Ixcellence Network®: an international educational network to improve current practice in the management of cervical dystonia or spastic paresis by botulinum toxin injection

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Summary

Botulinum toxin is a well-established treatment for a number of conditions involving muscle hyperactivity, such as focal dystonia and spastic paresis. However, current injection practice is not standardized and there is a clear need for structured training.
An international group of experts in the management of patients with cervical dystonia (CD) and spastic paresis created a steering committee (SC). For each therapeutic area, the SC developed a core slide set on best practice, based on the literature. International sites of expertise were identified for training and courses were designed to include lectures and case-based learning. Where possible, courses received accreditation from the European Union of Medical Specialists (UEMS). Each course was peer reviewed by the SC, the UEMS accreditation board and the attendees themselves (through evaluation questionnaires). Attendees' feedback was shared with the SC and the trainers to tailor future training sessions.
From the program launch in 2012 to December 2014, 328 physicians from 34 countries were trained in a total of 58 courses; 67% of the courses focused on spastic paresis and 33% on CD. Of the 225 (69%) physicians who completed feedback forms, 95% rated their course as 'above average/excellent' in meeting the preset learning objectives. Most (90%) physicians declared that attending a course would lead them to change their practice.
The development of the 'Ixcellence Network' for continuous medical education in the fields of spastic paresis and CD has provided a novel and interactive way of training physicians with previous experience in botulinum toxin injection.

KEY WORDS: botulinum toxin, cervical dystonia, spastic paresis, training

Introduction

Botulinum neurotoxin type A (BoNT-A) is a well-established and effective treatment for a number of clinical conditions involving muscle hyperactivity, including focal dystonia and spastic paresis. It is administered by local injections to the target muscles and results in a temporary decrease of muscle activity lasting for up to 12–16 weeks. To date, there are approximately 200 documented therapeutic and cosmetic applications for BoNT-A (Wortzman and Pickett, 2009), with the result that it has become one of the most frequently used biological agents worldwide (Wortzman and Pickett, 2009). However, existing guidelines focus on the efficacy of BoNT-A but do not provide clear guidance on dosing and injection technique (Simpson et al., 2008a,b; Albanese et al., 2011; Hallett et al., 2013; Simpson et al., 2016). Moreover, despite the widespread use of BoNT-A for rehabilitation and treatment of neurological disorders, most countries have no recognized training scheme. In Europe, only Austria and Germany have developed a nationally recognized certificate of training (AkBoNT, 2007; ÖDBAG, 2008), and while most regions make provision for some form of local education/training, no professional bodies oversee or regulate the quality of training. This is a key question to address as BoNT-A instruction leaflets in most countries advise that injections should *"be administered by appropriately trained physicians"* (Medicines, 2014).
Numerous studies have shown that the injection technique can have a significant impact on the effectiveness of the treatment. Insufficient BoNT-A dosing can lead to a lack of efficacy, while overdosing or accidental injection into inappropriate muscles can be associated with adverse events (Poewe et al., 1998; Hyman et al., 2000; Hong et al., 2012;

Hauser et al., 2013). However, in current practice, many injectors of botulinum toxin still use 'historic' protocols that vary very widely in injection practice (Hubble et al., 2013; Turner-Stokes et al., 2013a). International surveys identified distinct international differences in the muscles injected per indication (Hubble et al., 2013). For example, physicians in Germany and Sweden reported that they sometimes inject into the *levator scapulae, semispinalis capitis* and *scalenus* for the management of complex cervical dystonia (CD), but their peers in France and Greece did not report targeting these muscles (Hubble et al., 2013). This is important because suboptimal muscle selection may be a leading cause of non-response to treatment (Ferreira et al., 2012). The importance of distinguishing between the different neck and head types of CD is increasingly recognized, since different groups of muscles are affected (Reichel, 2012). Tailored treatment requires appropriate training in how to inject all the various muscles involved in CD. Such international differences in practice underline the need for harmonization of training according to best available evidence.

