Women's Satisfaction with Norplant As Compared with Oral Contraceptives

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Background. Women's satisfaction with their chosen method of contraception has seldom been evaluated, especially in the primary care setting. This study compared women who use Norplant with those who use oral contraceptives with regard to patient satisfaction with, and the perceived advantages and disadvantages of, their birth control method.

Methods. We sent questionnaires to 115 Norplant users and 148 oral contraceptive users. The questionnaire asked for demographic data; a rating of level of satisfaction with their contraceptive; whether they would choose their method again; whether they would recommend their contraceptive to a friend; and what they perceived as its advantages and disadvantages.

Results. Sixty percent of responding Norplant users were satisfied with their method as compared with 72% of oral contraceptive users ($P>.05$). Sixty-three percent of Norplant users indicated that they would use their method again, compared with 88% of oral contraceptive users ($P<.05$). Seventy-four percent of Norplant users said they would recommend their method to a friend as compared with 97% of oral contraceptive users ($P<.05$). Oral contraceptive users reported significantly less menstrual bleeding and cramping than did Norplant users ($P<.05$), and Norplant users reported significantly more acne and bleeding irregularities ($P<.05$).

Conclusions. In our study, the majority of responding Norplant and oral contraceptive users were satisfied with their current method of contraception. However, Norplant users reported being less willing to use their method again or to recommend it to a friend, as compared with women using oral contraceptives. Norplant users noted more bleeding irregularities, more cramping, and increased acne.

Key words. Family planning; contraception; contraceptive agents; patient satisfaction; oral contraceptives.
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Although 30 million women in the United States between the ages of 15 and 50 years use a reversible method of contraception,[1] women's satisfaction with their chosen method of contraception has seldom been evaluated, especially in the primary care setting.

In the only birth control study in a family practice setting, Rosenfeld and colleagues[2] studied women's satisfaction with various methods of contraception. Norplant was newly available and Depo-Provera was not available in the United States at the time of their study and therefore neither method was included in it. The results of this study revealed that only permanent methods of contraception, ie, vasectomy, tubal ligation, and hysterectomy, had a satisfaction rate of greater than 70%. Fifty-seven percent of the women studied were satisfied with oral contraceptives. In another study, Harlap et al[3] reported that oral contraceptives are the most popular reversible form of contraception, with a 28% rate of use among women aged 28 to 44. In the 1993 Ortho Annual Birth Control Study, 75% of oral contraceptive users and 33% of implant users had a favorable opinion of their method.[1]

Norplant, a relatively new subdermal progestin implant contraceptive, was first introduced and available to the general public in the United States in January 1991. The Norplant system consists of six

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silastic membrane capsules, each containing 35 mg of levonorgestrel.[4]

Studies demonstrate that 76% to 90% of Norplant users continue to use it at the end of the first year after insertion.[5–8] Approximately 10% of patients discontinue Norplant in the first year because of bleeding problems. At the end of 5 years, 25% to 55% of patients still use Norplant as reported in studies conducted outside the United States.[9,10] Fifty percent of oral contraceptive users continue to use this method at the end of the first year.[6]

Of the few studies evaluating patient satisfaction with Norplant in the United States, there is none in the primary care setting that compares women's satisfaction with Norplant with their satisfaction with other means of contraception. This study compares the side effects and patient acceptance rate among Norplant and oral contraceptive users in a family physician's office. The study was designed to address the following questions: (1) How satisfied are Norplant users and oral contraceptive users with their method of contraception? and (2) What are the benefits and disadvantages identified by women using Norplant and women using oral contraceptives?

Methods

The family medicine practice where the study was carried out is a community-based, university-administered residency training clinic located in Eau Claire, Wisconsin. The practice has 23,000 patient visits per year, and is staffed by five physician faculty members, two nurse practitioners, a physician assistant, and 19 residents. Twenty-one percent of the patients have no insurance, 40% have Medicaid, 9% have Medicare, and the remaining 30% have private insurance.

The study included all patients visiting the family medicine clinic between May 1, 1991, and February 28, 1993, for the purpose of Norplant insertion (n = 115), and all patients who were using oral contraceptives, were 40 years old or less, and whose clinic visits were coded as oral contraceptive use or gynecologic examination (n = 148). Although other patients using oral contraceptives were probably seen in our clinic during this time, they were not coded as such, and therefore could not be identified.

