Management of Referred Deep Brain Stimulation Failures

A Retrospective Analysis From 2 Movement Disorders Centers

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Background: Since the Food and Drug Administration approved DBS, there has been a surge in the number of centers providing the procedure. There is currently no consensus regarding appropriate screening procedures, necessary training of individuals providing the therapy, the need for an interdisciplinary team, or guidelines for the management of complications. An increasing number of patients come to experienced DBS centers after unsatisfactory results from DBS surgery. An attempt is made herein to evaluate the reasons for DBS failure in a series of such patients and to make recommendations to improve overall DBS outcomes.

Objective: To improve outcomes of deep brain stimulation (DBS) surgery by analyzing a series of patients who had suboptimal results from DBS.

Methods: Forty-one consecutive patients complaining of suboptimal results from DBS surgery came to the University of Florida Movement Disorders Center, or to Beth Israel Movement Disorders Center, over a 24-month period. All patients had undergone implantation of DBS devices at outside medical centers. Each patient was evaluated by a movement disorders neurologist, and the complete medical record was reviewed. The DBS device for each patient was interrogated for adverse effects and programmed for maximal benefit. Postoperative imaging studies were evaluated whenever possible.

Results: The average age of patients was 63.4 years (range, 49-84 years). The indication for surgery (by record review) included 9 patients with essential tremor, 31 with Parkinson disease, and 1 with dystonia. The diagnoses after referral examination included 5 with essential tremor, 26 with Parkinson disease, 3 with Parkinson disease and dementia, 1 with Parkinson disease and essential tremor, 1 with corticobasal degeneration, 1 with dystonia, 2 with multiple system atrophy, 1 with progressive supranuclear palsy, and 1 with myoclonus. *Issues related to inadequate preoperative screening:* Thirty (73%) of 41 patients saw a movement disorders specialist prior to DBS implantation. Fourteen (34%) patients had neuropsychological testing, 4 (10%) did not have testing, and in 23 cases (56%), it could not be determined whether or not they were tested. Five (12%) of 41 patients had an inadequate medication trial, and 5 patients (12%) had significant cognitive dysfunction prior to their DBS implantation. *Surgical and device-related complications:* Nineteen (46%) of 41 patients had suboptimally placed electrodes. Seven electrodes (17%) were replaced with improvement. Three patients' devices had failed due to end of battery life, 2 had infections, and 1 had a fractured lead. *Programming and medication adjustments:* Seven (17%) of 41 patients had no or poor access to programming. Two patients (5%) moved, and 2 physicians (5%) moved, creating issues with access to care. Eight patients (20%) required local follow-up (they flew to remote centers to have the surgery performed). Fifteen patients (37%) were inadequately programmed and improved significantly with reprogramming. Six patients (15%) experienced partial improvement with reprogramming, and 21 patients (51%) failed to improve despite extensive reprogramming. Thirty patients (73%) benefited from medication changes, 4 (10%) had antidepressants added to their regimens, and 1 (2%) had donepezil hydrochloride added. One patient's carbidopa/levodopa (2%) was restarted after complete discontinuation. *Outcomes:* With the various postoperative interventions described, 21 (51%) of 41 patients had good outcomes, 6 (15%) had modest clinical improvement, and 14 (34%) did not improve.

Conclusions: With appropriate intervention, 51% of patients who complained of "failed" DBS procedures ultimately had good outcomes. Thirty-four percent of these patients had persistently poor outcomes despite maximal intervention. This case series provides important insights into reasons for "DBS failure" and proposes strategies to manage patients with DBS more effectively.

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SINCE THE FOOD AND DRUG Administration approved deep brain stimulation (DBS) for Parkinson disease (PD), essential tremor (ET), and dystonia, there has been a surge in the number of centers providing the operative procedure. There remains no consensus in several important areas concerning DBS therapy. These areas include (1) appropriate patient screening procedures, (2) the training of health care pro-

fessionals performing DBS surgery, (3) the training of personnel providing DBS programming, (4) access to DBS programming, (5) the need for an interdisciplinary team approach, and (6) education to identify and treat complications of DBS.[1,2] With increasing frequency, patients are coming to experienced movement disorders centers complaining of suboptimal results from DBS surgery. In this article, we review 41 such cases to identify common reasons for DBS failure and make recommendations to improve overall DBS outcomes.