Large observational studies conducted in centers injecting for upper limb spastic paresis also show considerable variation in how injectors plan treatment and evaluate its success. The Upper Limb International Spasticity Study (ULIS-I) reported by Bakheit et al. showed that, although 78% of patients had pre-defined treatment goals, treatment success was usually judged only by the reduction of muscle tone (Bakheit et al., 2010). Very few investigators used functional outcomes, relevant to the patient's situation, and less than 5% evaluated goal attainment (Bakheit et al., 2010). In preparation for the ULIS-II study, a comprehensive goal attainment scaling (GAS) training program was implemented across all participating centers, to train clinicians unfamiliar with the use of GAS (Turner-Stokes et al., 2013b). This training significantly improved the quality of evaluation and its focus on functional results (Turner-Stokes et al., 2013b). Since then, the results of the ULIS-II study have provided important information on which types of goal (active function, pain, etc.) are most appropriate for different upper limb spasticity patterns, and how patient characteristics (e.g. presence of soft tissue shortening) impact on goal achievement (Fheodoroff et al., 2013 a,b; Turner-Stokes et al., 2013a).

Because current practice in the management of CD and spastic paresis is so diverse across the world, it was decided to develop an international network of training centers that would provide injectors with hands-on training, in line with the best medical evidence, in specific areas of expertise relevant to the management of patients with CD and/or spastic paresis. The ultimate goal of such programs is to improve patient management. We here describe the development of the network and report the attendees' feedback on this ongoing program.

Methods

Steering committee

A steering committee (SC) of six international experts in the management of CD and spastic paresis (neurologists and rehabilitation specialists) was convened in 2012 to design the program through a series of web conferences and face-to-face meetings. The SC members were invited by Ipsen Pharma on the basis of their long-established expertise in this field, supported by their leadership roles in international professional societies and/or their experience as editors of leading journals and international publications (Bhidayasiri and Truong, 2005; Bakheit et al., 2010; Bakheit et al., 2011; Batla et al., 2012; Colosimo et al., 2012; Aun et al., 2013; Turner-Stokes et al., 2013 b). During these meetings, the SC reviewed the training courses currently available and identified unmet educational needs. Initially, six courses (3 for spastic paresis and 3 for CD) were implemented in Europe. Six centers, in the UK, Germany, Italy, France, Portugal and Spain, were chosen and the content of the course for each site was defined according to the specific training skills of local trainers (neurologists and rehabilitation specialists), identified on the basis of their documented experience in the field (ranging from 8 to >26 years' experience). In October 2013 the network expanded to include centers in Mexico, Russia, Brazil and South Korea (Ipsen, 2014). Regular additional SC meetings have been organized, both web-based teleconferences and face-to-face meetings, to ensure trainers provide a well-structured and fully updated theoretical basis, share experiences, and improve the content and organization of the training modules.

Trainers and course development

For each area (CD, adult and child spastic paresis), the SC performed a comprehensive literature search (including peer-reviewed literature in English and in the first languages of the SC members, and abstracts presented at national and international meetings) in order to develop three slide kits (the core modules) that provide a concise overview of the current state of knowledge regarding the management of patients with CD and spastic paresis (adults and children). The core modules are updated every two years.

The training program and content were proposed by the trainers and fine-tuned with the SC members to ensure an appropriate combination of lectures and hands-on training. Each training course lasts one and half days (except for one, which has a duration of one day) and comprises a theoretical component (lectures using core slide decks) and a practical component (video case reports and face-to-face patient evaluation/treatment), which allows attendees to share their expertise and clinical practice experience with their peers. The program was purposely designed to provide education in one specific topic area at a time (diagnosis, evaluation, treatment) and to improve the use of BoNT-A by improving different aspects of the management of these patients (including pediatric patients with spastic paresis): identification of target muscles, injection guidance techniques, determination of patients' specific goals and measurement of goal achievement, using the gait analysis laboratory to improve diagnosis and monitor interventions, and rehabilitation. At the beginning of the program, two levels of training were offered: intermediate and advanced. Over time, the program focused on the advanced level, targeting physicians who wish to upgrade their knowledge or skills, and/or those who wish to train others at local level. The training courses were performed in accordance with the information contained

in the local labels of BoNT-A products. Although not an absolute rule, attendance was generally limited to six participants, to better adapt the training and to facilitate practical sessions and interaction. The program was supported by an unrestricted grant from Ipsen.

Attendees

Participants had to have at least one year's experience in treating patients with CD and/or spastic paresis with BoNT-A to be accepted onto the intermediate course, and at least two years' experience for the advanced course [irrespective of the specific BoNT-A product(s)used in their practice]. No pre-reading or pre-testing was required for course attendance. Participants were selected for a specific training course on the basis of their interest in this specific area, following a spontaneous request or by direct invitation from the sponsor.

