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# CASE STUDY: EFFECTS OF NALTREXONE AND SIBIS ON SELF-INJURY

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The present case study was an effort to determine the relative effectiveness of two variant treatment modalities, and to provide an exploratory study of the hypothesis that therapy with naltrexone might increase the effectiveness of an aversive stimulus in controlling self-injury. Data are presented for a man who was treated for severe self-injury with the Self-Injurious Behavior Inhibiting System (SIBIS) and naltrexone, conducted under open-trial conditions utilizing fixed doses of 50 mg, 75 mg, and 100 mg per day. The effects of naltrexone on SIB were evaluated alone and paired with SIBIS. When used alone, lower dosages of naltrexone produced moderate decrements in self-injury. However, the rate of SIB increased in a dose-dependent manner when naltrexone was paired with SIBIS. The data also suggested that naltrexone may have caused a generalized blunting of both positive and negative affect.

Self-injury among persons with developmental disabilities occurs in approximately 10% to 15% of persons who reside in institutional facilities (Johnson & Day, 1992), and a plethora of treatments have been developed to deal with this disorder. However, no treatments have proven consistently effective, and the care of an individual with severe self-injurious behavior (SIB) may exceed $100,000 per year (National Institutes of Health, 1989). Thus, the development of effective treatment modalities is a major research priority in order to lower costs associated with this disorder both financially and in terms of human suffering.

Self-injury is frequently hypothesized to be the result of operant conditioning

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and/or to serve a communicative function (Carr & Durand, 1985). However, theories regarding possible biological mechanisms underlying SIB have also received much support (Harris, 1992). Of recent interest as a possible treatment for self-injury is naltrexone, an orally administered opiate antagonist. To date, there have been at least 17 published studies reporting its use with individuals who emit self-injurious responses (Ricketts, Ellis, Singh, & Singh, in press). The suggestion that naltrexone may be effective in the treatment of SIB is derived from theories regarding possible dysfunctions of endogenous pain control mechanisms, specifically the endorphinergic system. Two fundamental theories have been postulated which focus on dysfunctions of endorphinergic mechanisms as a mediator in the development and maintenance of SIB. The first is that there is excessive basal activity of endorphins resulting in increased pain thresholds. The second is that self-injurious responses produce endorphins which have analgesic and euphoric properties and which may therefore function as positive reinforcers for SIB (Sandman, 1990/1991; Singh, Ellis, Singh, & Ricketts, in press).

We present a case report on a 28-year-old man who had a 25-year history of self-injurious behavior. Treatment consisted of naltrexone and utilization of the Self-Injurious Behavior Inhibiting System (SIBIS), an aversive treatment procedure which has been the focal point of much debate (Axelrod, 1990; Linscheid, Iwata, Ricketts, Williams, & Griffin, 1990). Extant literature regarding the treatment of self-injury with either naltrexone or SIBIS is limited. This case study is therefore highly unique in that the effects on SIB of naltrexone and SIBIS, alone and in combination, were assessed in order to determine their relative effectiveness. Further, because naltrexone therapy may act to decrease pain thresholds, it was hypothesized that treatment with an opiate antagonist would enhance the effectiveness of the aversive stimulation.

## METHOD

### Subject

The subject was a man with profound mental retardation and epilepsy. He was one of five subjects with whom SIBIS had previously been used (Linscheid *et al.*, 1990). In this report, the subject was referred to as "Michael". SIBIS was highly effective in controlling SIB for almost 3 years, at which time significant decrements in the effectiveness of the procedure began to occur (Ricketts, Goza, & Matese, 1992). It was at this time that the trial of naltrexone therapy was conducted.

Michael had a long history of SIB with mild head-banging reportedly occur-

ring as early as 3 years of age. At age nine he was institutionalized, and severe SIB was reported as early as age 10. Medical consultation prior to the use of SIBIS, at age 25, indicated that the intensity and frequency of SIB would result in gradual and cumulative neurological damage if left uncontrolled.