All patients who were visiting the clinic to have Norplant inserted received contraceptive counseling and standard written patient education information on Norplant from their providers and viewed a Norplant patient education video. These patients were seen for follow-up 3 months after Norplant insertion and then on an annual basis. All patients in the oral contraceptive group saw their provider for contraceptive counseling and received written patient education information on using this form of birth control. These patients were seen on an annual basis for follow-up.

Each patient was sent a questionnaire to obtain demographic data, information as to type of birth control currently being used, and contraceptive history. Patients responded to the question "How do you feel about your contraceptive (Norplant or oral contraceptive)?" on a Likert-type scale on which 1 = very dissatisfied and 5 = very satisfied. They answered yes or no to the questions "Would you use your contraceptive method (Norplant or oral contraceptives) again?" and "Would you recommend your method (Norplant or oral contraceptives) to a friend?" Patients responded to the question "What do you like about using (birth control pills or Norplant)" by checking all advantages they considered important, according to the options listed ("convenient," "quickly reversible," "less overall bleeding," "effective," "less cramping with periods," "safety [few side effects]") or by listing other reasons. When asked whether there was "anything you dislike about using (Norplant or oral contraceptives)," they checked whatever disadvantages applied, according to the options listed ("worsened acne," "weight gain," "swelling," "bleeding"), or listed other reasons. Patients responded yes or no to the question "Have you had any difficulty with bleeding irregularities?" To the following question, "If yes, how much of a problem was it?" patients answered on a Likert-type scale on which 1 = very few problems and 5 = severe problems.

Patients received a reminder card asking them to complete the questionnaire 2 weeks after it was mailed. Patients who did not respond were sent a second letter and a second copy of the questionnaire 1 month after the initial survey was mailed. Two subsequent attempts were made to contact the nonresponders by telephone requesting that the questionnaire be completed.

Univariate analysis was used initially on the demographic data. Because of the possible interaction of demographic variables affecting the choice for Norplant, a model-computed logistic regression analysis was performed to adjust for the effects of other variables on the potentially significant variables affecting the likelihood of choosing Norplant. Logistic regression was performed, with use of Norplant or oral contraceptives as the independent variable, and educational level, number of children, insurance status, and spouse employment as the dependent variables. The remainder of the data were analyzed by chi-square.

Table 1. Responses to Questionnaire About Patient Satisfaction with Norplant and Oral Contraceptives

Question	Response Options	% of Patients Using Norplant (n = 73)	% of Patients Using Oral Contraceptives (n = 94)	*P* Value
How do you feel about your contraceptive?	Very satisfied	27	37	NS
	Satisfied	33	35	
	Neutral	22	18	
	Dissatisfied	10	5	
	Very dissatisfied	8	4	
Would you use your method again?	Yes	63	88	
	No	30	9	<.001
	No answer	7	3	
Would you recommend your method to a friend?	Yes	74	97	
	No	22	3	<.001
	No answer	4	0	
Have you had any difficulty with irregular bleeding?	Yes	73	34	<.001
	No	23	66	
	No answer	4	0	

NS denotes not significant.

Results

Of the 115 Norplant questionnaires sent, 15 were undeliverable because the patients had moved without leaving a forwarding addresses. Of the remaining 100 questionnaires, 73 were returned, for a usable response rate of 63%. Of the 148 oral contraceptive questionnaires, 16 were undeliverable because the patients had moved leaving no forwarding addresses. Of the remaining 132 questionnaires, 94 were returned, for a usable response rate of 64%.

Demographic data showed no significant difference between the groups regarding age, marital status, educational level, patient or spouse employment, and having HMO insurance or medical assistance. Logistic regression showed that the relative probability of using Norplant was five times greater among respondents with one to two children than among those having no children ($P = .002$) and 4.5 times greater among respondents having more than two children ($P = .009$). Respondents with private insurance had a decreased probability of using Norplant (relative probability = .24, $P = .03$).