Training evaluation

To ensure that the training courses were formally recognized, it was decided to apply for accreditation from the European Union of Medical Specialists (UEMS). This process required the submission of a dossier that included: trainers' CVs, course contents, learning objectives, material for independent review and, importantly, attendees' voluntary feedback. An evaluation form based on the standard questions recommended by the UEMS (Table I) was handed out to, and collected back from, the trainees at the end of each course (T0). The analysis of the questionnaires was shared with each trainer to ensure ongoing improvement of the training courses for the next participants. Six months after the training, the participants who had attended the courses between February 2013 and December 2014 were invited to fill in a second, follow-up evaluation form (T6) online (Table II). Both questionnaires contained multiple-choice questions and open questions.

Results

Attendance

Between the launch of the network in 2012 and December 2014, 328 physicians were trained in a total of 58 educational courses. The majority of attendees came from Europe and they were mainly neurologists or rehabilitation specialists (Table III). The median attendance was six people per training course. Approximately 67% of the courses concerned spastic paresis (149 physicians participated in adult spastic paresis courses and 71 in child spastic paresis courses) and 33% concerned CD (108 physicians) (Table IV). The mean duration of the participants' clinical experience was 13.6 years (range: 1–40). Overall, 54.9% of the participants declared their experience in BoNT-A injection as "advanced", while 14.9% declared themselves to be "beginners" (Table V).

Evaluation according to the UEMS questionnaire (T0)

A total of 225 attendees of 38 training courses held between July 2013 and December 2014 provided feed-

Table I - Evaluation form distributed onsite at the end of each course (T0).

Multiple-choice questions	Poor	Fair	Neutral	Above average	Excellent
1. Overall, how satisfied are you with this educational event?	□	□	□	□	□
3. Did this training meet your learning objectives?	□	□	□	□	□
4. How would you evaluate the educational value of the training?					
a. Relevance of the theoretical part	□	□	□	□	□
b. Relevance of the practical part	□	□	□	□	□
5. How would you evaluate the educational skills of the trainers?					
a. Theoretical part	□	□	□	□	□
b. Practical part	□	□	□	□	□
6. Will this event change your practice?	□	□	□	□	□
7. Will the information provided in this program benefit your patient care?	□	□	□	□	□
13. How satisfied are you with the organization of the event?					
a. Welcome	□	□	□	□	□
b. Accommodation	□	□	□	□	□
c. Lunch	□	□	□	□	□
d. Transport	□	□	□	□	□
14. Was the location appropriate for the event?	□	□	□	□	□

Yes/No questions	Yes	No
10. Would you recommend this program to a colleague?	□	□
2. Did the course give you some new information?	□	□
12. Did you feel the event was biased by commercial interests?	□	□

Open questions
8. What educational tools would you like to receive at the end of the training?
9. Regarding this training, what suggestions do you have to improve its impact/learning objectives?
11. Would you be interested in another training topic? If so, what?

Table II - Extended evaluation form sent to the trainees 6 months after the end of each course (T1).

Multiple-choice questions	Poor	Fair	Neutral	Above average	Excellent
Overall, has the training program had an impact on your daily practice?	□	□	□	□	□
Overall, has the training program had an impact on your self-confidence?	□	□	□	□	□

Open questions
How did the training program change your approach to the disease?
Would you be interested in another training topic? If so, what?
Six months after the training, what do you remember?

Table III - Attendees' geographic origin and specialty (2012–2014).

Country/Region	Number (n) (n=328)
Nordics	50
Italy	48
Spain	30
Ireland	20
Russia	20
United Kingdom	17
Germany	16
Estonia	14
Portugal	14
Latin America	12
Czech Republic	11
Colombia	10
Lithuania	6
France	6
Austria	5
Venezuela	4
Serbia	4
Iran	4
Greece	3
South Korea	3
South Asia	2
Hungary	2
Jordan	2
Turkey	2
Morocco	2
Romania	2
Netherlands	1
Thailand	1
Algeria	1
Australia	1
Switzerland	1
Vietnam	8
Slovakia	3
Brazil	3