Comprehensive functional and ecological assessments failed to reveal any operant or environmental factors which were significantly correlated to the self-injurious responding. SIBIS was the only treatment procedure that was found to decrease SIB response rates. Also, Michael rarely demonstrated any external behavioral signs (e.g., crying, grimacing) which indicated that engaging in even intense episodes of SIB was painful. Similarly, except on the rarest of occasions, he did not exhibit any physical or affective response to the administration of shock from SIBIS (e.g., startle responses, flinching, jerks, change in facial expression, crying). Taken together, these factors suggested that endogenous factors might be primarily responsible for his self-injury. Therefore, due to the decreasing effectiveness of SIBIS and Michael's apparent insensitivity to pain, the treatment team determined that a trial of an opiate antagonist would be the appropriate next step in his treatment plan. This plan was further approved by his legal guardian and a Human Rights Committee.

## Apparatus

SIBIS is designed specifically for use with humans and delivers response contingent electric stimulation (84 volts, 3.5 milliamperes) to the arm or leg. It has the capability of either automatic stimulus delivery via an impact detector module worn on the head, or manual stimulus delivery via a remote wireless transmitter. Only the manual system of stimulus delivery was utilized as part of the present investigation. A more complete description of the device is provided by Linscheid *et al.* (1990).

## Procedures

The study consisted of an open trial of naltrexone incorporating a 17-day baseline phase followed by four fixed-dose drug phases of 50 mg (0.8 mg/kg), 75 mg (1.2 mg/kg), 100 mg (1.6 mg/kg), and 50 mg, followed by a 3-week return to baseline phase. The drug phases lasted 7 weeks, 3 weeks, 4 weeks, and 1 week, respectively. A single dose of naltrexone was administered each morning.

During baseline phases, data on rates of SIB were collected under two conditions: No SIBIS and SIBIS Active. SIBIS Active conditions consisted of the application of SIBIS to Michael's arm or leg, and delivery of a single stimulation contingent on a SIB response. In No SIBIS conditions, SIBIS was not applied and no consequences were delivered contingent on SIB responses.

Procedures utilized during active drug phases were identical to baseline phases, except that Michael received naltrexone. Thus, self-injury was assessed under two conditions: No SIBIS (or naltrexone alone) and SIBIS Active (or naltrexone plus SIBIS).

## Response measurement and reliability

### *Self-injurious behavior*

Michael's SIB response topography of interest was head-hitting and head-banging, defined as any forcible contact between hand and head or head and object, or contact between hand and head or head and object which was not forcible but was otherwise topographically identical to forceful SIB. His other SIB responses (e.g., leg slapping and eye poking) were mild in nature and were not addressed. Data were collected each day in Michael's bedroom area, Monday through Friday, from approximately 8:30 A.M. to 4:30 P.M. Observation sessions were conducted on a 30 min cycle. At the beginning of each 30 min period, event data were collected on the occurrence of SIB for 5 min under the No SIBIS condition. Immediately subsequent to this observation session, SIBIS was placed on Michael and event data were collected on the occurrence of SIB for an additional 5 min under the SIBIS Active condition. This sequence was chosen in order to minimize the potential for carryover effects.

No demands were made on Michael during observation sessions and observers did not initiate any interaction during these sessions. However, Michael occasionally initiated interaction which typically consisted of holding hands and walking about the room. In such cases, observers passively engaged in the interaction, making no attempts either to assist or resist the interaction. In addition, no leisure or training materials were available during the observation sessions, although their presence or absence was probably not significant for Michael because he did not show any interest in such materials.

A total of 789 and 853 observation sessions were conducted in the SIBIS Active and No SIBIS sessions, respectively. Independent reliability observations were conducted during 25.5% of the SIBIS Active sessions and 51.2% of the No SIBIS sessions. Session agreement scores for both conditions ranged from 0% to 100%, with a mean of 97.9% for the SIBIS Active sessions and a mean of 94.7% for the No SIBIS conditions. Total agreement was calculated for each 5 min session (Page & Iwata, 1986).

During SIBIS Active conditions, 159 sessions (20.2%) were terminated early. Session length of these sessions ranged from 0.56 to 4.85 min with a mean duration of 2.2 min. SIBIS Active sessions were terminated early if the number of stimulations received reached 30, or if the number of SIB responses exceeded

100. No SIBIS sessions were not terminated early regardless of frequency of SIB responses as Michael wore protective equipment at all times other than during SIBIS Active sessions.