METHODS

Forty-one patients complaining of poor outcomes from DBS surgery visited the University of Florida Movement Disorders Center, Gainesville, or Beth Israel Movement Disorders Center, New York, NY, over a 24-month period. All patients were implanted with DBS devices at other medical centers and sought specialist management for DBS-related problems. Each patient was seen and examined by a movement disorders neurologist. Their complete medical records were reviewed. Their DBS devices were interrogated to assess thresholds for adverse effects at each contact, and the devices were programmed for maximal benefit. Documenting the preoperative selection process included noting the diagnosis and indication for surgery, the cognitive status, and medication trials. Preoperative indication for surgery was based on what the referring physician documented in the medical record. The movement disorders neurologist at the experienced DBS center then reassessed each patient and assigned a diagnosis. These diagnoses adhered to strict criteria.[3-9] Preoperative cognitive status was based on a detailed interview with the patient and family, medical-record review, and the neurological examination. Medication trials were documented using the medical records as well as interviews of the patients and families. An inadequate medication trial for this study was defined by the movement disorders neurologist as the failure to administer, for a reasonable period of time, appropriate combinations of medications for PD, ET, or dystonia. Whether referred patients consulted a movement disorders neurologist prior to surgery was verified by medical-record review and by patient interview. Surgical targets were confirmed by medical-record data and postoperative imaging (when available). Lead location was judged quantitatively either by reconstructing the lead with a computed tomography/magnetic resonance imaging (MRI) fusion technique or by estimating the mediolateral and anteroposterior aspects of the lead using coronal MRIs. Lead location was also assessed functionally by checking thresholds for adverse effects and benefits during programming (eg, number of volts needed to induce a capsular/sensory or other response). The neurologist and neurosurgeon decided whether a lead was misplaced after examining all the imaging and clinical data. Information on hardware complications and programming was obtained from patient history, examination, medical-record review, and device interrogation. The device interrogation included an impedance and battery check. Extensive and systematic DBS programming was performed for adverse effects, threshold mapping, and maximal clinical benefit at each of the 4 contacts on the lead. The movement disorders specialist subjectively judged overall outcome. Patients in this study may have had 1 or more of several problems leading to a DBS failure (eg, poor patient selection and electrode misplacement).

RESULTS

DEMOGRAPHICS

The average age of patients was 63.4 years (range, 49-84 years). Preoperative indications for surgery included 9 patients with ET, 31 with PD, and 1 with dystonia. The patients underwent the following DBS implantations: 8 unilateral ventralis intermedius, 8 unilateral subthalamic nucleus, 1 unilateral globus pallidus interna, 1 bilateral ventralis intermedius, 21 bilateral subthalamic nucleus, and 1 bilateral globus pallidus interna. The movement disorders neurologist agreed with the preoperative indication for surgery in 32 of 41 patients. The diagnosis was revised in 9 cases, including PD and dementia,[3] multiple system atrophy,[2] corticobasal degeneration,[1] progressive supranuclear palsy,[1] and myoclonus.[1]

SCREENING AND MEDICATION TRIALS

Thirty (73%) of 41 patients were evaluated by a movement disorders specialist prior to DBS implantation. Fourteen patients (34%) underwent documented preoperative neuropsychological testing, 4 (10%) did not have testing, and in the remaining 23 (56%) patients, it could not be ascertained whether or not they were tested. Five (12%) patients had an inadequate medication trial, and 5 (12%) patients had significant preoperative cognitive dysfunction.

MISPLACED LEADS AND HARDWARE COMPLICATIONS

Nineteen (46%) of 41 patients had misplaced leads (**Figure 1**). Seven leads (17%) were replaced with marked improvement, and 3 others (7%) were replaced with partial improvement (*partial improvement* was defined as symptom improvement but not to the level expected by the movement disorders neurologist and neurosurgeon). Three patients had problems with the battery, 2 had infections, and 1 had a lead fracture.