Specialty	Number (n) (n=328)
Neurology	164
Rehabilitation	88
Pediatrics	20
Orthopedics	7
Anesthesiology	3
Other	20
Missing data	26

back about the quality of the courses. The results are summarized in Table VI. The attendees' satisfaction was rated "above average" or "excellent" in 96.4% of cases (n=217), while 95.1% (n=214) declared that the course was "above average" or "excellent" in meeting the learning objectives set out in the course description. A majority of participants (n=199, 88.4%) acknowledged that the training had given them new information. The educational value of the training and the educational skills of the trainers were rated "above average" or "excellent" in 87.6% (n=197) and 87.1% (n=196) of cases, respectively. When questioned about whether attending the course would change their practice, 203 of the 225 physicians (90.2%) responded affirmatively. In addition, 208 participants (92.4%) thought that the information delivered during the training would benefit their patient care. Finally, all but one of the attendees responded that they would recommend the course to their colleagues, and 92.4% felt that the event was not biased. As regards the open questions, many participants would have liked to receive key references after the training and suggested that further courses might include more days and more practice, and be more technical (ultrasound guidance, injection techniques, electrical stimulation).

Follow-up evaluation six months after the training course (T6)

The follow-up evaluation form was sent six months post training to 235 physicians from 36 courses (conducted between February 2013 and December 2014). Of these, 106 provided feedback (45% response rate). A majority (92.5%) of the participants responded that the program had had an impact on their daily practice and 95.3% reported that it had improved their self-confidence (Table VII). Overall, 96 of the 106 (90.6%) physicians who provided feedback responded that they would be interested in attending training courses on other topics. Table VIII shows the answers to the open questions.

Discussion

Continuing medical education is now established as essential to maintaining the quality of practice. The amount of basic training in neurorehabilitation is highly variable across countries (Grisold et al., 2007). The training program described in this paper aimed at building a high-quality, expert-level educational network to help physicians improve their management of patients with CD or spastic paresis who receive BoNT-A injections.
The need for a well thought-out training program was confirmed by the experts' own experience and their re-

view of the training programs currently available, most of which are designed along traditional lines, using didactic plenary methods and focus only on the efficacy and safety of BoNT-A. Courses with an interactive component have been shown to be more likely to change behavior (Mazmanian and Davis, 2002). Therefore, to improve practical expertise, we preferred to design 'hands-on' training sessions that can be directly applied within the attendees' own clinical settings. The courses were deliberately kept small to facilitate practical training and interaction with the expert trainer. Our program was specifically designed to improve the skills of physicians who already had experience with BoNT-A. In the early stages of the program, the selection process was relatively unstructured, resulting in heterogeneous groups of trainees with different levels of experience. In the current selection process, each prospective attendee fills out an application form detailing his/her experience with BoNT-A.

In this program, the course content is regularly reviewed and updated. Each course is peer reviewed in a number of ways: (1) by the SC, (2) by the UEMS accreditation board and (3) by the attendees. At present most courses (62%) have received UEMS accreditation (each course being awarded 6 to 9 points); physicians typically require around 45–50 points per year (Lo and Field, 2009).

The success of this program can currently be evaluated only by analyzing the feedback provided by the attendees. The 45% response rate for the follow-up evaluation can be considered encouraging given that it was an online questionnaire sent six months after the training. The feedback was almost unanimously positive. However, it should be considered that the physicians who were happiest with the training were possibly the ones most likely to respond. In the future, it would also be very interesting to evaluate the success of the program by assessing changes in the attendees' practice. The

Table IV - Distribution of participants across training courses (2012–2014).

Center of expertise	Course	Content	Number (n) (n=328)
Cervical dystonia			
United Kingdom	Simple & Complex CD and EMG guided injection	Use of EMG guidance for improved targeting of muscles involved in complex cases of CD	31
Germany	Col-Cap concept	A new anatomical classification for improved diagnosis of CD patterns	39
Italy	Motor re-learning technique in CD	An innovative approach of rehabilitation in CD	31
Korea	Management of CD	Diagnosis, assessment and treatment of CD	7
Spastic paresis			
France	Ultrasound guided injection	Use of ultrasound guidance for improved targeting of muscles involved in spastic paresis	84
Portugal	GAS and gait analysis	Use of GAS and gait analysis to improve treatment outcomes	46
Spain	Management of pediatric spastic paresis and assessment	Diagnosis, assessment, treatment and prevention of cerebral palsy	65
Mexico	Patient-centered goals in movement and function disorders	Patient- and family-centered goals in cerebral palsy patient management	11
Brazil	Multidisciplinary approach for optimal rehabilitation in adult spastic paresis	Benefits of multidisciplinary team to improve patient rehabilitation in adult spastic paresis	5
Russia	EMS and rehabilitation in adult spastic paresis	EMS used as a rehabilitation technique in adult spastic paresis	9