Follow-up was conducted 5 weeks, 8 weeks, and during weeks 10 through 13, following the discontinuation of treatment with naltrexone. This corresponds to 2, 5, and 7–10 weeks following the end of the 3-week return to baseline phase. Rate of self-injury was recorded under naturalistic conditions, at random times throughout the day, during 37, 30, and 20 ten min observation sessions, respectively. SIBIS was not utilized during any of these follow-up observations. Interrater agreement was assessed during 22% of the sessions and ranged from 92.1% to 100%, with a mean of 95.6%. Total agreement (Page & Iwata, 1986) was utilized to calculate reliability.

### *Collateral behavior*

A continuous 15-s partial interval recording procedure was used to collect data on collateral behaviors during SIBIS Active and No SIBIS conditions, with the intent of providing a measure of his affective response to treatment. The measured behaviors included smiling, happy vocalizations, and distressed vocalizations. Happy vocalizations consisted of "singing" and stereotypic noises. Distressed vocalizations were defined as moaning, crying, or making whining noises. Data were collected on each of the collateral behaviors during a total of 161 of the SIBIS Active observation sessions previously described, and during a total of 170 of the No SIBIS observation sessions.

Independent reliability observations were conducted during 28% of the total sessions for the SIBIS Active and No SIBIS sessions. For smiling, mean session agreement scores for the SIBIS Active sessions ranged from 50% to 100%, with an overall mean of 97.7%; while mean session agreement scores for the No SIBIS sessions ranged from 83.3% to 100%, with an overall mean of 99.6%. For happy vocalizations, mean session agreement scores for the SIBIS Active sessions ranged from 0% to 100%, with an overall mean of 96.9%; while mean session agreement scores for the No SIBIS sessions ranged from 0% to 100%, with an overall mean of 96.7%. For distressed vocalizations, 100% reliability was obtained during both the SIBIS Active and No SIBIS conditions. Total agreement was used to calculate session reliability (Page & Iwata, 1986).

## RESULTS

### SIBIS active conditions: SIB

With SIBIS in effect, mean baseline rates of SIB were 1.92 hits per min (see Figure 1). With the introduction of naltrexone, rates of SIB increased with