Of the 73 questionnaires returned by Norplant users, 62 respondents continued to use Norplant for contraception at the time of the survey (85%). Of the 94 oral contraceptive users, 69 continued to use oral contraceptives for birth control (73%).

Of the 59 patients who responded to the question "Do you plan to have the Norplant removed before 5 years?" 19 (32%) said yes, whereas 40 (68%) patients said no. The most common reason women cited for planning to have the Norplant removed before 5 years was to have another child. Sixty-three (86%) of the Norplant responders had used oral contraceptives previously, whereas only 1 (1.1%) of the oral contraceptive responders had used Norplant previously. There were no other significant differences in prior contraceptive use.

Norplant and oral contraceptive users did not differ statistically in how they responded to the question "How do you feel about your contraceptive?" However, they did differ significantly ($P<.05$) regarding choosing their current method again, recommending it to a friend, and experiencing bleeding irregularities (Table 1). The degree of bleeding irregularities, illustrated in the Figure, was also significant ($P<.05$).

Perceived benefits and disadvantages are listed in

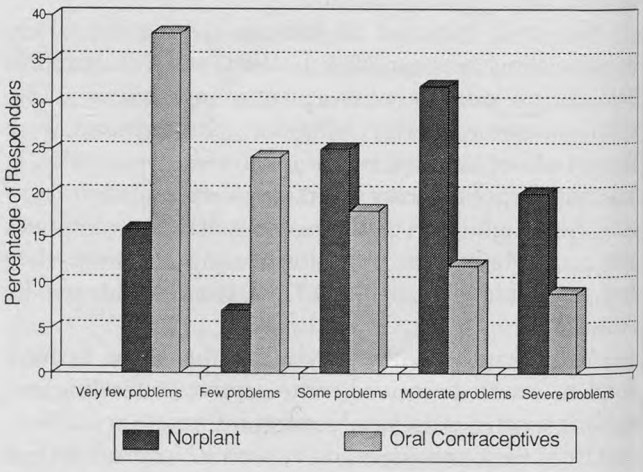

Figure. Patient self-report of bleeding problems among Norplant users and oral contraceptive users.

Table 2. Advantages and Disadvantages of Norplant and Oral Contraceptives, as Identified by Women Responding to a Survey About Patient Satisfaction with Contraceptives

Contraceptive Characteristic	% of Oral Contraceptive Users (n = 73)	% of Norplant Users (n = 94)	*P* Value
Convenience	92	89	NS
Reversible	50	59	NS
Less bleeding	72	30	<.001
Effectiveness	78	71	NS
Less cramping	60	30	<.001
Safety	58	49	NS
Acne	7	29	<.001
Weight gain	33	49	<.04
Swelling	15	23	NS
Bleeding irregularities	8	60	<.001

NS denotes not significant.

Table 2. In a comparison of the two responding patient groups, oral contraceptive users reported experiencing less bleeding and cramping ($P<.05$), and Norplant users reported increased acne, bleeding irregularities, and weight gain ($P<.05$), but there were no significant differences between the two groups in respondent perceptions regarding convenience, reversibility, safety, effectiveness, or swelling.

Discussion

Few previous studies have evaluated patient satisfaction with Norplant in the United States, and none has taken place in a family practice setting. Most large studies have been done elsewhere, namely in Indonesia, Singapore, Sri Lanka, and Egypt.[11–15] A clinical drug trial in 1989 at San Francisco General Hospital's Family Planning Clinic showed that 93% of Norplant users were satisfied with this method of contraception and 74% planned to use it again.[16] A recent US study of 21 inner-city adolescents showed that 86% were satisfied with Norplant,[17] and a Planned Parenthood study showed that 96% of patients were satisfied.[18] The difference between these findings and those of the 1993 Ortho Annual Birth Control Study, which showed a favorable rate of only 33%, may be related to different patient populations.[1]

We evaluated each patient's satisfaction with her contraceptive by asking how she felt about it, whether she would choose the same method again, and whether she would recommend it to a friend, and we found no statistically significant differences between Norplant and oral contraceptive users in how they felt about their contraceptive method. However, in contrast to numerous studies of Norplant users outside the United States, in which more than 85% were satisfied with their method,[12–14,16] only 60% of the Norplant users in our family practice survey were satisfied.