Abbreviations: GAS=goal attainment scaling; EMG=electromyography; EMS=electrical muscle stimulation; Col-Cap=collum-caput; CD=cervical dystonia.

Table V - Participant-declared level of experience in BoNT-A injection, by training course specialty (2012–2014) (number of answers).

Level of experience	Adult spastic paresis training courses	Child spastic paresis training courses	Cervical dystonia training courses	TOTAL (%)
Advanced (≥ 3 years)	91	38	51	180 (54.9)
Beginner (< 3 years)	26	9	14	49 (14.9)
No answer	32	24	43	99 (30.2)
TOTAL	149	71	108	328

early indications are promising, with attendees spontaneously reporting, for example, that they have implemented the use of ultrasound to improve injection guidance in their clinic, or have started habitually establishing person-centered treatment goals. Another aim of this program is to enable the attendees to give training to their peers. This train-the-trainer approach has been successfully used to educate physicians in the areas of Alzheimer's disease and alcohol abuse, and has been shown to facilitate changes in knowledge, attitudes, and self-confidence among health care providers (Coogle et al., 2000; Connell et al., 2002).

An interesting aspect of the program is that it brings together specialists in neurology and rehabilitation and offers opportunities for exchanges and networking. The involvement of the SC experts from the two areas and the shared learning experience have led to new ideas to develop the courses further. For example, whereas the application of individualized goal setting is becoming standard practice in spastic paresis management, it is not often used in CD. Feedback from attendees has also highlighted the need for more training in aspects of the holistic management of CD, such as quality-of-life assessment. The SC is now incorporating this feedback into the course contents.

We are aware of the limitations of the Ixcellence Network. The most important and ultimate goals of such programs are to improve physicians' practice and benefit patients. We did not evaluate this latter aspect and the changes in practice reported in the questionnaires are only subjective. Assessment of benefits for patients should be undertaken in further studies, although it is very difficult to demonstrate the correlation between physician training and patient benefit, as many other factors can intervene. Another theoretical goal of the program was to harmonize BoNT-A use in clinical practice. However, the methods used to develop and implement the training courses did not lend themselves to standardization, given that the participants attended different courses, depending on the site where they were trained. Only the core slide kits were similar, but this is not sufficient to claim that practices in CD and spastic paresis management could be harmonized by our training. The core slide kit can be seen as an experts' opinion rather than a guideline, although it is entirely based on the literature and fully referenced. In general, satisfaction was very high after these sessions. However, it should be acknowledged that there could be a potential methodology bias, especially for the T0 questionnaires which were not anonymized and were completed in the room where the training took place. However, the six-month feedback, collected online, corroborates this high level of satisfaction: more than 90% of the participants stated that the training had had a positive impact on their daily practice and self-confidence and that they would be interested in another training topic. Finally, it can be hypothesized that the provision of financial support may have biased the activities. The Ixcellence Network program is, indeed, sponsored by industry. Nevertheless, in most countries there are no other alternatives since universities, medical schools or governments do not provide this type of expert training. Furthermore, the SC members ensured that the company had no influence on the training course content or on the data collected. Ipsen supported the program in terms of logistics, but did not in any way alter the development of course material, in line with current recommendations

Table VI - Attendees' feedback at T0 (number of answers).