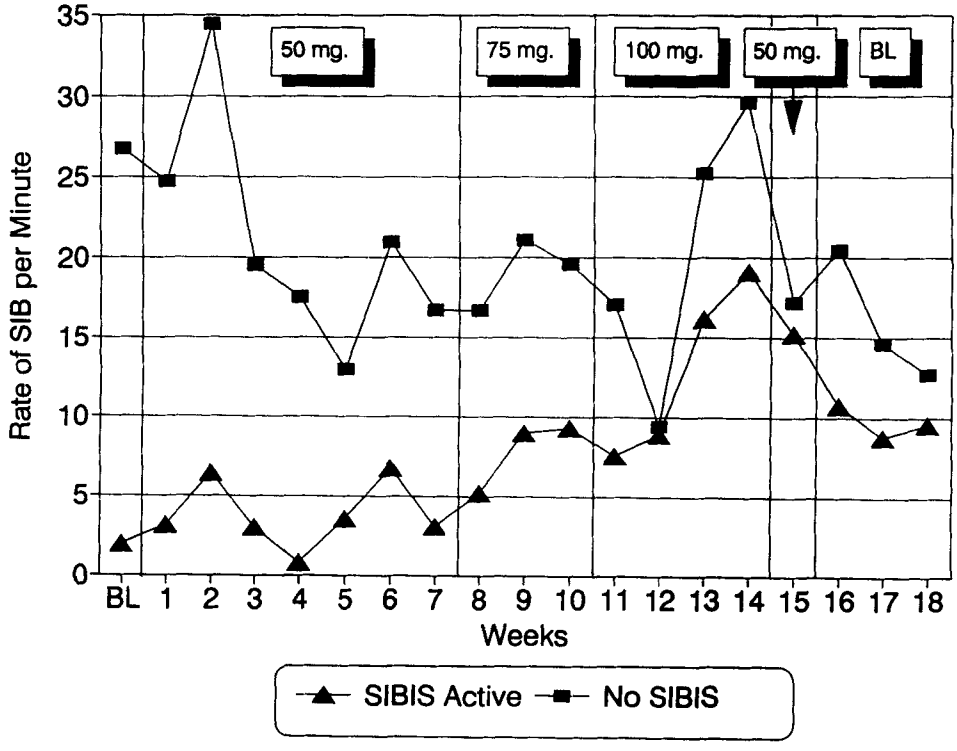


Figure 1. Head hits exhibited by Michael with Naltrexone

a particularly significant increase occurring during the second week of the 75 mg phase, and again during the 3rd week of the 100 mg phase. Mean rates of SIB per min during the four fixed-dose phases were as follows: naltrexone 50 mg, 3.86; naltrexone 75 mg, 8.80; naltrexone 100 mg, 12.42; and naltrexone 50 mg, 15.26. A 3 week return to baseline phase resulted in a decrease in SIB ($M = 9.71$ hits per min), although the rates remained well above original baseline rates.

## No SIBIS conditions: SIB

Without SIBIS, the mean baseline rate of SIB was 26.73 hits per min. During the second week of naltrexone therapy (50 mg dose) there was an increase in the rate of SIB to 34.41 hits per min. This increase may have reflected an extinction burst or simply chance variation as rates of SIB at this level of occurrence were not atypical. From the third through 11th week of drug therapy, rates of SIB appeared to show a moderate and fairly stable decrease, varying

between 12.96 and 21.09 hits per min. During the second week at the 100 mg dose a significant decrease in SIB was observed (9.43 hits per min) although self-injury then increased substantially. Thus, it was decided to discontinue naltrexone following the 14th week of drug therapy, and dosage was decreased to 50 mg per day for 1 week before discontinuation.

Mean rates of SIB per min during the four fixed dose phases were as follows: naltrexone 50 mg, 20.84; naltrexone 75 mg, 19.04; naltrexone 100 mg, 21.00; and naltrexone 50 mg 17.18. The 3-week return to baseline showed a deceleration of SIB ($M = 16.24$ hits per min) to rates similar to those obtained during the 50–75 mg naltrexone phases.

## Collateral behavior

During baseline, Michael's affect was noticeably more positive under SIBIS Active conditions than under No SIBIS conditions (see Figures 2–4), with higher rates of smiling ($M = 17.31$ vs. $M = 4.67$) and higher rates of happy vocalizations ($M = 9.92$ vs. $M = 5.33$). In addition, distressed vocalizations were significantly lower with SIBIS than without ($M = 1.15$ vs. $M = 18.00$).

With the initiation of naltrexone therapy, positive affect continued with greater relative frequency under SIBIS Active conditions than under No SIBIS conditions. However, the relative frequency of distressed vocalizations reversed (see Figure 4) and became more frequent in SIBIS Active conditions ($M = 5.07$) than in No SIBIS conditions ($M = 1.40$).

Figure 5 presents a comparison of the combined frequency (i.e., SIBIS Active + No SIBIS) of measured affect which occurred during baseline and naltrexone conditions, and indicates that the exhibition of all affect decreased considerably with the initiation of naltrexone. During baseline, smiling, happy vocalizations, and distressed vocalizations occurred during 22.0%, 15.3%, and 19.2% of the intervals sampled. With naltrexone, these rates decreased to 6.6%, 6.4%, and 6.5%, respectively. With the cessation of naltrexone therapy smiling and distressed vocalizations continued to occur at very low rates, 4.3% and 1.9%, respectively. A partial return to baseline was evidenced only for happy vocalizations, which occurred during 10.5% of the intervals sampled.

## Follow-up on self-injury

Without SIBIS or naltrexone, rates of self-injury at week 5 of follow-up ($M = 15.37$ per min) were unchanged from the 3-week return to baseline phase ($M = 16.24$ per min). At 8 weeks of follow-up, these rates decreased substantially to an average of 8.49 hits per min. However, during weeks 10 through 13, self-injury increased to a mean of 31.31 times per min.