Although a majority of the Norplant users indicated that they would use their method again or recommend it to a friend, or both, the Norplant users and oral contraceptive users differed significantly in response to these questions ($P<.05$). Again, this demonstrates a lower level of satisfaction with Norplant among the respondents in our practice as compared with the results of a 1992 study in Singapore. In that study, 88.1% of the Norplant users had recommended the implant to their friends, whereas only 74% of our respondents had done so.[15]

Seventy-two percent of the oral contraceptive users in our study were satisfied or highly satisfied with their method. This is a higher level of satisfaction than that of the Rosenfeld study,[2] in which 57% of oral contraceptive users were satisfied, but is comparable to the results of the Ortho Contraceptive study.[1]

Precontraceptive counseling is similar in our clinic for both Norplant and oral contraceptives users. In addition to the usual counseling, patients using Norplant also view an educational video before Norplant is inserted. Although the majority of both oral contraceptive and Norplant users said they were satisfied with their method of birth control, the high level of satisfaction among oral contraceptive users created significant differences in our study.

Irregular bleeding was the primary side effect that created dissatisfaction among the Norplant users. Only 34% of the oral contraceptive users reported bleeding irregularities, compared with 73% of the Norplant users. The rate of irregular bleeding with Norplant found in this study is comparable to the 60% to 70% rate of menstrual irregularities found in previous studies.[10,17,19]

Although Norplant users in this study described significant bleeding problems, other studies have shown that, despite an increased number of days of bleeding during the first year of use, the average amount of blood loss per cycle actually decreases.[7,9,10,20] Fifty-two percent of the Norplant users described their bleeding as moderate to severe as compared with 21% of oral contraceptive users. The number of days of bleeding usually decreases after the first year,[6,9] but because Norplant is still relatively new in the United States and to our clinic, the length of time women in our study had had Norplant in place ranged from 3 months to 2 years. Irregular bleed-

ing may actually be a benefit in that it lowers the risk for pregnancy.[21]

In a preliminary study of 246 women, Cullins and colleagues[22] found that intensive counseling about side effects, especially menstrual changes, was crucial for patient satisfaction. However, they evaluated women after only 3 months of Norplant use. Patients in our clinic received standardized written and video patient education before Norplant was inserted. Since the completion of our study, we have refocused our counseling on expected bleeding irregularities and other side effects that may be perceived as a nuisance.

Our finding that Norplant users are less likely to have private insurance is similar to that of previous studies.[16,11–13,18,22] In a study of 21,276 patients who received Norplant during a 2-year period, Planned Parenthood found that the cost of insertion was covered by public medical assistance in 87% of the cases.[18] Since many private insurance plans do not cover Norplant, the $500 to $600 cost may be prohibitive to patients without financial assistance.

There are several limitations to this study. First, because it took place in one teaching site in a small midwestern city, the results may not be generalizable to other populations. In addition, we have been inserting Norplant for only 2 years, so the Norplant users are relatively new to their method as compared with patients who have been using oral contraceptives. Since Norplant side effects tend to decrease with time, patient perceptions of Norplant identified in this study may not be representative of that following several years of use. Finally, respondents may view their contraceptive differently from nonrespondents, resulting in an undetected response bias.

Conclusions

In our study, the majority of the Norplant and the oral contraceptive users were satisfied with their birth control method. However, the Norplant users were less satisfied, as measured by their willingness to use Norplant again or to recommend it to a friend ($P<.05$). Norplant users differed significantly ($P<.05$) from oral contraceptive users in noting increased bleeding irregularities, cramping, and acne.

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NORPLANT VS ORAL CONTRACEPTIVES

TITLE: Women's satisfaction with Norplant as compared with oral contraceptives
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Background. Up to 50% of women who start oral contraceptives will discontinue use within the first year, most presumably due to dissatisfaction with nuisance side effects such as irregular bleeding, cramping, and amenorrhea.[1] Only one study has evaluated women's satisfaction with their method of contraception in the family practice setting, and it did not include the Norplant system.[2]

Clinical question. How do the reported side effect profiles and patient acceptance rates of Norplant and oral contraceptive users compare in the family practice setting?