	July to December 2013 n=85 (15 training courses)					January to December 2014 n=140 (23 training courses)				
	P/ F	N	AA	Exc	NA	P/ F	N	AA	Exc	NA
How satisfied are you with this educational event?	1	0	17	64	3	0	0	24	112	4
Did the training meet your learning objectives?	1	0	22	60	2	1	0	46	86	7
How would you evaluate the educational value of the training?	0	3	13	61	8	0	1	26	97	16
How would you evaluate the educational skills of the trainers?	0	1	9	65	10	0	1	12	110	17
Will this training change your practice?	2	1	25	55	2	1	11	56	67	5
Will the information benefit your patient care?	2	6	23	51	3	0	3	53	81	3
	No		Yes		NA	No		Yes		NA
Did the course give you any new information?	2		74		9	1		125		14
Would you recommend this program to a colleague?	1		83		1	0		134		6
Did you feel the event was biased?	74		1		10	125		6		9

Abbreviations: P/F=poor/fair; N=neutral; AA=above average; Exc=excellent; NA=no answer

Table VII - Attendees' feedback at T6, quantitative questions (number of answers).

	Attendees trained in 2013 (52 answered among 115)				Attendees trained in 2014 (54 answered among 120)			
	P/F	N	AA	Exc	P/F	N	AA	Exc
Overall, has the training program had an impact on your daily practice?	1	4	27	20	1	2	28	23
Overall, has the training program had an impact on your self-confidence?	0	4	27	21	0	1	38	15

Abbreviations: P/F=poor/fair; N=neutral; AA=above average; Exc=excellent; NA=no answer

Table VIII - Responses to open-ended questions (T6).

How did the training program impact on your approach to the disease?
Injection procedure
• Modification of our injection procedure
• I learnt some important points on injection strategy and also shared information with the teacher
• More confident on injection technique, and on muscle anatomy
• Encouraged me not to be afraid of performing botulinum toxin injections
• In terms of confidence to treat, together, upper and lower limbs and to measure results
• New approach to injecting certain muscles in the lower limbs
• Injections with BoNT are done more precisely
New techniques (goal attainment scaling, gait analysis, ultrasound guided injections and EMG)
• In our clinic we have adopted the ultrasound guided injection technique as our primary mode of treatment
• Greater analysis of movement patterns in identifying functionally important muscle (clinically, according to EMG, etc.)
• Provided new approach with ultrasound guided injections of BoNT-A
• We now use ultrasound to guide BoNT-A injections on a regular basis
• I now use ultrasound guided injection
• Ultrasound guided BoNT-injections are in progress in our clinic
• This was my first experience with ultrasound guided BoNT-A injection and I would follow it in my practice
• Use of GAS in daily practice
• Knowledge on how to use GAS in practice and I try to include it in my work. Very much liked the practical part of training and the clinical cases on GAIT analysis usage
• Greater analysis of movement patterns in identifying functionally important muscle (clinically, according to EMG, etc.)
• After the training course I have in-depth knowledge on GAS, and am more confident when discussing with doctors
• Apply SMART goal setting
• Improved my approach with therapy in cervical dystonia especially for deep muscles
• The course increased my awareness of the need for further training before I start injecting deep muscles of head and neck
• Understanding of Col-Cap concept
Patient evaluation
• It has allowed me to make decisions more easily and correctly than before
• New ways of evaluating
• I got some practical tips to use in everyday practice
• Prof. broadened my insights into and understanding of backgrounds of dystonia; improved technique for examining such patients, which ultimately improves choice of treatment
• The course helped me realize the importance of precise diagnosis of the type of dystonia for correct choice of treatment modality
Practice in pediatric spastic paresis
• Totally changed my practice regarding evaluation and treatment of children with cerebral palsy with BoNT-A. Also changed the setting in our outpatient clinic to accommodate the new knowledge
• This program improved my approach to the treatment of spastic paresis in children, making it more complete and comprehensive
• I have started using ultrasound guided injections for treating spastic paresis in children

on avoiding conflicts of interest in medical education (Varetto and Costa, 2013). In accordance with compliance rules, funding was restricted to travel costs, accommodation and food. Thus, most of the training courses were accredited by the UEMS.

In conclusion, there is significant diversity in BoNT-A injection practice in the management of patients with CD and spastic paresis that must be addressed through continuing medical education. To the best of our knowledge, the Ixcellence Network is the first international educational program that targets physicians who already have some experience in the use of BoNT-A injections in the fields of spastic paresis and CD. It covers patient management from clinical assessment through to rehabilitation and allows participants to attend courses of interest. Qualitative feedback from attendees indicated that they were satisfied and serves as a basis for the continual development of the program. A further step would be to evaluate the impact of this educational program on local peer training, daily practice and benefits to patients.

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