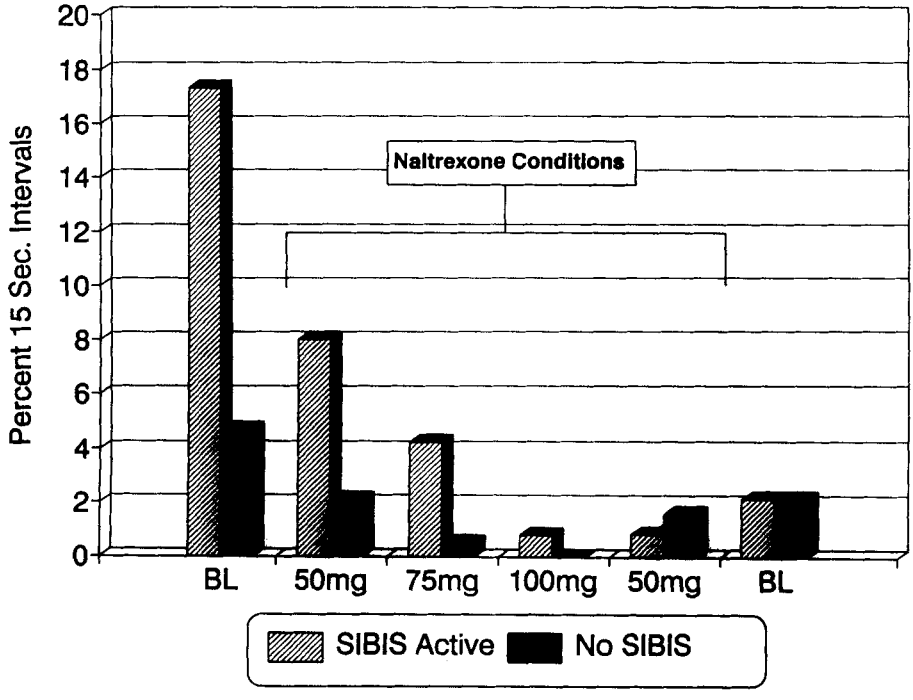


Figure 2. Smiling exhibited by Michael

## DISCUSSION

Naltrexone was marginally effective in the treatment of Michael's self-injurious behavior. Overall results indicated a reduction in self-injury by about one-third when naltrexone was used alone. This reduction was maintained ($M = 15.37$ hits per min) at a 5-week follow-up, and rates of SIB decreased further at an 8-week follow-up ($M = 8.49$ hits per min). These rates were considered to be extremely low and not likely the result of chance variation. No factors which could account for this finding were identified, except for possible carryover effects of naltrexone. However, data collected during weeks 10 through 13 indicated that SIB had increased to 31.31 hits per min, representing a complete return to baseline levels of responding. Thus, these data indicate that naltrexone may have resulted in moderate decrements in the rate of self-injury for up to 10 weeks following drug discontinuation.

Overall, the reductions in self-injurious responding were not considered clinically significant. Further, while in SIBIS, Michael's rate of SIB increased dramatically. It is not known if this was an effect of naltrexone therapy or possibly a reflection of a more pronounced adaptive response to SIBIS which occurred

