to stop drug use was the most frequent (and simplest) answer, but the need to have psychological support and access to social-work rehabilitation were chosen by half the group, suggesting a strong motivation to change and a need for interventions addressed to targets different from drug use alone.

The items investigating psychic areas were particularly rewarding, because they brought into focus new aspects beyond typical dual diagnosis. The presence of psychic disturbances is relatively frequent before the onset of drug use, and increases considerably after drug consumption has started (table 6); it seems to be directly related to drug effects, but some other conditions could be involved in the onset of such symptoms. Simply, a longer exposure over time (the ageing factor) raises the probability of encountering this kind of problem, and, even if it is now known that addicts show a higher prevalence of psychiatric problems, it would be interesting to compare these data with those from the general population when matched for age. Anyway, when patients are asked about the same psychic disturbances independently of drug use (table 7), the prevalence is similar to what was declared for the period leading up to drug use. It is

therefore likely that the increase in symptomatology after drug use starts is really due to the effects of psychotropic drug.

CS and other value scales have been brought together in figure 2, in spite of the differences in their significance, to yield a comprehensive view of severity. It is important to note that some areas show sharp differences: the employment area has a very high CS value partly because of the higher rate of unemployment at enrollment time compared with the situation during the previous three years. The low CS value for drug area depends on a mathematical bias, as the algorithm that generates CS in this area comprises several items (all the kinds of drugs included in ASI); this helps to dilute the final result. The PAT2 and EMP evaluations seem to give a better picture of the real situation of severity in the drug area.

The comparisons between the cocaine and heroin subgroups bring out some differences which, if confirmed, could offer distinctions between populations of cocaine or heroin addicts. The employment and drug areas showed a higher CS for the heroin group, while legal issues were more severe in the cocaine group. These observations are confirmed by the PAT and EMP values. The legal area seems to be more at issue in the cocaine group, whereas the heroin group is significantly more involved in the problematic drug area. No differences emerge between the groups in the employment area, while the cocaine group records higher values in the alcohol area, so supporting the evidence that cocaine users are often alcohol consumers. In fact, table 8 shows that the cocaine group admits a higher double dependence on alcohol and a drug (probably cocaine); the X^2 test was significant but that was due to the specificity of heroin and cocaine users, and not to the data for the alcohol+drug problem. Reasons for treatment differ significantly for two items: the need to stop using drugs and the need to reduce withdrawal symptoms. The first result depends on the absence of any treatment drug able to control cocaine consumption; the heroin group can use substitution therapies which are very effective in controlling drug use, whereas cocaine abusers have no such opportunity. As to withdrawal symptoms, acute heroin abstinence implies a severe physical symptomatology, whereas cocaine abstinence is sometimes less evident and critical.

More detailed comparisons confirm that cocaine patients are more deeply involved in the legal area: probation or parole are significantly higher in the cocaine group, as well as crime and imprisonment in the preceding year. Heroin addicts consider the SERTs a resource (independently of the legal problems), while cocaine addicts are more inclined to use them if legal problems must be faced — if, that is, the Public Service becomes the only way of enjoying legal benefits. This kind of hypothesis could best be investigated adding a new possible answer, such as "*to decrease the consequences (real or hypothesized) of an administrative or penal sanction*" in the item 'reason for treatment', even if the Italian legal system provides sanctions to urge subjects to enrol in a treatment programme.

This higher propensity to experience problems with the legal system may also be related to the observation that this group is significantly worse in its psychic symptoms

of aggressive type, which are directly related to the psychotropic effects of cocaine (figure 5).

Conclusion

Although this report is based on preliminary data and intermediate observations, the richness and detail of the information provided allow qualitative and quantitative findings. Several different items taken from an enrolment questionnaire (economic data, overdoses, infectious diseases and previous treatment data) can be processed for a study population to identify group characteristics. Follow-up interviews and data from treatment records are tools which complete the scenario of addiction problems in Milan, because their acquisition will give specific information about the kinds of intervention provided (outputs) and the results obtained (outcomes). Collaterally, the collection of economic data is ongoing and cost-benefit analysis will be performed using information from VEdeTT-ASI.

At this time, our observations suggest that addiction to psychotropic drugs is a severe disease which involves all the facets of a subject's life. Even if drug consumption is the main issue, it is only the core area of a general situation that ramifies out to include the social, work, legal and psychic fields. The implementation of our protocol till it achieves standard, stable use after project and study completion will allow us to monitor with great accuracy epidemiological changes in the Milan area and the clinical evolution of single patients.

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