DBS PROGRAMMING

Seven (17%) of 41 patients had no or poor access to programming; 2 patients (5%) and 2 physicians (5%) moved away from their centers, resulting in an access problem. Eight patients (20%) required local follow-up (patients flew to a remote center to have the surgery performed). Fifteen patients (37%) were inadequately programmed, and 21 leads (51%) could not be reprogrammed. Fifteen patients (37%) were reprogrammed successfully, and 6 more patients (15%) had partial improvement (*partial improvement* was defined as symptom improvement but not to the level expected by the movement disorders neurologist). These programming sessions took more than twice as long as typical DBS evaluations by the movement disorders neurologists.

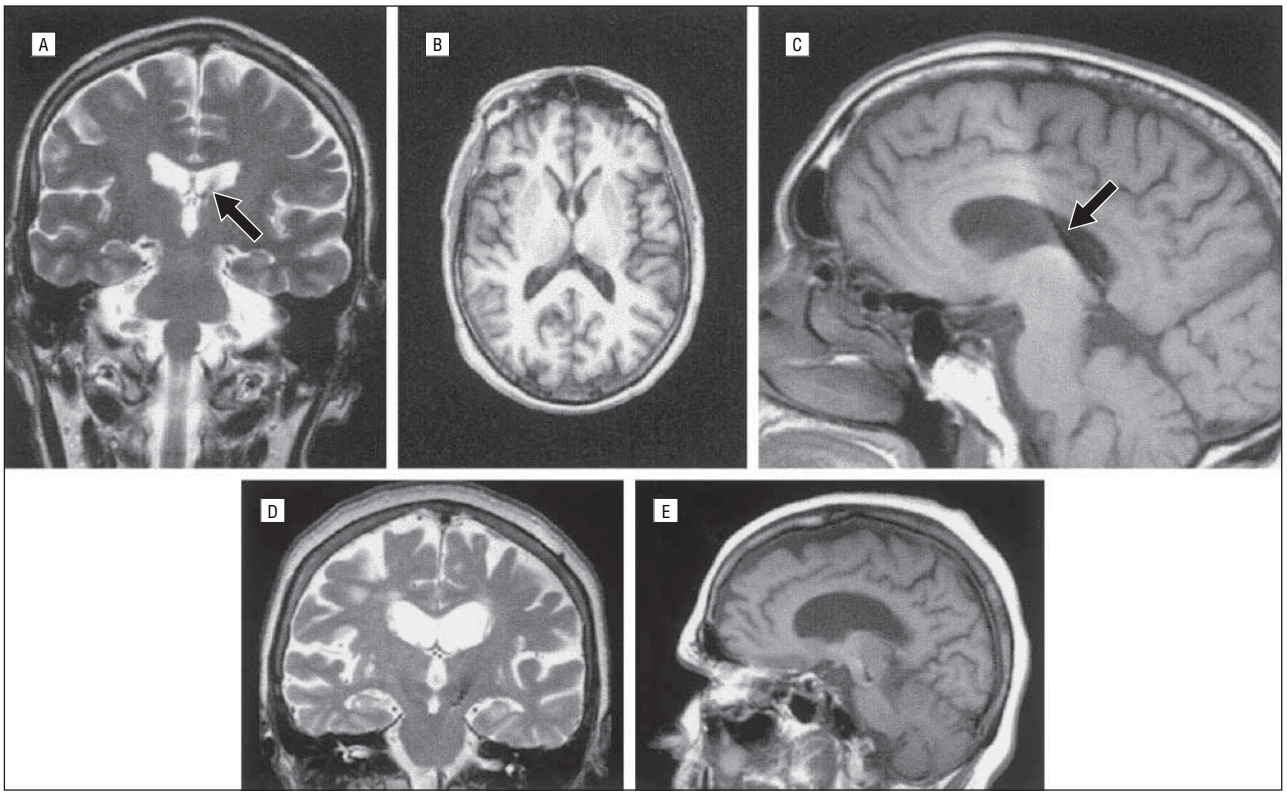

Figure 1. Examples of misplaced deep brain stimulation (DBS) leads. A, Case 1. The coronal magnetic resonance image (MRI) reveals the lead in the ventricle. B, Case 1. The lead is not visualized on the axial sections. C, Case 1. The sagittal MRI reveals that the lead was in the ventricle and lying on top of the thalamus. (Case 1 had a diagnosis of essential tremor, which failed to respond to DBS programming; subsequent reimplantation in the thalamus led to marked resolution of the tremor.) D, Case 2. The sagittal MRI reveals a lead that was deep and posterior to the intended subthalamic nucleus target for tremor. E, Case 2. The coronal MRI reveals a misplaced lead. Lead measurements relative to the midcommissural point were done to assist in confirming lead misplacement. Case 2 lead measurements reveal that the lead was misplaced posterior and deep. The deep contact measured anteroposterior coordinate (AP) –8.9, lateral coordinate (LT) 8.6, and axial coordinate (AX) 12.2; the 1 contact, AP –7.4, LT 9.9, and AX 9.9; the 2 contact, AP –6.0, LT 11.1, and AX 7.6; and the 3 contact, AP –4.5, LT 12.4, and AX 5.3. Lead misplacement was confirmed by a combination of clinical response, thresholds for adverse events, imaging, and discussions by the neurologist and neurosurgeon.

POSTOPERATIVE MEDICATION CHANGES

Thirty (73%) of 41 patients required medication changes in parkinsonian drugs, 4 (10%) had antidepressants added to their regimens, and 1 (2%) received donepezil hydrochloride. One patient's carbidopa/levodopa (2%) was restarted, having previously been stopped following the initial surgery.

PATIENT OUTCOMES

Twenty-one (51%) of 41 patients citing "failure" of DBS therapy ultimately had good outcomes with additional medical or surgical management, 6 (15%) had modest clinical improvement, and 14 (34%) failed to improve (**Table**).

COMMENT

The patients in this study provided important insights into the difficulties of DBS management. Because DBS offers dramatic benefits for appropriate candidates, it is important to carefully evaluate the problems identified by this study and to propose and encourage reasonable management solutions. This study highlights the important point that all of these complications were potentially preventable. As more DBS is performed, practitioners will need to be aware of the timeline of preventable problems (**Figure 2**), which may include failures of triage, screening, surgery, and postoperative follow-up.