Population studied. Patients were recruited from a community-based family practice residency training clinic in a small midwestern city. Nearly 50% of the patients were on medical assistance, with the remainder having either private (30%) or no insurance (20%). No information is provided regarding race or ethnicity.

Study design and validity. The study design was a cross-sectional analysis using a self-administered mailed questionaire. Information was requested regarding current and past contraceptive use and overall acceptance of current methods. Nonresponders were contacted by a second mailing and then by telephone.

The method of patient selection may have introduced bias. All women who received the Norplant were first-time users of this method, whereas some of the women using oral contraceptives had been doing so for a number of years. Women satisfied with oral contraceptives would be likely to continue use and thus have a higher chance of being represented in the study. By contrast, some Norplant users were questioned in the initial months of their use, a time when many of the expected side effects are more common. Also, recall bias may have made it more likely for women who had been warned of particular side effects to recall them.

Outcomes measured. Women were queried as to general level of satisfaction with their current method of contraception; whether they would use the same method again or recommend it to a friend; perceptions of the advantages and disadvantages of their current method; and the degree of difficulty they were having with irregular bleeding and cramping.

Results. The usable response rate was 64%. The two groups were similar regarding age, marital status, educational level, patient or spouse employment, and HMO or medical assistance representation. Norplant users were more likely to have children and less likely to have private insurance. During the 21-month review period, 15% of Norplant users and 27% of oral contraceptive users discontinued their method. A greater percentage of oral contraceptive users reported being satisfied with their method than did Norplant users (72% vs 60%), although this difference did not achieve statistical significance ($P > .05$). Norplant users were significantly more likely to identify acne, irregular bleeding, and cramping as disadvantages. There were no significant differences between respondents' perceptions of weight gain or swelling with Norplant and oral contraceptive use.

Recommendations for clinical practice. The current study takes an important step toward understanding which method results in the lowest rate of unwanted pregnancy. Effectiveness is determined by two characteristics: the pharmacologic efficacy of the drug, combined with the factors that influence patient acceptance. Norplant and oral contraceptives have been shown to have equivalent, high pharmacologic efficacy, and, when used correctly, both are highly effective in preventing pregnancy. What is left to determine is the degree to which patients are satisfied with their method, since dissatisfaction leads to noncompliance, which in turn, can lead to unwanted pregnancy.

This study suggested that users of oral contraceptives were more satisfied than were Norplant users with their choice of contraception. The selection and recall bias introduced by the method of data collection may be responsible to some degree for this finding. In contrast, Norplant users were more likely to continue use, possibly because of the effort required to remove the device. Prospective studies are needed to compare first-time users of each method, measuring patient compliance and unwanted pregnancy rates as the outcomes of interest.

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Until then, emphasizing satisfaction with a woman's choice of contraception, as addressed in this study, may be the best means of avoiding unwanted pregnancy.

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COMPLICATIONS OF IDDM

TITLE: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus
AUTHORS: The Diabetes Control and Complications Trial (DCCT) Research Group
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Background. Long-term microvascular, macrovascular, neurologic, and immunologic complications of insulin-dependent diabetes mellitus (IDDM) contribute to the morbidity and mortality experienced by patients with this disease. A previous study of patients with preexisting disease has suggested that greater benefit can be achieved with tight control of blood glucose concentrations.[1]

Clinical question. Can intensive insulin therapy using three or more daily injections or an insulin pump prevent the development (primary prevention) or progression (secondary prevention) of diabetic nephropathy, neuropathy, and retinopathy in patients with IDDM?

Population studied. Patients aged 13 to 19 years with IDDM as documented by a lack of C-peptide were recruited by a widespread media campaign across the United States and Canada. Though not stated, this recruitment strategy was likely to select patients who were highly motivated to control their diabetes. The primary prevention group patients had had IDDM for 1 to 5 years and had no evidence of retinopathy or nephropathy. The secondary prevention cohort had had IDDM for 1 to 15 years with mild to moderate retinopathy and microalbuminuria. Exclusion criteria: hypertension, hypercholesterolemia, and severe diabetic complications or medical conditions.