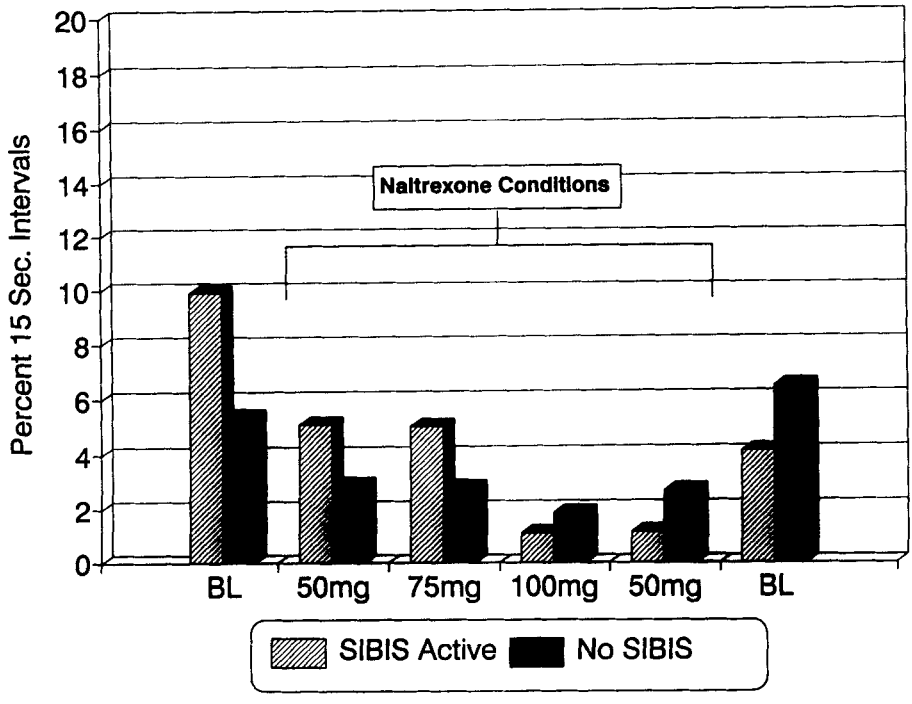


Figure 3. Happy vocalizations exhibited by Michael

independent of naltrexone therapy. However, it is clear that at least in this case, naltrexone did not act in such a manner as to increase the effectiveness of the aversive stimulus.

With regard to measured collateral behaviors, the only effect which appears fairly clear is that naltrexone blunted all affect, both positive and negative. There also appeared to be a slight increase in distressed vocalizations under SIBIS Active conditions concurrent with the administration of naltrexone. If this was a reliable effect, rather than chance variation, it might be hypothesized that this was indicative of increased pain perception associated with shock. Anecdotally however, this did not appear to be the case because Michael's distressed vocalizations rarely occurred concurrently with or immediately subsequent to SIB responses or the administration of contingent shock. Further, there were no other indications of increased sensitivity to pain such as increased distressed vocalizations in No SIBIS conditions subsequent to SIB responses, or other reactions which may have indicated that he was beginning to feel pain either from his SIB or from shock (e.g., startle responses or increased effectiveness of SIBIS).

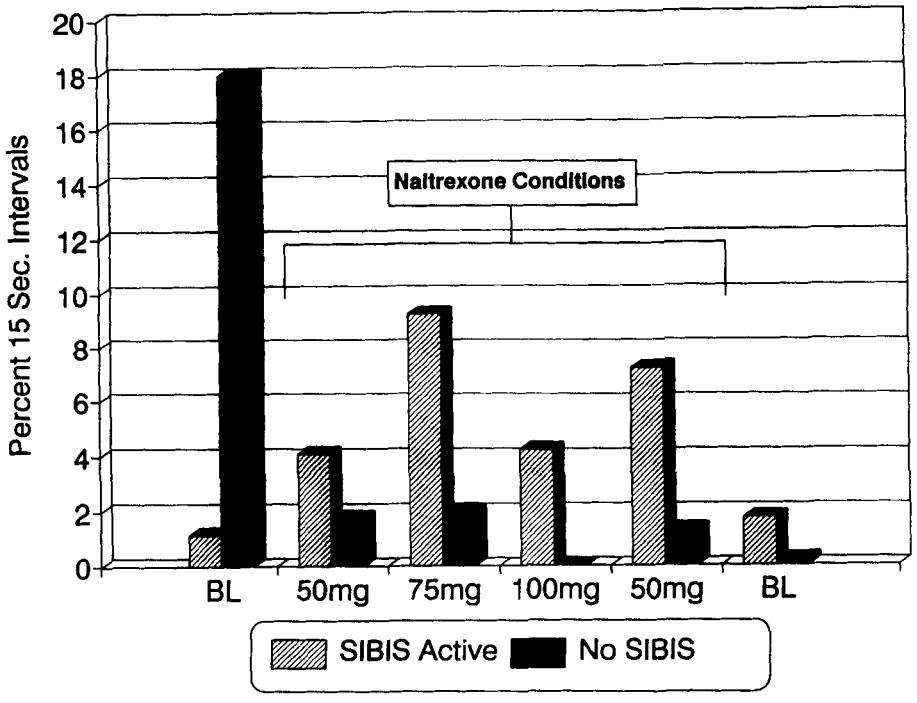


Figure 4. Distressed vocalizations exhibited by Michael

It also should be noted that a significant weight loss (approximately 15 pounds) occurred during the first month of naltrexone therapy. This corresponded to meal refusals, and although he never dropped below his recommended weight range, Michael was placed on meal supplements by a dietician. Five weeks after discontinuation of naltrexone, Michael's weight remained stable, that is, he had not regained any weight. Other possible adverse side-effects of naltrexone included anecdotal reports of increased sleep disturbance and that Michael did not seem to be as happy or to derive as much pleasure from certain leisure activities as he once did.