DETERMINING THE DIAGNOSIS

Thirty (73%) of the 41 patients in this study were evaluated by a movement disorders neurologist prior to DBS implantation. Despite this high percentage, problems related to incorrect initial diagnosis, or inappropriate indication for surgery, were not uncommon. Arguably, the most important predictor of success or failure of DBS therapy is appropriate patient selection. Deep brain stimulation therapy has been shown to consistently provide significant benefit in the treatment of idiopathic PD, ET, and dystonia. These 3 disorders have been extensively studied and are, to date, the only indications for DBS approved by the Food and Drug Administration. The DBS practitioners who initially treated the patients in this case series believed they had identified 41 patients, all of whom had 1 of these 3 diagnoses. Careful review revealed that 36 (88%) of the 41 patients did have 1 of these 3 diagnoses, but 12% of the patients had other disorders that would not be expected to respond to DBS therapy. Also concerning was the observation that 20% of the patients

had significant preoperative dementia. Patients with multiple system atrophy (n=2), progressive supranuclear palsy (n=1), corticobasal degeneration (n=1), and myoclonus (n=1) were misdiagnosed as either PD or ET. The multiple system atrophy and progressive supranuclear palsy cases had parkinsonian features, but the patients failed to demonstrate a significant response to levodopa. In the corticobasal degeneration and myoclonus cases, which were mistaken for ET, the phenomenologic analysis of the tremor and the presence of other signs (apraxia in the case of corticobasal degeneration) were presumably missed in preoperative evaluations.

SCREENING FOR SURGERY

There is currently no standard screening for DBS surgery.[1,2] There are no accepted guidelines that recommend patients undergo an on-off levodopa challenge, medication optimization, or neuropsychological screening. The Florida Surgical Questionnaire for PD is 1 screening tool that was designed to aid referring physicians in identifying potential candidates for DBS. This questionnaire examines several domains, including appropriate diagnosis, potential contraindications, favorable and unfavorable patient characteristics, medication trial, and refractory tremor.[2] Many of the DBS failures in this series may have been avoidable if such a systematic patient screening approach had been employed. The results from the current study support the need for more thoughtful screening to identify appropriate surgical candidates. Additionally, the use of neuropsychological screening may be helpful in many if not all cases. Ongoing efforts to improve the screening of surgical candidates by all DBS practitioners will likely improve overall outcomes. Despite the best screening procedures, a small number of patients will "convert" from what appears to be idiopathic PD to another parkinsonian syndrome. Many of these patients who convert from one diagnosis to another have seen highly qualified specialists.[10-12]

