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A Comparison of Patient Dosage Deviation Reports with Pill Counts*

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Introduction

In a recent article, JOYCE (1962) has indicated that clinical trials may be made more sensitive by identifying "participators" and "non-participators"; e.g., patients who adhere or do not adhere to dosage regimen.

Since verbal reports are usually relied upon to accomplish this, an attempt to compare the congruence between patients' verbal reports and a more objective index of "participation", namely, pill count, is reported here.

Method

These data were collected during a controlled study of the effects of imipramine and placebo on a group of 42 neurotically depressed outpatients seen at the Henry Phipps Psychiatric Clinic of the Johns Hopkins Hospital (UHLENHUTH and PARK 1964).

At each of four brief biweekly interviews patients were given a surplus of pills and asked to cooperate by returning the remaining pills at the next scheduled interview. At the following interview, patients were asked whether they had taken the prescribed number of pills and, if a deviation was reported, the patient was asked to estimate the number of pills missed.

Results

A total of 36 patients (86% of the sample) returned at least one bottle, with 118 out of a possible 168 bottles (70%) being returned. Since the contents of one bottle could not be matched with the patient's verbal report, 117 bottles constitute our sample. Examination of these 117 bottles revealed that 51% contained more pills than they would have if patients had taken 2 pills three times a day as prescribed by the treating

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doctor. The bottles were then classified by pill content as those where the count indicated no deviation, minor deviation ($\leq 1/3$ prescribed dosage returned) and major deviation ($> 1/3$ prescribed dosage returned) as shown in the Table.

The verbal reports of the 36 patients who returned bottles were also classified as indicating no deviation, minor deviation ($\leq 1/3$ prescribed dosage missed) or major deviation ($> 1/3$ prescribed dosage missed). In the Table, these patient report classifications are compared with the deviation classifications obtained from the actual pill count.

Table. *Data by matched pill counts and verbal reports for returned bottles*

		Dosage deviation by report			
		None	Minor	Major	
Dosage deviation by pill count	None	55	2	0	57
	Minor	39	6	1	46
	Major	6	1	7	14
		100	9	8	117

As examination of the Table reveals the following interesting statistics:

a) In 47 out of 117 instances (40%) there is a discrepancy between the patient report of any deviation (major plus minor) and the pill count index of any deviation (major plus minor).

b) This discrepancy is mainly attributable to the fact that pill counts reveal a much larger percentage of deviation (51%) than patients' reports (15%).

c) In general, when patients report deviations (17 instances) there is close correspondence to deviation by pill count (15/17, 88%). On the other hand, the converse of this statement is not true. That is, when no verbal report of deviation is made (100 instances) the corresponding pill counts are only slightly less likely to be classified as non-deviant (55/100, 55%) than deviant (45/100, 45%).

d) A higher proportion of major deviations by pill count is accompanied by deviation reports (8/14, 57%) as compared with minor pill count deviations vs. reports (7/46, 15%). In other words, patients are more likely to report a deviation when a major deviation has actually occurred. Of the 14 major deviations by pill count, 7 are accompanied by verbal reports sufficiently accurate to indicate the deviations are this extensive. Thus, verbal reports pinpoint 50% of the major deviations located by pill counts. (Conversely, there is only one instance in which a patient reports a major deviation which is not supported by pill count.)

Discussion

These data strongly support the concept that accuracy of patient reports can be improved if aids to objectivity are furnished (1960). They also indicate the relative inaccuracy of patient observation in reporting absence of deviation and minor deviations as compared with reporting of major deviations.

Subsequent experience shows that the high percentage of patient cooperation in returning excess pills (70%) can be increased by more thorough instructions. The fact that patients did not make comments indicating concern over the procedure suggests this is a relatively painless way to obtain objective information regarding medication intake. Following another drug study in which this and other obvious research procedures were employed (tape recorder, one-way screen and frequent doctor changes), patients were asked to comment on their reactions and were questioned whether research was involved; again, there were no complaints about returning pills and bottles, and only 3 of 72 patients were positive that research was involved at all (PARK and SLAUGHTER).

With regard to specific recommendations, it is felt that a drug study in which patients taking insufficient medication are to be identified should include both pill counts and verbal reports. When the patient returns his bottle, the pill count method can be relied on as more accurate than the patient's report. However, the data suggest that in just those instances in which it is particularly important to know how much patients deviate from dosage schedule, i.e., when patients take less than two-thirds of their medication ("technical drop-outs"[1]), a good percentage can be determined by verbal reports. Thus, verbal reports help to some extent in classification of data for those patients who do not return bottles.

Summary

This is a report of a comparison between patient verbal reports of dosage deviation during a drug study and pill counts. Pill counts are much more reliable, but verbal reports are of some value, since when there are statements of major deviations they tend to be correct.

References

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[1] With regard to the evaluation of drug effects in this study, the importance of such a distinction was not assumed at the time of patient intake and data analysis.

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