At the outset of this clinical trial, SIBIS was clearly superior in the treatment of SIB when compared either to no treatment or to naltrexone. Yet throughout the course of the trial, the effectiveness of SIBIS decreased in an apparent dose-dependent manner. That is, as dosage of naltrexone increased, effectiveness of the aversive stimulus decreased. This is in clear opposition to our hypothesis that an opiate antagonist might decrease the pain threshold, thereby increasing pain sensitivity and the effectiveness of contingent aversive stimulation. Further, by the end of this trial, the effectiveness of SIBIS was decreased to the extent

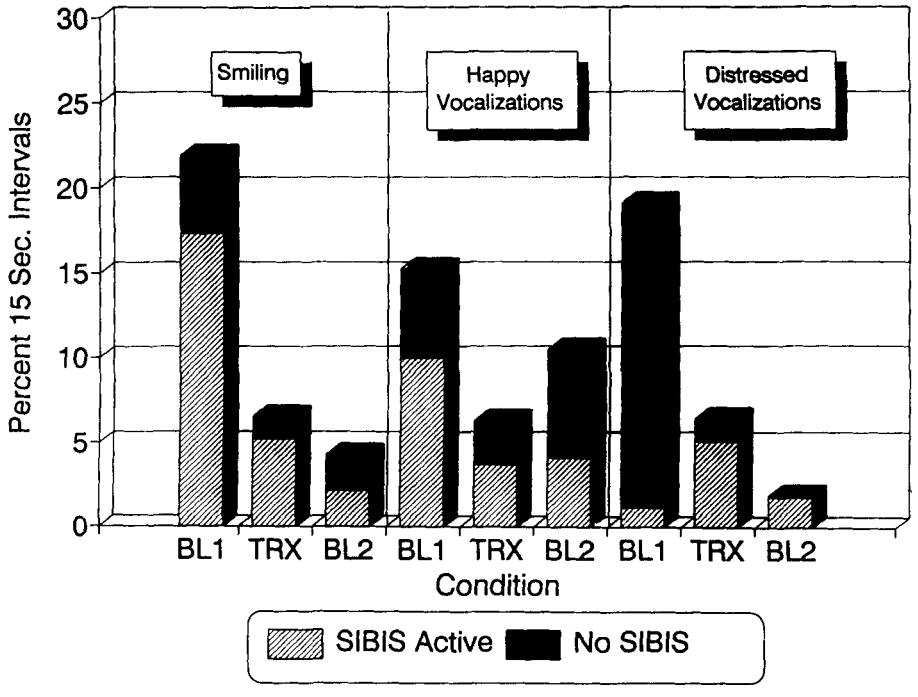


Figure 5. Comparison of affect: Baseline vs. Naltrexone

that there was no longer a clear difference in treatment effectiveness of SIBIS or naltrexone.

This trial of naltrexone suffers from many of the same methodological problems as other open-trial studies, including the lack of placebo controlled or double-blind conditions. Sequencing effects confounded the results, making it impossible to evaluate dosage effects in a confident manner. However, we believe that the lack of double-blind or placebo controlled conditions are at least partially compensated for by the strength of the behavioral measures and high reliability (Townes, Singh, & Beale, 1984). Staff persons collecting the behavioral data were highly trained and the observation sessions were conducted within a controlled environment to eliminate potential confounding variables. As an exploratory study, we are therefore reasonably confident in the accuracy of the data and the general results which they suggest.

In summary, while the clinical and exploratory nature of this study must be emphasized, a number of questions and areas for future studies are indicated by the current results. First, future studies on the effects of naltrexone on self-injury should assess its effects on collateral behavior, specifically affective beha-

vior, appetite, and sleep patterns. Second, future studies should examine the interaction between naltrexone and reinforcement-based procedures, because if naltrexone does blunt affect, it may also have a generalized negative impact on learning. Finally, future studies should evaluate the effects of naltrexone on pain perception/response in a systematic manner.

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