MISPLACED LEADS

Many techniques can be used effectively for DBS implantation, and the necessity for microelectrode recording continues to be a controversial issue.[13,14] One point that is not controversial, however, is that regardless of the implantation technique, appropriate electrode placement is absolutely necessary to achieve optimal results from DBS. No amount of expert DBS programming can compensate for a poorly placed electrode. In this series of patients with suboptimal results, 19 (46%) of 41 patients had a misplaced DBS electrode. This alarmingly large number should be interpreted with caution because there was clearly a significant selection bias. One may hypothesize that electrodes were misplaced because of the use of inadequate localization techniques or equipment or because of inadequate training for DBS implanters. On the other hand, these patients with misplaced electrodes may represent a small minority of patients with DBS implanted in the region, but their poor outcomes led them to congregate at a tertiary care–level movement disorders center. We suspect there was a wide spectrum of reasons for electrode misplacement.

Table. Main Reasons for Deep Brain Stimulation Failure, Action Taken, and Outcome

Patient No.	Principal Reason for Failure	Action Taken	Outcomes
1	Lead misplaced	RI	I
2	Dementia, lead misplaced	M	NI
3	Lead misplaced	M	I
4	Lead misplaced	Cannot be replaced	NI
5	Programming	P, M	I
6	Wrong diagnosis	M	NI
7	Programming	P, M	PI
8	Dementia, lead misplaced	M	I (by medication change)
9	Dementia, lead misplaced	P, M	I
10	Symptoms not responding	M	NI
11	Wrong diagnosis	M	NI
12	Lead misplaced	None; leads in old lesion	NI
13	Wrong diagnosis, lead misplaced	P, M	NI
14	Programming	P, M	I
15	Dementia	P, M	I
16	Lead misplaced	P, M	I
17	Wrong diagnosis	P, M	NI
18	Lead not needed	M	I
19	Symptoms not responding	P, M	NI
20	Lead misplaced	P, M	I
21	Programming	P, M	I
22	Dementia	P, M	NI
23	Lead misplaced	RI	I
24	Lead misplaced	RI	I
25	Programming	P, M	I
26	Wrong diagnosis, lead misplaced	P, M	SI
27	Programming	P, M, RI	I
28	Programming, medications	P, M, RI	NI
29	Lead misplaced	P, M	NI
30	Programming, medications	P, M	SI
31	Lead misplaced	RI	PI
32	Programming, medications	P, M	SI
33	Lead misplaced	P, M	NI
34	Programming, medications	P, M	NI
35	Programming	P	I
36	Lead misplaced	RI	I
37	Programming, medications	P, M	I
38	Programming, medications	P, M, RI	SI
39	Lead misplaced	P, M, RI	SI
40	Lead misplaced	RI	I
41	Lead misplaced	P, M	SI

Abbreviations: I, marked improvement; M, medications adjusted; NI, no improvement; P, programming change in deep brain stimulation; PI, partial improvement (improved symptoms but not improved gait); RI, reimplantation of the lead; SI, some improvement.

Although this case series cannot answer the question as to why there were so many misplaced electrodes, it does suggest that better follow-up and evaluation pro-

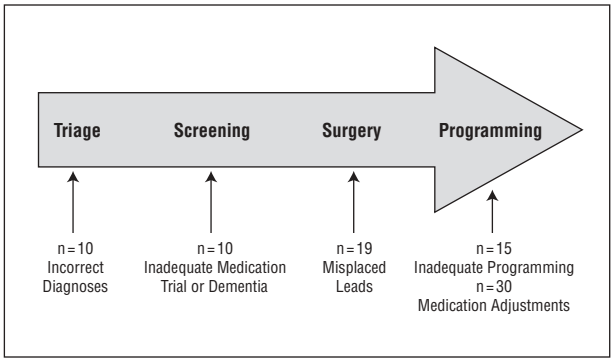

Figure 2. Examples of preventable "deep brain stimulation failures" (n=events) in this study. Improvements in triage, screening, operative procedure, and follow-up programming and medication changes may have eliminated the issues identified in the 41 patients in this study.

cedures can help identify and potentially correct electrode-misplacement problems. Centers managing "DBS failures" should obtain imaging to determine as accurately as possible the location of the DBS electrode (relative to midline and the midcommissural point). Programming should also be performed to assess thresholds for adverse effects and benefits at each electrode contact. This information is quite useful when judging the appropriateness of an electrode's location and when making decisions about a potential lead revision. Given the importance of electrode location and the apparently significant incidence of electrode misplacement, a strong case may be made for recommending routine postoperative imaging in all DBS cases. Certainly imaging is indicated to assess the electrode location in any patient who does not derive the expected benefits from DBS programming.