Study design and validity. The study was a randomized controlled trial comparing intensive insulin therapy with conventional therapy of one to two insulin injections per day. Neither patients nor investigators were masked to their treatment assignment, though neither group was made aware of outcome data unless the results indicated the need for medical intervention. All outcome evaluators were blinded to the treatment assignment.

The aim of the intensive insulin therapy was to maintain preprandial blood glucose concentrations between 70 and 120 mg/dL, postprandial levels of less than 180 mg/dL, and hemoglobin A_{1c} levels less than 6.05%. Insulin was administered to patients in this group by either an insulin pump or by multiple daily injections. Patients in the intensive therapy group were seen monthly and contacted by telephone between visits to review their regimens.

Outcomes measured. Retinal changes were evaluated using seven-field stereoscopic fundus photographs. Renal changes were monitored using 24-hour urinary albumin excretion. Neuropathy was evaluated using a clinical examination along with either peripheral nerve conduction study or autonomic nerve testing. Other outcomes measured included death, incidence of hypoglycemia, low-density lipoprotein (LDL) cholesterol, weight gain, and quality of life.

Results. A total of 1441 patients were recruited into the trial. Randomization resulted in an equal distribution of patients with regard to demographic and disease severity indices, though there were significantly more patients with retinal microaneurysms in the secondary prevention section of the intensive therapy group.

Patients were followed for an average of 6.5 years, and almost everyone in this highly motivated sample (99%) completed the study. Intensive therapy produced better blood glucose control as evaluated by glycosylated hemoglobin levels and all measurements of serum glucose, though less than 5% of patients in this group were able to maintain the goal level for hemoglobin A_{1c} of less than 6.05%. In the primary prevention group, the development of funduscopic changes, clinical neuropathy, and microalbuminuria was significantly less in the intensive therapy group. The more clinically relevant markers of retinopathy (macular edema, proliferative or severe nonproliferative retinopathy), and nephropathy (frank albuminuria) were not affected by intensive therapy.

Results were better in patients with preexisting disease. All measures of retinal effects were significantly diminished in the intensive treatment group. The risk of both microalbuminuria and albuminuria was diminished in this group, though there was no difference in the average level of renal function between the two therapy groups. The development of clinically apparent neurop-

athy was less likely in patients treated with intensive therapy.

Mortality was nearly doubled in the intensive treatment group (7 vs 4), but this difference was not statistically significant. The incidence of severe hypoglycemia was three times higher in the intensive therapy group: 60 vs 19 episodes/100 patients/year. Intensive therapy patients were more likely to gain weight but had a lower LDL cholesterol. Quality-of-life scores were similar between the two groups.

Recommendations for clinical practice. Diabetes is a disease common to primary care, making the relevance of this study high. The Diabetes Control and Complications Trial (DCCT) looked only at patients with IDDM (type I/ketosis-prone) and cannot be extrapolated to patients with the more commonly seen NIDDM (type II/nonketosis-prone). In fact, concern has been expressed that insulin therapy for patients with NIDDM may actually accelerate macrovascular disease, leading to increased morbidity and mortality.[2,3]

The DCCT was terminated prematurely by the monitoring committee before there was sufficient evidence to conclude that patients would be truly better off as a result of the intervention. Intermediate "disease-oriented" outcomes, such as a progression of retinopathy, reduced occurrence of microalbuminuria, and abnormal nerve conduction, do not necessarily correlate with significant "patient-oriented" outcomes, such as blindness, renal failure requiring dialysis, or neuropathic pain, skin ulcers, or amputation.[4] What we really need to know is whether the benefits of intensive therapy are justified by the risks: a three-fold increase in the incidence of hypoglycemia, which could result in seizure, coma, and related disabling or fatal accidents.

For patients with IDDM who are highly motivated and have sufficient financial resources, an attempt at tight control might be considered. The level of care provided in the DCCT for the intensive therapy group consisted of a team of physicians, nurses, dietitians, and behavioral specialists. Patients whose primary care clinicians do not have access to these resources may require referral to a specialty center. Until further **p**atient-**o**riented **e**vidence that **m**atters (POEM)[4] is available, it seems inappropriate to unquestionably accept intensive therapy as the standard of care.

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