HARDWARE FAILURES

The number of hardware complications seen in this series is likely not representative of all implanting centers. These numbers may again be partially explained by the selection bias in this patient cohort. Because we included only patients with poor DBS outcomes, we obviously expected to see a high complication rate in this cohort. It is important, however, when evaluating a DBS device that is not performing effectively, to test electrode impedances during programming. If abnormally high or infinite impedances are found, a series of plain x-rays should be obtained to look for fractures or disconnections. End of battery life, lead fractures or short circuits, tissue erosions, and infections are all potentially correctable reasons for poor DBS outcomes.

PROGRAMMING

Only 15 (37%) of 41 patients in this series could be successfully improved by reprogramming the DBS device. Reasons for the difficulties in reprogramming likely included (1) diagnoses that do not respond well to DBS, (2) electrode misplacement, (3) hardware failure, and (4) issues with the DBS programmer (eg, inadequate experience, lack of time commitment).

Ideally, patients treated with DBS should receive programming at the same institution and by the same team that implanted their devices. Programming at the implanting center provides continuity among caregivers, immediate access, direct knowledge of the preoperative history and examination, availability of imaging studies, information on initial programming and thresholds, and information about electrode placement from the operating room.

Inadequate access to DBS programming was a significant problem uncovered by this small study. Appropriate access to postoperative care will continue to be an important determinant of the overall success or failure of DBS in general, and global outcomes should improve as expert postoperative care becomes more readily available. Access can be hampered not only by a lack of trained local physicians available to program devices, but also by physicians and patients moving from one area to another. Patients who have their devices implanted at remote institutions also have the added burden of seeking local follow-up, not only for programming but also for potential complications.

Many surgeons implant DBS devices but do not participate in programming or follow-up. This creates an unfortunate disconnection between the procedure and the outcome. For surgeons to responsibly monitor the effectiveness of their DBS interventions, they must have feedback regarding the measured benefits to the patient or the difficulties encountered in programming. Surgeons who are unaware of poor outcomes are unlikely to make appropriate corrections in technique, and suboptimal results may be unnecessarily propagated. Extensive DBS programming and in-depth assessment of the effect of DBS on the patient's neurological function and quality of life by the implanting neurosurgeon may be impractical, but close communication with a multidisciplinary DBS treatment team, including specialists in movement disorders neurology and DBS programming (at a minimum), can provide the necessary outcomes data to the implanting surgeon.

POSTOPERATIVE MEDICATION CHANGES

Patients with movement disorders, with and without DBS, require frequent medication adjustments. Thirty (73%) of 41 patients in our series required medication changes. Three patients in our series improved markedly from medication changes alone, 1 from DBS programming alone, and 17 after a combination of DBS programming and medication changes. As evidenced by the numbers in this series, surgery does not replace appropriate medical management. In many cases, simultaneous adjustment of medications and stimulation parameters is difficult, and a greater effort should be made to educate DBS practitioners regarding the concurrent management of DBS and medical therapy.

CONCLUSIONS

Ultimately, with diligent reprogramming, medication adjustments, and in some cases electrode replacement, 21 (51%) of the 41 DBS failures in our study were successfully salvaged. Many patients, however, had persistently poor outcomes despite our interventions. This case se-

ries provides important insight into the common reasons for "DBS failures" and proposes some effective strategies for their management.

Future studies will be designed to more adequately assess patient and physician perceptions of postoperative outcomes relative to their preoperative expectations.

As the prevalence of DBS therapy increases, implanting centers are becoming more experienced. We are hopeful that this experience, along with ongoing efforts to educate DBS practitioners regarding effective practices, will result in global improvement in the outcomes of DBS surgery.

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